UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 6-K

REPORT OF FOREIGN PRIVATE ISSUER PURSUANT TO RULE 13a-16 OR 15d-16
UNDER THE SECURITIES EXCHANGE ACT OF 1934

FOR THE MONTH OF NOVEMBER 2024

COMMISSION FILE NUMBER 001-39081

BioNTech SE
(Translation of registrant's name into English)

An der Goldgrube 12
D-55131 Mainz
Germany
+49 6131-9084-0
(Address of principal executive offices)

Indicate by check mark whether the registrant files or will file annual reports under cover Form 20-F or Form 40-F: Form 20-F ☒ Form 40-F ☐

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1): ☐

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7): ☐

DOCUMENTS INCLUDED AS PART OF THIS FORM 6-K

On November 14, 2024, BioNTech SE is hosting an edition of its Innovation Series Day. The presentation is attached as Exhibit 99.1.

SIGNATURE

Pursuant to the requirements of the Exchange Act, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

BioNTech SE

By: /s/ Jens Holstein
Name: Jens Holstein
Title: Chief Financial Officer

By: /s/ Dr. Sierk Poetting
Name: Dr. Sierk Poetting
Title: Chief Operating Officer

Date: November 14, 2024

EXHIBIT INDEX

Exhibit	Description of Exhibit
99.1	Presentation

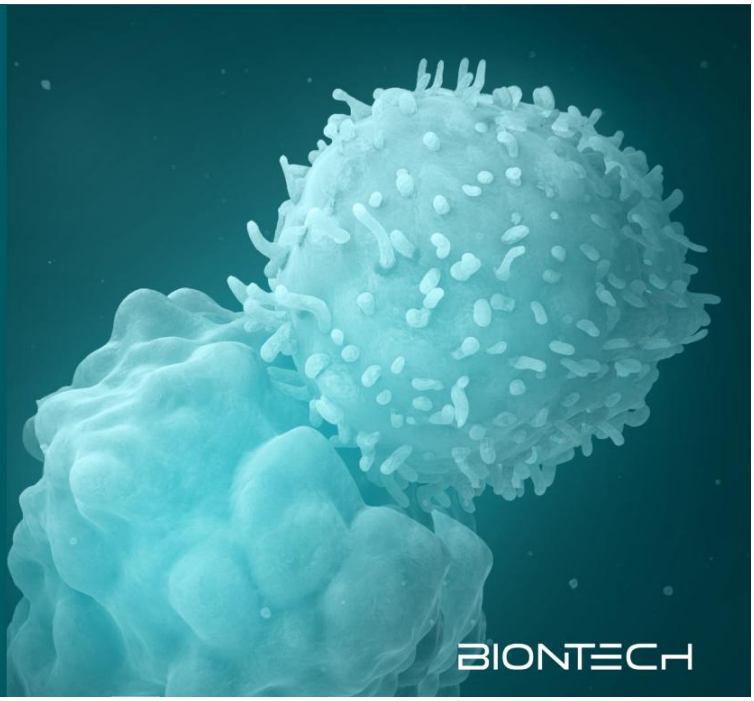
Exhibit 99.1


Innovation Series 2024
November 14, 2024
10:30 AM – 2:15 PM ET
BIONTECH

_1

Welcome & Introductory Remarks

Ryan Richardson,
Chief Strategy Officer



This Slide Presentation Includes Forward-Looking Statements

This presentation contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including, but not limited to, statements concerning: BioNTech's expected revenues and net profit/(loss), particularly for those figures that are derived from preliminary estimates provided by BioNTech's partners; the rate and degree of market acceptance of BioNTech's COVID-19 vaccine and, if approved, BioNTech's investigational medicines; expectations regarding anticipated changes in COVID-19 vaccine demand, including changes to the ordering environment and expected regulatory recommendations to adapt vaccines to address new variants or sublineages; the initiation, timing, progress, results, and cost of BioNTech's research and development programs, including BioNTech's current and future preclinical studies and clinical trials, including statements regarding the expected timing of initiation, enrollment, and completion of studies or trials and related preparatory work and the availability of results, and the timing and outcome of applications for regulatory approvals and marketing authorizations; BioNTech's expectations regarding potential future commercialization in oncology, including goals regarding timing and indications; the targeted timing and number of additional potentially registrational trials, and the registrational potential of any trial BioNTech may initiate; discussions with regulatory agencies; BioNTech's expectations with respect to intellectual property; BioNTech's acquisition of Biotheus, which is subject to customary closing conditions, including regulatory approvals; the impact of BioNTech's acquisition of Biotheus upon closing; collaboration and licensing agreements; the development, nature and feasibility of sustainable vaccine production and supply solutions; the deployment of AI across BioNTech's preclinical and clinical operations; BioNTech's estimates of revenues, research and development expenses, selling, general and administrative expenses, and capital expenditures for operating activities; and BioNTech's expectations of net profit / (loss). In some cases, forward-looking statements can be identified by terminology such as "will," "may," "should," "expects," "intends," "plans," "aims," "anticipates," "believes," "estimates," "predicts," "potential," "continue," or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these words.

The forward-looking statements in this presentation are based on BioNTech's current expectations and beliefs of future events, and are neither promises nor guarantees. You should not place undue reliance on these forward-looking statements because they involve known and unknown risks, uncertainties, and other factors, many of which are beyond BioNTech's control and which could cause actual results to differ materially and adversely from those expressed or implied by these forward-looking statements. These risks and uncertainties include, but are not limited to: the uncertainties inherent in research and development, including the ability to meet anticipated clinical endpoints, commencement and/or completion dates for clinical trials, projected data release timelines, regulatory submission dates, regulatory approval dates and/or launch dates, as well as risks associated with preclinical and clinical data, including the data discussed in this release, and including the possibility of unfavorable new preclinical, clinical or safety data and further analyses of existing preclinical, clinical or safety data; the nature of the clinical data, which is subject to ongoing peer review, regulatory review and market interpretation; BioNTech's pricing and coverage negotiations regarding its COVID-19 vaccine with governmental authorities, private health insurers and other third-party payors; the future commercial demand and medical need for initial or booster doses of a COVID-19 vaccine; competition from other COVID-19 vaccines or related to BioNTech's other product candidates, including those with different mechanisms of action and different manufacturing and distribution constraints, on the basis of, among other things, efficacy, cost, convenience of storage and distribution, breadth of approved use, side-effect profile and durability of immune response; the timing of and BioNTech's ability to obtain and maintain regulatory approval for its product candidates; the ability of BioNTech's COVID-19 vaccines to prevent COVID-19 caused by emerging virus variants; BioNTech's and its counterparties' ability to manage and source necessary energy resources; BioNTech's ability to identify research opportunities and discover and develop investigational medicines; the ability and willingness of BioNTech's third-party collaborators to continue research and development activities relating to BioNTech's development candidates and investigational medicines; the impact of COVID-19 on BioNTech's development programs, supply chain, collaborators and financial performance; unforeseen safety issues and potential claims that are alleged to arise from the use of products and product candidates developed or manufactured by BioNTech; BioNTech's and its collaborators' ability to commercialize and market BioNTech's COVID-19 vaccine and, if approved, its product candidates; BioNTech's ability to manage its development and related expenses; regulatory developments in the United States and other countries; BioNTech's ability to effectively scale its production capabilities and manufacture its products and product candidates; risks relating to the global financial system and markets; and other factors not known to BioNTech at this time. You should review the risks and uncertainties described under the heading "Risk Factors" in BioNTech's Report on Form 6-K for the period ended September 30, 2024 and in subsequent filings made by BioNTech with the SEC, which are available on the SEC's website at www.sec.gov. These forward-looking statements speak only as of the date hereof. Except as required by law, BioNTech disclaims any intention or responsibility for updating or revising any forward-looking statements contained in this presentation in the event of new information, future developments or otherwise.

Innovation Series 2024 – Today's Presenters

Prof. Ugur Sahin, M.D.
Chief Executive Officer, Co-founder

Prof. Özlem Türeci, M.D.
Chief Medical Officer, Co-founder

Ryan Richardson
Chief Strategy Officer

Annemarie Hanekamp
Chief Commercial Officer

Prof. Ilhan Celik, M.D.
Vice President, Clinical Development

Michael Wenger, M.D.
Vice President, Clinical Development

Innovation Series 2024 Agenda

1	Welcome and Introductory Remarks	10:30 AM	15 min
2	The Next Frontiers in Oncology	10:45 AM	45 min
3	Commercialization: Next Era of BioNTech	11:30 AM	15 min
4	BNT327[1] Clinical Development Strategy	11:45 AM	45 min
	Break	12:30 PM	15 min
5	mRNA Cancer Vaccines	12:45 PM	30 min
6	Select Targeted Therapies: HER2-ADC BNT323/DB-1303[2] & CLDN6 CART BNT211	1:15 PM	25 min
7	Path to Value Creation	1:40 PM	5 min
8	Closing Remarks and Q&A	1:45 PM	30 min

Partnered with: 1. Biotheus; 2. DualityBio.

BIONTECH

BioNTech's Journey

2008

Founding & Platform Building

Seed financing & first collaborations

2019

Nasdaq IPO

2020-2022

COMIRNATY®[1]
Development, approval & worldwide launch

From 2023

Advancing towards becoming a multi-product biotechnology company

- BNT327/PM8002[1]
- mRNA
  - Autogene cevumeran[2]
  - FixVac
- BNT211 (CAR-T)
- BNT323/DB-1303[3]

Entering a new stage of value creation for patients, society and shareholders

Partnered with 1. Pfizer; 2. Genentech, a member of the Roche Group; 3. DualityBio.

BIONTECH

Driven to Address the World's Most Pressing Health Challenges
With pioneering technologies delivered at scale

COVID-19 VACCINE[1] GLOBAL LEADERSHIP

>4.9 billion doses distributed

>80 countries globally

>50 % Comirnaty market share[2]

STRONG FINANCIAL POSITION

€ 17.8 bn
total cash plus security investments[3]

MULTIPLATFORM ONCOLOGY PORTFOLIO

20 Clinical programs

13 Ongoing Phase 2 or 3 trials

Genentech – A Member of the Roche Group · REGENERON · Genmab · BIOTHEUS · DualityBio · MediLink Therapeutics · OncoC4

INFECTIOUS DISEASE PIPELINE

7 Clinical programs in high unmet need indications

Partnership with Pfizer in respiratory and other high need indications

LEADER IN AI

InstaDeep™

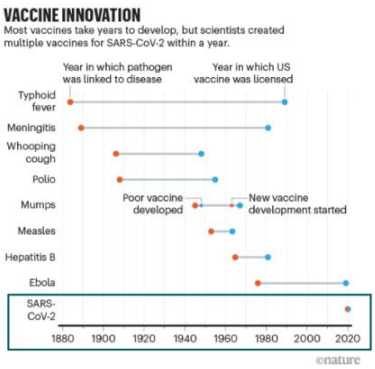
IN-HOUSE MANUFACTURING

Bulk mRNA · Individualized mRNA · Modular mRNA · Autologous Cell Therapy

1. Partnered with Pfizer; 2. As of Q3 2024; 3. Consists of cash and cash equivalents of €9,624.6 million, non-current security investments of €1,137.2 million, and current security investments of €7,078.0 million, as of September 30, 2024.

Developing and Approving the First mRNA Medicine

The fastest vaccine development in the history of medicine[1]



The strongest launch of any pharmaceutical product[2]

>4.9 billion doses of BNT162b2 shipped

>180 countries and territories[3]

1. Ball P. Nature. 2021; 2. Measured by sales recorded for a single product in a single year (>$40 billion combined of direct sales recorded by Pfizer or BioNTech in both 2021 and 2022); 3. Cumulative doses shipped in the years 2021, 2022 and 2023.

BIONTECH

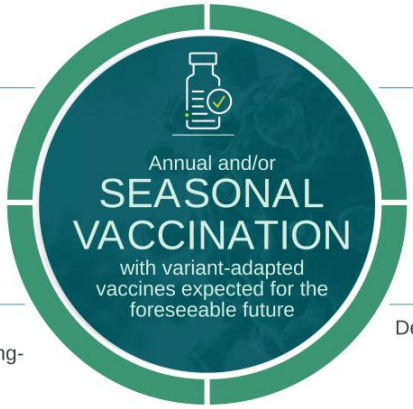
Long-Term Need for Seasonally Adapted Vaccines Anticipated

Continuous evolution

Ongoing antigenic evolution of SARS-CoV-2[1,2]

Risk remains high

For severe COVID-19 in vulnerable populations[3]



Long-term health consequences

Accumulating evidence demonstrates that COVID-19 vaccination reduces long-COVID[4]

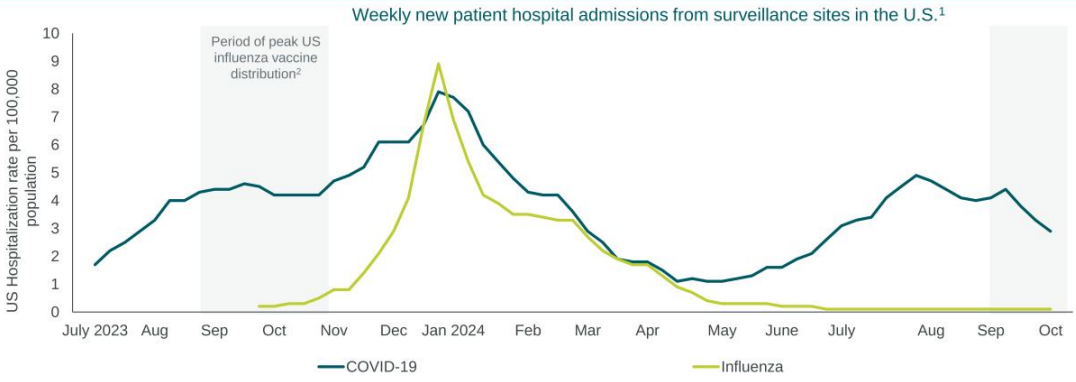
Variant-adapted vaccines

Designed to be effective against multiple variants of concern[5]

1. World Health Organization Tracking SARS-CoV-2 variant www.who.int/en/activities/tracking-SARS-CoV-2-variants accessed 30 October 2023; 2. Global Initiative on Sharing All Influenza Data https://gisaid.org/ accessed 30 October 2023; 3. FDA Briefing Document Vaccines and Related Biological Products Advisory Committee Meeting June 15, 2023; 4 Brannock et al, Nature Comm. 2023; 5. Stankov M. V. et al., medRxiv pre-print, 5 October 2023.

BIONTECH

COVID-19 and Influenza Disease Burdens Show Different Seasonality Patterns



COVID-19

- Hospitalization rates have been consistently and significantly above the level of influenza
- Epidemiology patterns do not perfectly overlap with influenza
- Market has been characterized by dual strain vaccine launches in two of the last three years

1. Respiratory Virus Hospitalization Surveillance Network; Data last updated: November 1, 2024; 2. https://www.cdc.gov/flu/hcp/vaccine-supply/2023-2024.html

BIONTECH

Variant-Adapted Vaccine Approval Timelines Came Earlier as Compared to 2023

Approval dates of variant-adapted COVID-19 vaccines[1]

	2023	2024	Approval Date Change
US	Sep 11 (XBB.1.5)	Aug 22 (KP.2)	← 20 days
EC	Sep 1 (XBB.1.5)	Jul 3 (JN.1)	← 60 days
UK	Sep 5 (XBB.1.5)	Jul 24 (JN.1)	← 43 days
JP	Sep 1 (XBB.1.5)	Aug 8 (JN.1)	← 24 days

Potential for further alignment of regulatory timelines and COVID-19 seasonal epidemiology to meet public health needs

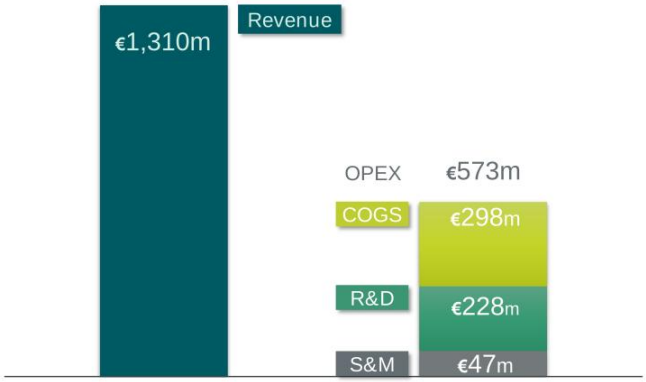
1. Partnered with Pfizer;
JN.1 is a SARS-CoV-2 variant, KP.2 is a lineage of the JN.1 variant. KP.2 vaccine approval took place on September 26 and October 10 in the EU and UK, respectively.

COVID-19 Vaccine Franchise[1] with Lean Cost Structure

Key Business Features:

1. Global Market Leadership
2. Lean Fixed Cost Base Business
3. Potential for Cashflow Generation

2024 Financials up to 30 September (Q1-Q3)



1. Partnered with Pfizer.

BIONTECH

Leveraging COVID-19 Vaccine Business Model for Sustainable Value Creation

Financial Strength

- Cash generative COVID-19 vaccine business[1]
- Balance sheet

Innovative R&D Engine

Progressive Path Towards Value Creation

- Data updates across pipeline — 2025
- First launches in oncology — 2026 - 2028
- Multi-product portfolio — 2030

1. Partnered with Pfizer.

BIONTECH

Today's Focus: Key Value-Driving Oncology Programs

Transformational Opportunities with Pan Tumor Potential	
	BNT327/PM8002 (bispecific PD-L1xVEGF)[1]
	Autogene cevumeran[2] (personalized mRNA cancer vaccine)
	FixVac (off-the-shelf TAA-targeting mRNA cancer vaccine)
	BNT211 (CLDN6-targeted CAR-T + CLDN6 CAR-T amplifying vaccine)
	BNT323/DB-1303 (HER2 ADC)[3]

Partnered with: 1. Biotheus; 2. Genentech, a member of the Roche Group; 3. DualityBio.

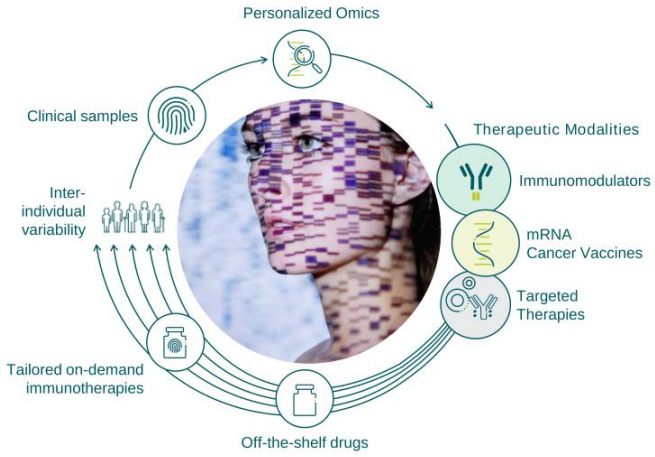
_2

The Next Frontiers in Oncology

Prof. Ugur Sahin, M.D.
CEO and Co-founder

Charting the Course for Tomorrow's Personalized Precision Medicine

- Deep genomics & immunology expertise to analyze patient data
- Individualized treatment platforms to address inter-individual variability
- AI & digitally-integrated target & drug discovery and development
- Automated in-house manufacturing to serve patients on time and globally



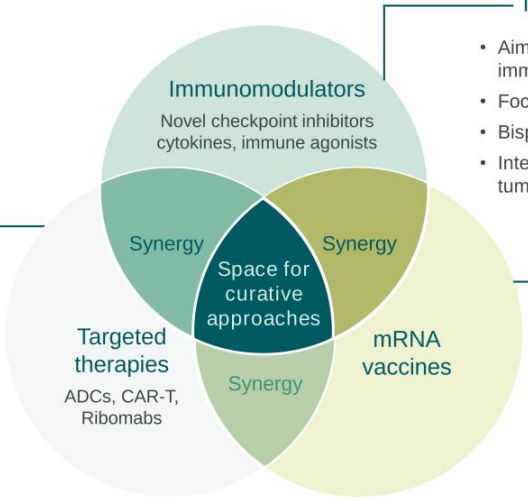
Our Concept Towards a Potentially Curative Approach to Cancer

Immunomodulators

- Aiming to augment anti-tumor-immunity
- Focus on crucial IO pathways
- Bispecific targeting aimed for synergy
- Intended to promote durable anti-tumor effect

Targeted therapies

- Precise therapies aimed to reduce tumor burden across all disease stages including late lines
- ADC as potential "augmenters" of immunomodulators and mRNA cancer vaccines
- Ongoing focus on HER2, HER3, TROP2, B7-H3 as combination partners



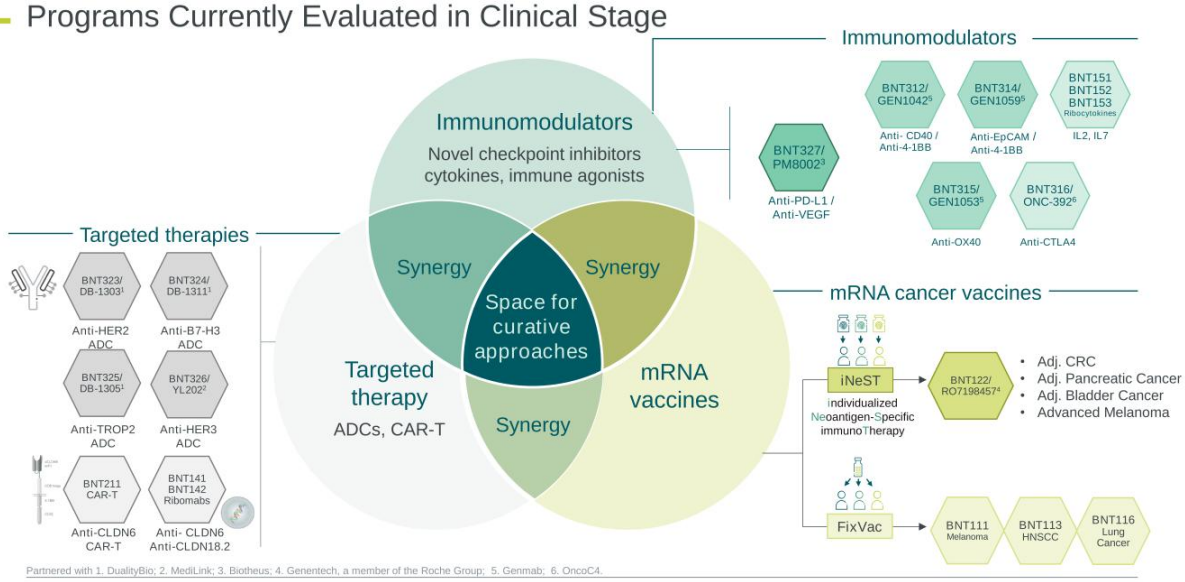
mRNA cancer vaccines

- Eliminate polyclonal residual disease with multi-antigen approaches and individualized vaccines
- Polyspecific activity by targeting multiple antigens at once
- Establish long-lasting immunological memory to prevent relapses

This is a conceptual slide and does not imply published data as bases for.

BIONTECH

Programs Currently Evaluated in Clinical Stage



Partnered with 1. DualityBio; 2. MediLink; 3. Biotheus; 4. Genentech, a member of the Roche Group; 5. Genmab; 6. OncoC4.

BIONTECH

Select Candidates Suitable for Late-Stage Development Across Multiple Cancer Indications

Immunomodulators

BNT327/PM8002[1]

PD-L1 × VEGF bispecific antibody

Validated across 25+ tumor types with >700 patients treated

- Broad applicability across range of cancers
- Planned Ph3 in SCLC, NSCLC and TNBC

mRNA Cancer Vaccines

BNT122 Autogene cevumeran[2]

Individualized Cancer Vaccine Candidate

Personalized medicine targeting patient-specific tumor antigens

- Targeting cancers in adjuvant stage
- Studies ongoing in CRC, PDAC, urothelial cancer and other solid tumors

Targeted Therapy

BNT211

Autologous CLDN6-targeting CAR-T

±

CAR-T cell amplifying RNA vaccine (“CARVac”)

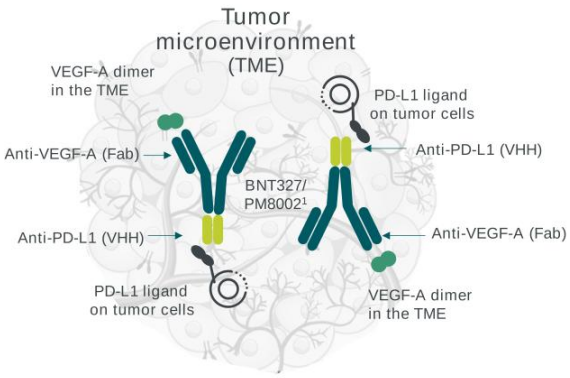
- Targeting CLDN6+ cancers, including ovarian, testicular, endometrial, sarcoma, lung, and gastric cancer

Partnered with: 1. Biotheus. 2. Genentech, a member of the Roche Group.

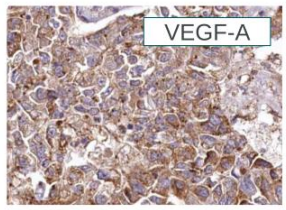
BIONTECH

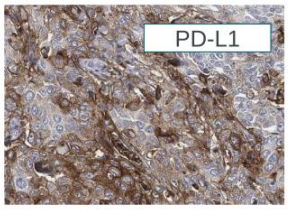
BNT327/PM8002[1]: Synergistic Targeting of PD-L1 and VEGF

BNT327/PM8002[1] characteristics: combined tumor targeting[2]



Selected NSCLC IHC[3]





Bispecific MOA

Targeting of PD1/PDL1 blockade to VEGF high tumors

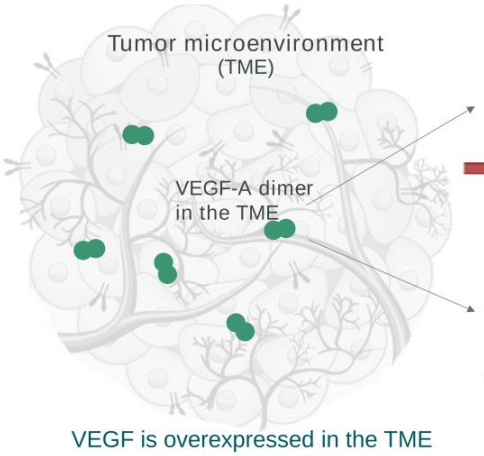
Targeting of VEGF neutralization to PDL1 high tumors

1. Partnered with Biotheus; 2. Khan KA Nat Rev Clin Oncol 2018; 3. IHC data: Human Protein Atlas.

BIONTECH

Anti-VEGF Treatment May Reverse Immune-Suppressive Effects and Potentially Improve Outcome of IO Treatment

VEGF signaling has immunosuppressive effects in addition to angiogenesis



Tumor angiogenesis

Abnormal blood vessel formation leads to hypoxia, acidosis, and restricted drug delivery

Immunosuppression

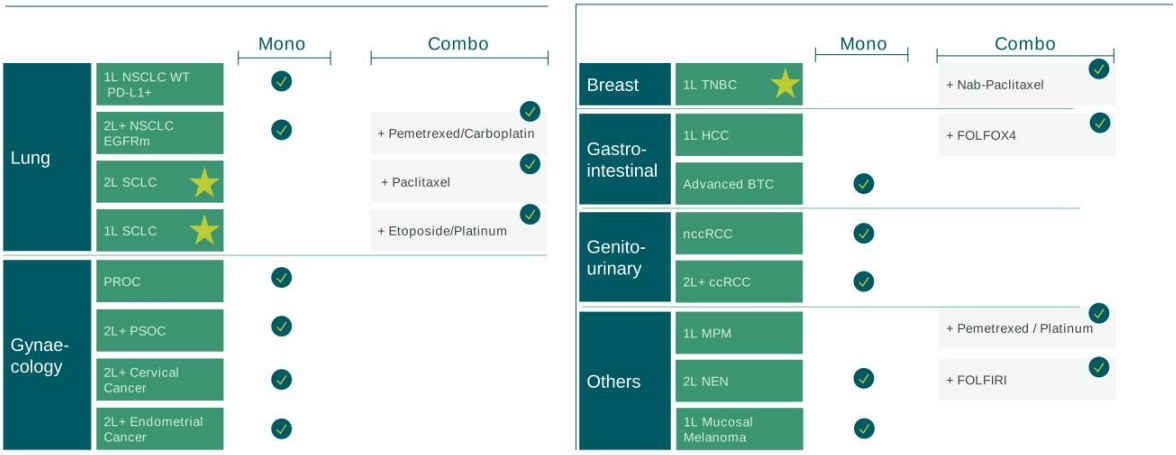
- Inhibit the recruitment, activity, and maturation of effector immune cells
- Promote the recruitment and proliferation of suppressive immune cells

VEGF is overexpressed in the TME

Source: Khan KA Nat Rev Clin Oncol 2018; Marin-Acevedo JA and Hanna NH, ASCO 2023.

BIONTECH

BNT327/PM8002[1] is Being Investigated Across Multiple Tumor Types with >700 Patients Treated



1. Partnered with Biotheus.

BIONTECH

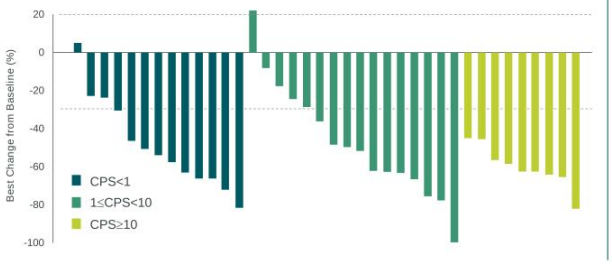
BNT327/PM8002[1] with nab-paclitaxel Shows Clinically Meaningful Efficacy Irrespective of PD-L1 Status in 1L TNBC

Phase 1/2b (NCT05918133): clinical activity of BNT327/PM8002[1] in combination with nab-paclitaxel

Y. Meng et al. Presented at ESMO 2024. Presentation 384MO

Variable	ITT*	PD-L1 CPS<1	PD-L1 **1≤CPS<10**	PD-L1 **CPS≥10**
Population (n)	42	13	16	9
ORR %	73.8	76.9	56.3	100.0
DCR %	95.2	100.0	93.8	100.0
mPFS (mo)	13.5	NR	14.0	10.8

ITT population: mDoR 11.7 mos; mOS not reached



Benchmark comparator data by PD-L1 expression level

Indication	Benchmark regimen	ORR	mPFS	mOS	Benchmark Study
TNBC (CPS <10)	Chemo	35%	5.6 mo	15.0 mo	KEYNOTE-355 [2]
TNBC (CPS ≥10)	Pembro + Chemo	62%	9.7 mo	23.0 mo	KEYNOTE-355 [2]

1. Partnered with Biotheus; 2. Cortes, J, et al. N. Engl. J. Med. 2022.
*PD-L1 testing was not done in 4 patients (not shown). ORR: 75.0% and mPFS 14.0 months

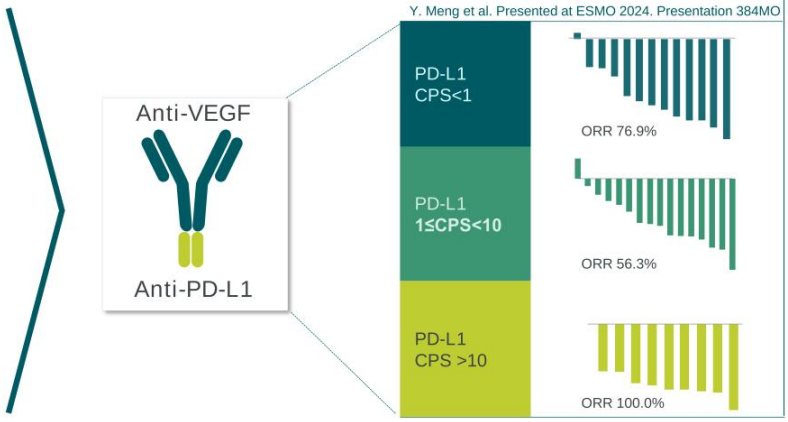
BIONTECH

BNT327/PM8002[1] May Drive Clinical Benefit Irrespective of PD-L1 Status

BNT327/PM8002[1] can potentially become backbone IO therapy irrespective of PD-L1 status

BNT327/PM8002[1] MOA
dual mechanisms: tumor targeting and synergy in reversing immunosuppression

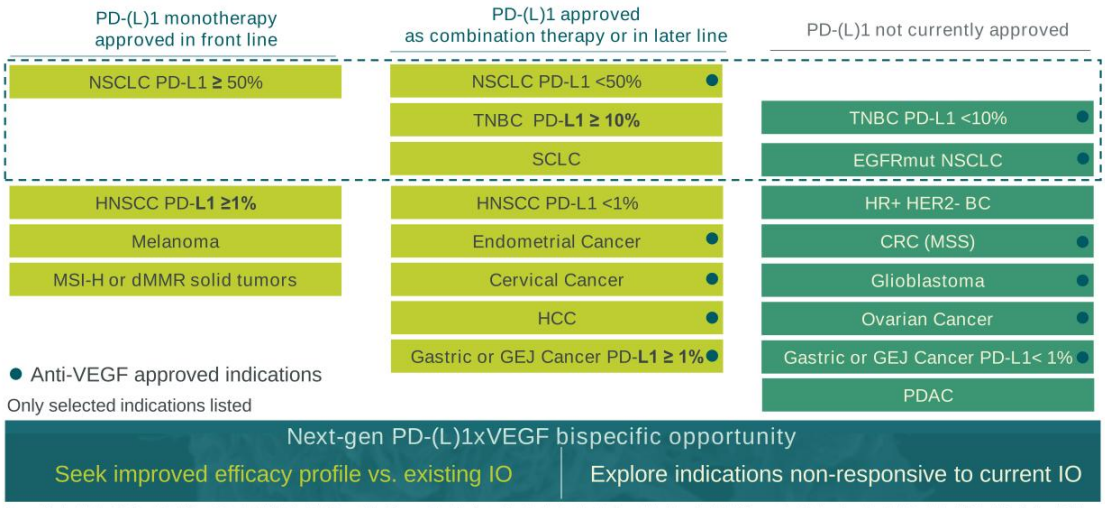
Clinical signals observed
in studies enrolling >700 patients across 10+ Indications



1. Partnered with Biotheus; Source: Y. Meng et al. Presented at ESMO 2024. Presentation 384MO.

BIONTECH

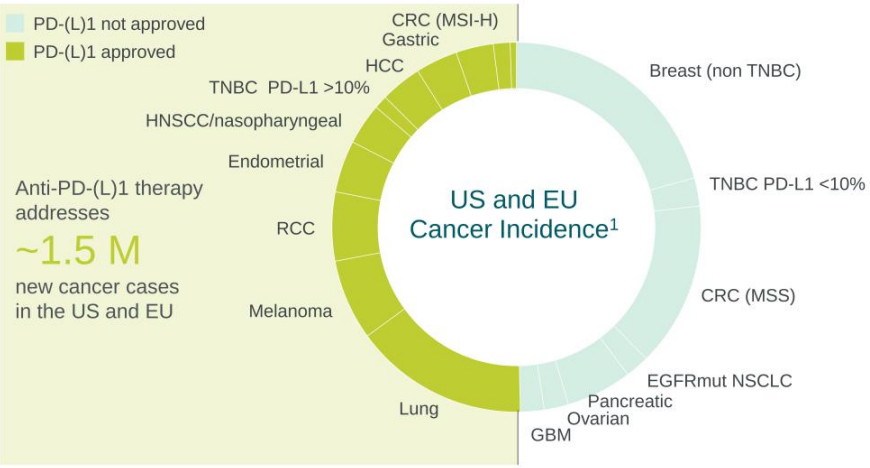
Next-generation Bispecific Can Potentially Expand the Reach of IO Therapy



Source: Keytruda Label; Opdivo Label; Tecentriq Label; Imfinzi Label; Libtayo Label; Bavencio Label; Jemperli Label; Loqtorzi Label; Zynyz Label; Avastin Label; Cyramza Label; Lenvima Label; Votrient Label . Selected indications listed based on FDA approval.

BIONTECH

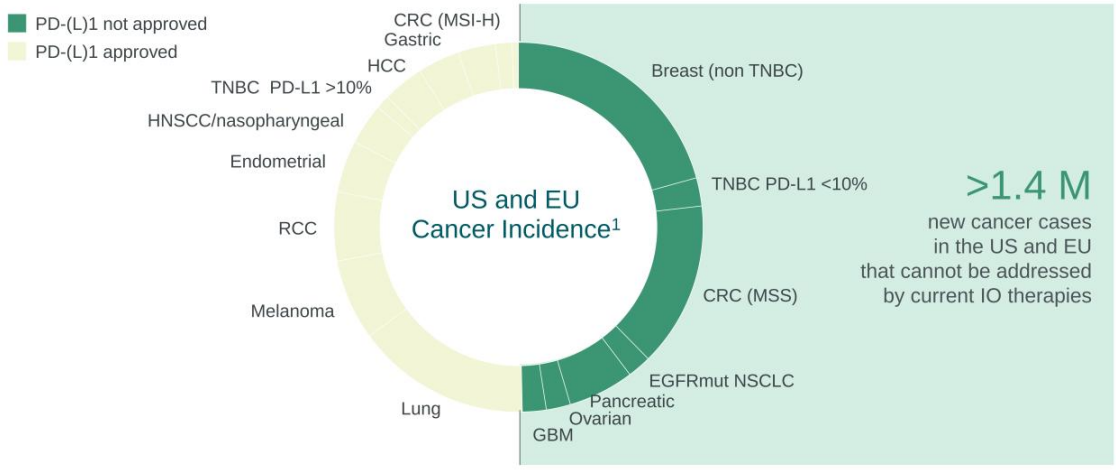
Anti-PD-(L)1 Therapy Only Addresses a Fraction of Cancer Incidence



1. US incidence source: NIH and American Cancer Society data EU incidence source: European Cancer Information System, Indications listed on the previous slide are shown.

BIONTECH

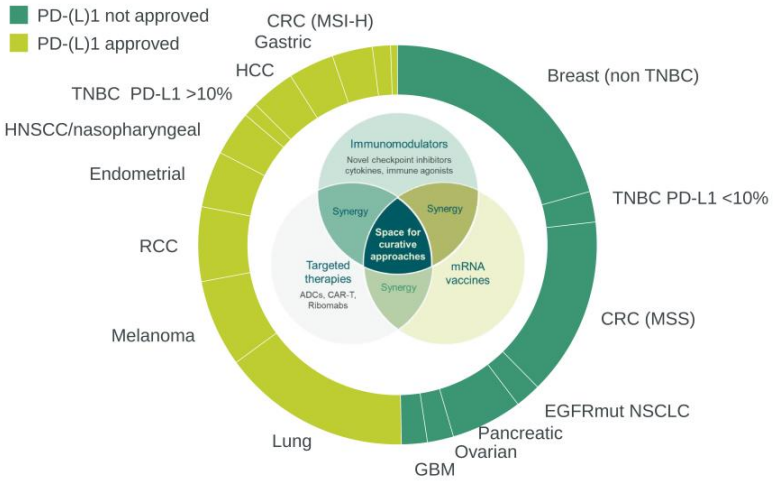
Significant Patient Population Not Addressed by Existing IO Therapies



1. US incidence source: NIH and American Cancer Society data EU incidence source: European Cancer Information System, Indications listed on the previous slide are shown.

BIONTECH

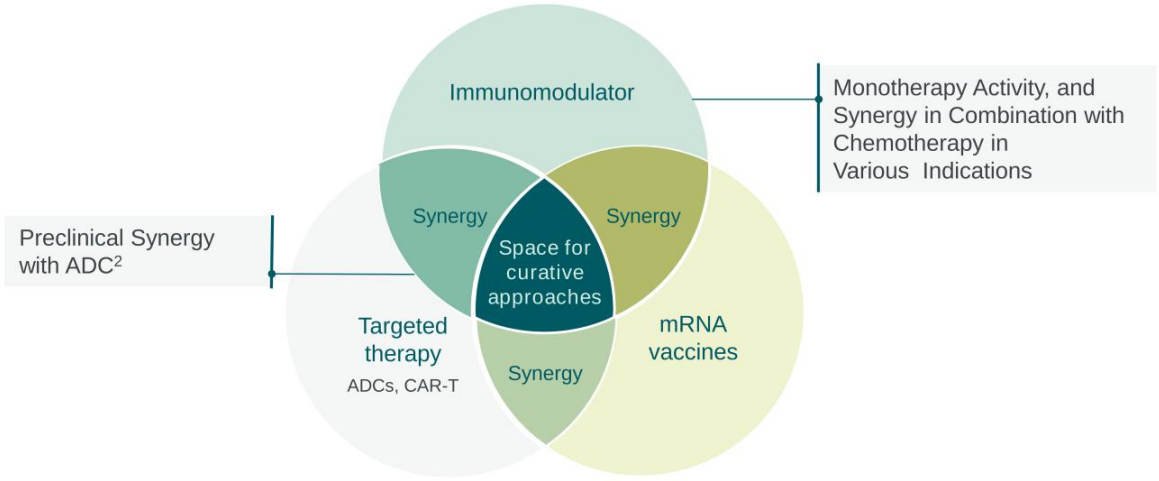
We Aim to Bring New Approaches Across Indications through Our Combination Strategy



1. US incidence source: NIH and American Cancer Society data EU incidence source: European Cancer Information System, Indications listed on the previous slide are shown.

BIONTECH

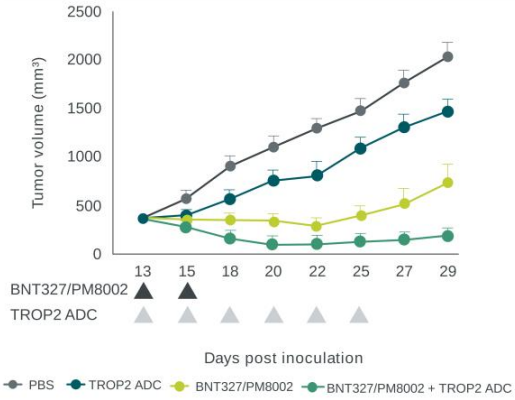
Focus on BNT327/PM8002[1] as Backbone for Late-Stage Development



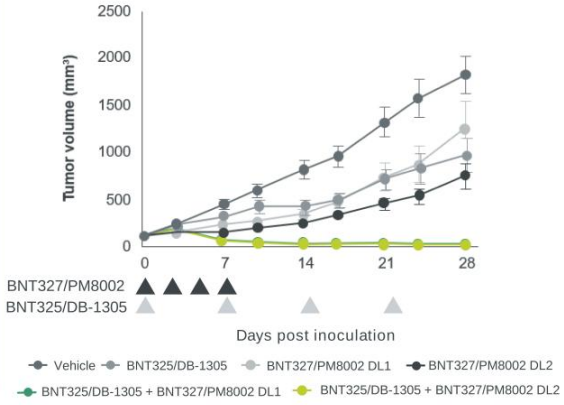
1. Partnered with Biotheus; 2. Data on file.
Disclaimer: Conceptual schema, illustrative purpose only.

BNT327/PM8002[1] + BNT325/DB-1305[2] TROP2-ADC: Preclinical Data Demonstrate Enhanced Anti-Tumor Efficacy when Combined

Xenograft A375 PBMC-co injection model – A375 expressing TROP2 in B-NDG B2M



hTROP2-MC38 in wt mice



Partnered with: 1. Biotheus; 2. DualityBio.

BIONTECH

BNT327/PM8002[1] Clinical Development
Taking Full Control of Global Rights and Clinical Programs

Global clinical trials

Indication	Target population	Regimen	Phase	Status
SCLC	1L or 2L	+ chemo	2	Ongoing
TNBC	1L or 2L	+ chemo	2	Ongoing
SCLC	1L	+ chemo vs. atezolizumab + chemo	3	US IND approved
NSCLC	1L	+ chemo vs. pembrolizumab + chemo	2/3	US IND approved
TNBC	1L	+ chemo vs. chemo	3	Planned
Selected solid tumors		+ BNT325/DB-1305[2]	1/2	Ongoing
Selected solid tumors		+ BNT324/DB-1311[2]	1/2	US IND approved
Selected solid tumors		+ BNT323/DB-1303[2]	1/2	US IND approved

China-based clinical trials

Indication	Target population	Regimen	Phase	Status
TNBC	1L	+ chemo vs. chemo	3	Ongoing
SCLC	2L	+ chemo vs. chemo	3	Ongoing
NSCLC	2L+ EGFRmut	+ chemo	2/3	Ongoing
SCLC	1L	+ chemo	2/3	Ongoing
	2L	+ chemo	2	Primary completion
TNBC	1L	+ chemo	1/2	Ongoing
HCC	1L	+ chemo	2	Ongoing
	1L	+ TIGIT x PVRIG (PM1009)	1/2	Ongoing
NEN	2L	+ chemo	2	Ongoing
MPM	1L	+ chemo	2	Ongoing
Advanced solid tumors[3]		mono	1/2	Primary completion

BNT327/PM8002
Proven capabilities of BioNTech + Biotheus

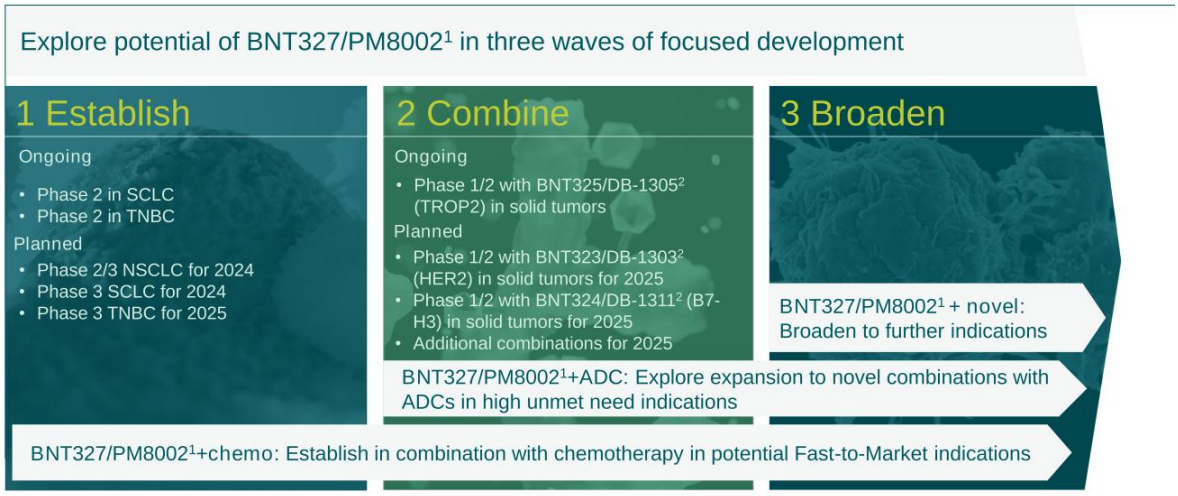
>700 patients enrolled across 10+ indications

19 clinical trials ongoing or planned, including 3 global registrational trials in 1L TNBC, SCLC, and NSCLC

Partnered with: 1. Biotheus; 2. DualityBio; 3. Indications included in Ph2a: NSCLC, mucosal melanoma, renal cell carcinoma, endometrial cancer, cervical cancer, platinum resistant ovarian cancer.

BIONTECH

Accelerating Global Clinical Development Program for BNT327/PM8002[1]



Partnered with: 1. Biotheus; 2. DualityBio.

BIONTECH

Announced Planned Acquisition of Biotheus

BioNTech to Acquire Biotheus to Boost Oncology Strategy

November 13, 2024

- *Acquisition to support the global execution of BioNTech's oncology strategy and provide full global rights to BNT327/PM8002, an investigational PD-L1 x VEGF-A bispecific antibody, with potential to replace current checkpoint inhibitor standard of care treatments for solid tumors*
- *With the acquisition of Biotheus, BioNTech aims to further strengthen its capabilities to develop, manufacture and commercialize next-generation bispecific antibodies and novel treatment combinations*
- *BioNTech and Biotheus plan to initiate multiple registrational trials with BNT327/PM8002 in late 2024 and 2025; further clinical trials evaluating BNT327/PM8002 as combination therapies are planned to start in 2024 and 2025*
- *BioNTech to pay $800 million to acquire 100 percent of the issued share capital and up to $150 million in potential milestone payments*
- *Additional details will be shared at BioNTech's Innovation Series R&D Day event on 14 November 2024*

Upfront cash and BioNTech stock payment of $800 Million	Milestone-based cash earn-out of up to $150 million
Biotheus to become a wholly-owned BioNTech subsidiary	Closing expected Q1 2025[1]

1. Subject to regulatory approvals and other customary closing conditions.

Biotheus Acquisition to Accelerate BNT327/PM8002[1] Development Execution

Advancing BNT327/PM8002[1] in multiple indications, aiming for first-to-market approvals

BNT327/ PM8002[1] development acceleration and expansion

Global control of BNT327/PM8002[1] development and commercialization program

Streamline execution of initial BNT327/PM8002[1] + ADC development plans

Clinical development capability establishment in China

~80-person clinical development organization in China with demonstrated execution ability

Manufacturing site supporting initial launch

cGMP manufacturing facility with multiple 2000L bioreactors

Full pipeline and platform ownership

Comprehensive E2E bispecific antibody discovery and development capabilities

6 clinical stage assets

Pre-clinical ADC pipeline

1 Partnered with Biotheus.

BIONTECH

Biotheus Manufacturing Facility to Supply Clinical Trial Expansion and Early Launches

Biotheus Brings Fully-Integrated CMC, Manufacturing and Fill Finish Capabilities

200L Pilot plant: support IND and Phase 1 studies

2000L Production plant:

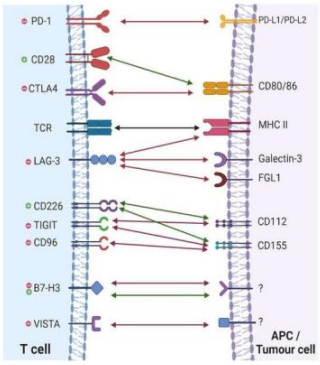
Support global clinical development and early launches

IND documentation has met global regulatory standards including China, Australia and US

Biotheus 2000L cGMP manufacturing site

Oncology Treatment is Entering the Bispecific Antibody Era

IO therapies have relied on mAbs with a single target[1]



TAA: tumor-associated antigen

Bispecific antibodies enable new opportunities

10 new bispecifics approved in the U.S. since 2021

FDA approval of bispecifics

- **2014** Blinatumomab (CD20 × CD3)
- **2017** Emicizumab (factor IXa × factor X)
- **2021** Amivantamab (EGFR × cMet)
- **2022** Tebentafusp (gp100 × CD3); Faricimab (Ang-2 × VEGF); Teclistamab (BCMA × CD3); Mosunetuzumab (CD20 × CD3)
- **2023** Epcoritamab (CD20 × CD3); Glofitamab (CD20 × CD3); Talquetamab (GPRC5D × CD3); Elranatamab (BCMA × CD3)
- **2024** Tarlatamab (DLL3 × CD3)

Selected MoAs of novel bispecific antibodies

Tumor targeting | Immune redirecting

BNT327/PM8002[2] combines tumor targeting and immune redirecting

1. Qin et al. Molecular Cancer (2019) 18:155. 2. Partnered with Biotheus.

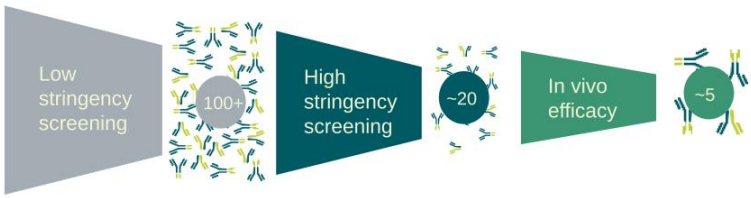
BIONTECH

Biotheus' Fully-Integrated Antibody Discovery and Engineering Workflow

"Plug and Play" design enables screening of multiple formats for optimized lead selection

Selected antibody formats generated

2 Fabs + 2 VHHs | 1 Fab + 1Fab | 2 Fabs + 2 scFvs



24 months for BNT327/PM8002[1] from discovery to IND submission

9 clinical stage bispecifics generated

30+ preclinical bispecifics generated

Bispecific produced with a single cell line

BIONTECH

Biotheus Pipeline Enables Exploration of Novel IO + IO Combinations

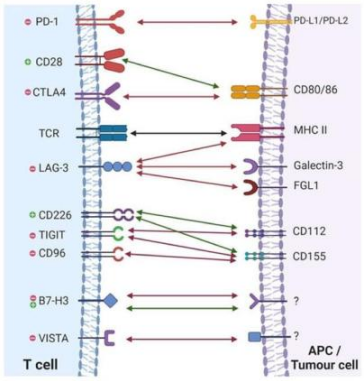
Biotheus Pipeline overview

Selected Clinical Assets

BNT327/PM8002[1] (PD-L1 × VEGF bispecific)	Phase 2 / Phase 3 in China
PM1009 (TIGIT × PVRIG bispecific)	Phase 1
PM1022 (TIGIT × PD-L1 bispecific)	Phase 1
PM1015 (CD73 mAb)	Phase 1
PM1080[2] (EGFR × cMET bispecific)	Phase 1
PM1032 (4-1BB × CLDN18.2 bispecific)	Phase 1

Multiple Pre-clinical Candidates
Multiple bispecifics in pre-clinical development, including bispecific ADCs.

A broad range of targets to be explored for IO+IO combos



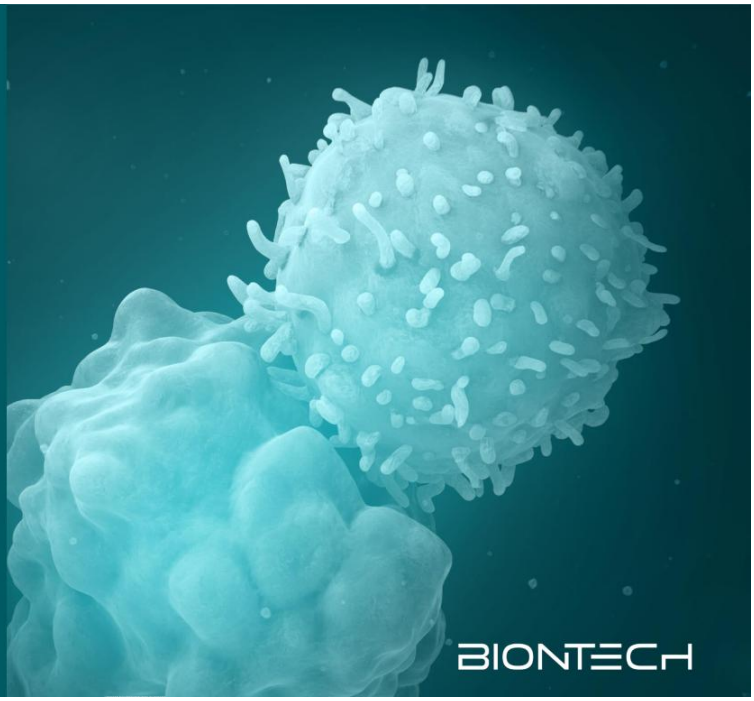
1. Partnered with Biotheus; 2. Hansoh has been granted by Biotheus the exclusive rights to develop, commercialize and manufacture PM1080 in Greater China. Biotheus has ex-China rights.

BIONTECH

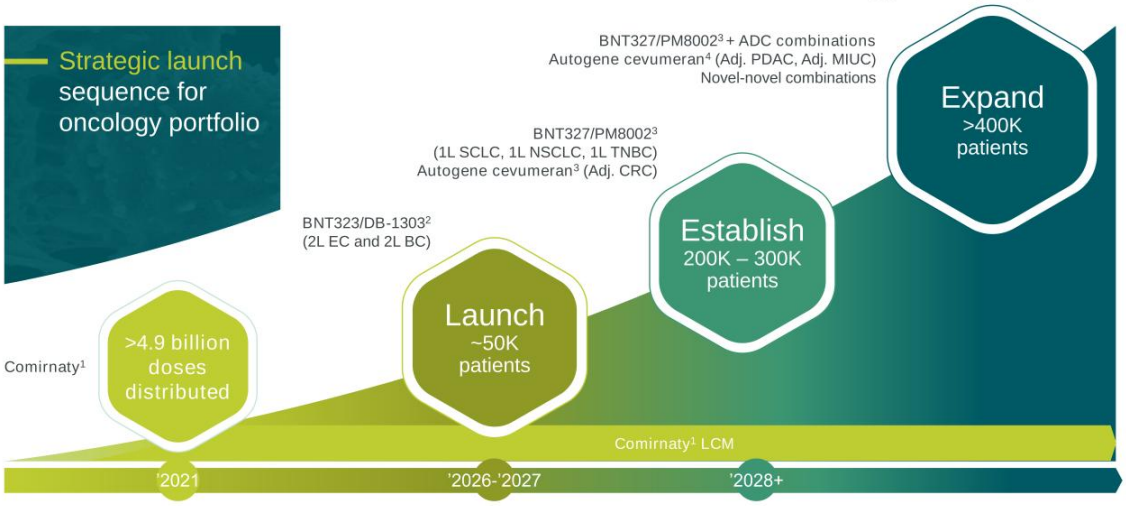
3

Commercialization: Next Era of BioNTech

Annemarie Hanekamp,
Chief Commercial Officer



BioNTech is in Transition to a Multi-Product Commercial Oncology Company



Partnered with: 1. Pfizer; 2. DualityBio; 3. Biotheus; 4. Genentech, a member of the Roche Group; Patient numbers sourced from DRG; LCM = Lifecycle Management.

BIONTECH

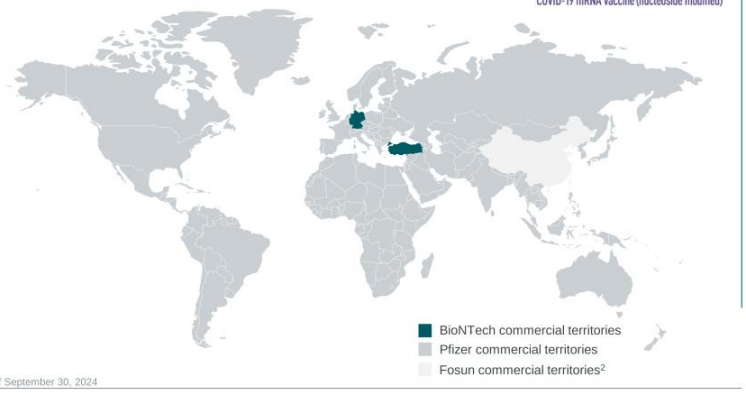
Maintaining COVID-19 Vaccine Franchise[1] with Lean Commercial Infrastructure

Cash generating COVID-19 business structure

- Maintained ~80% gross margin[3]
- Low sales & marketing expenses
- Shared R&D expenses

Lean commercial organization in Germany and Türkiye, leveraging partners' commercial infrastructures for global rollout of Comirnaty

COMIRNATY™
COVID-19 mRNA Vaccine (nucleoside modified)



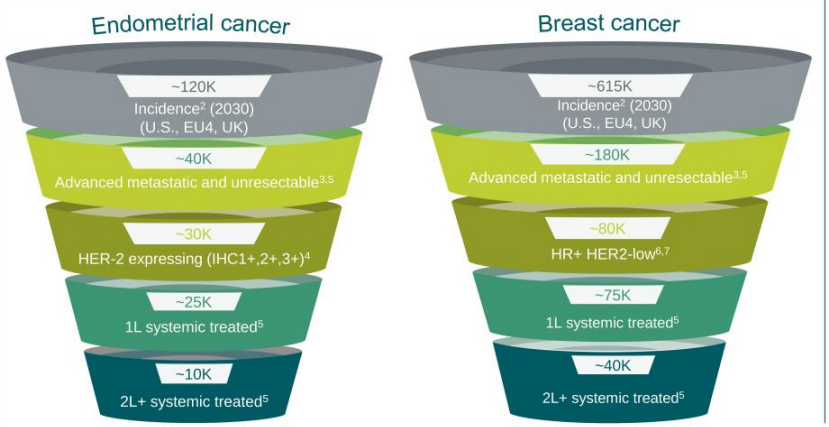
1. Partnered with Pfizer; 2. Comirnaty is not approved in mainland China; 3. As of September 30, 2024

BIONTECH

First Launch with BNT323/DB-1303[1] to Address Unmet Need in Endometrial and Breast Cancer Patients

Strategic launch to build-up BioNTech commercialization capabilities for future launches

- Establish relationships with oncology community and payors
- First step in building expertise in breast and gynecologic cancers



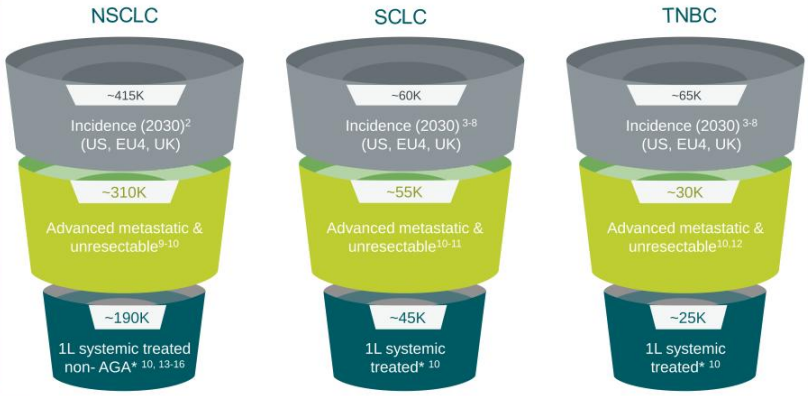
2030 projected incidence
1. Partnered with DualityBio; 2. Projected incidence using historical figures from American Cancer Society (US); Globocan (EU4+UK); 3. SEER; 4. Triangulation of Plotkin, et al., 2024, and Fleming, et al., 2009; 5. CancerMPact; 6. Modi et al., 2022; 7. Bergeron et al., 2023.

BIONTECH

BNT327/PM8002[1]: Combine with SoC Chemotherapy in Potential Fast-to-Market Indications

Building on existing commercial infrastructure, rapidly scaling up to establish lung and breast cancer franchises

- Aiming to address remaining high unmet need through improved duration of response and survival
- Expanding breast cancer franchise while building a presence in lung cancer
- Establishing next-generation IO backbone for novel combinations



2030 projected incidence; * Final patient pool will depend on Ph3 design

1. Partnered with Biotheus; 2. Globocan – Cancer Tomorrow; 3. SEER data for diagnosed SCLC and TNBC incidence in US; 4. Cancer Research UK; 5. Zentrum für Krebsregisterdaten; 6. Sante Publique; 7. AIOM; 8. EPDATA
9. SEER Stat Research Tool; 10. CancerMPact 2024; 11. Dayen et al (2019); 12. Halpern et al (2007); 13. Devarakonda, et al., 2015; 14. Pikor, et al., 2013; 15. Lam, et al., 2019; 16. Friedlaender et al., 2019.

BIONTECH

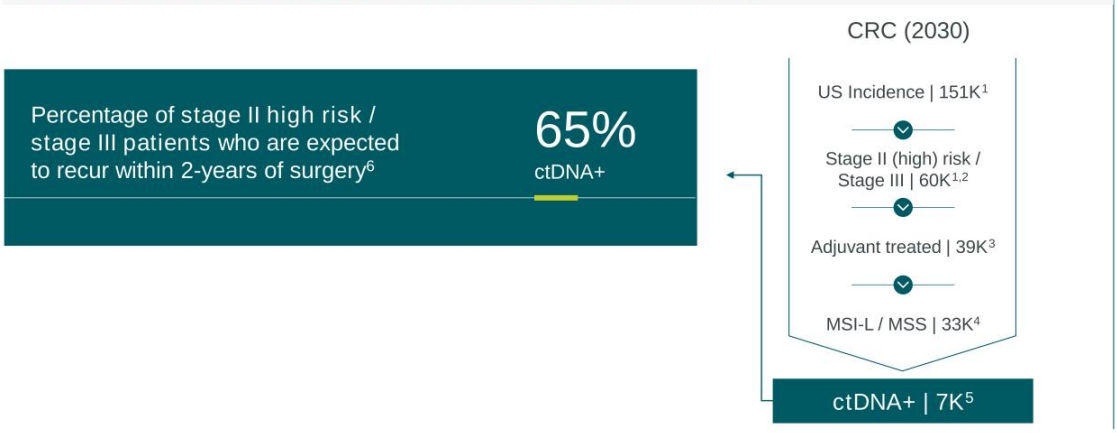
Creating an AI Infused Commercialization Model Focused on Delivering our Innovations to Patients at Scale

Partnered with: 1. DualityBio; 2. Biotheus.

BIONTECH

Aiming to Establish New Pillar of Care for Early-Stage Colorectal Cancer Patients with Autogene Cevumeran

Phased expansion into early-stage tumors with a novel platform modality

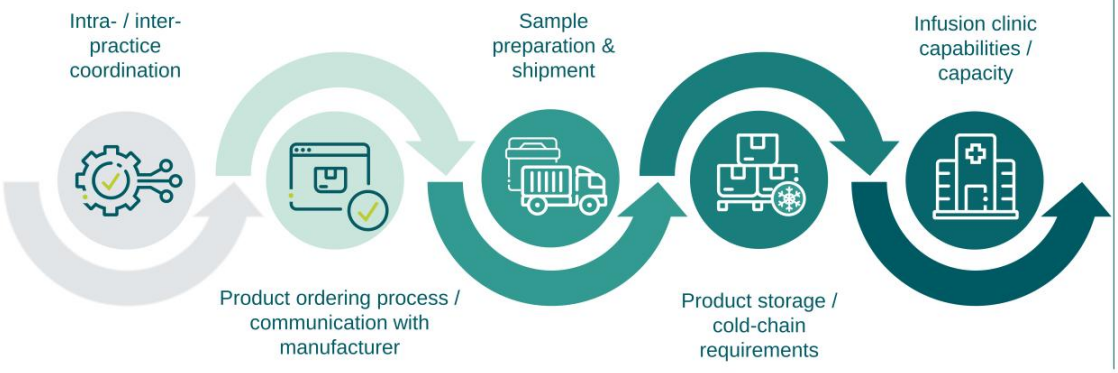


1. Based on CancerMPact® Patient Metrics U.S., accessed in Feb 2024; 2. Babcock, B. et al. Ann. Surgical Onc., 2018; 3. Kotani D. et al. Nat Med, 2022; 4. Mulet-Margalef N. et al. Cancers, 2023; 5. Cohen, S.A. et al. Ann. Onc. 2022. 6. Nakamura Y. et al. Nat. Med., 2024.

BIONTECH

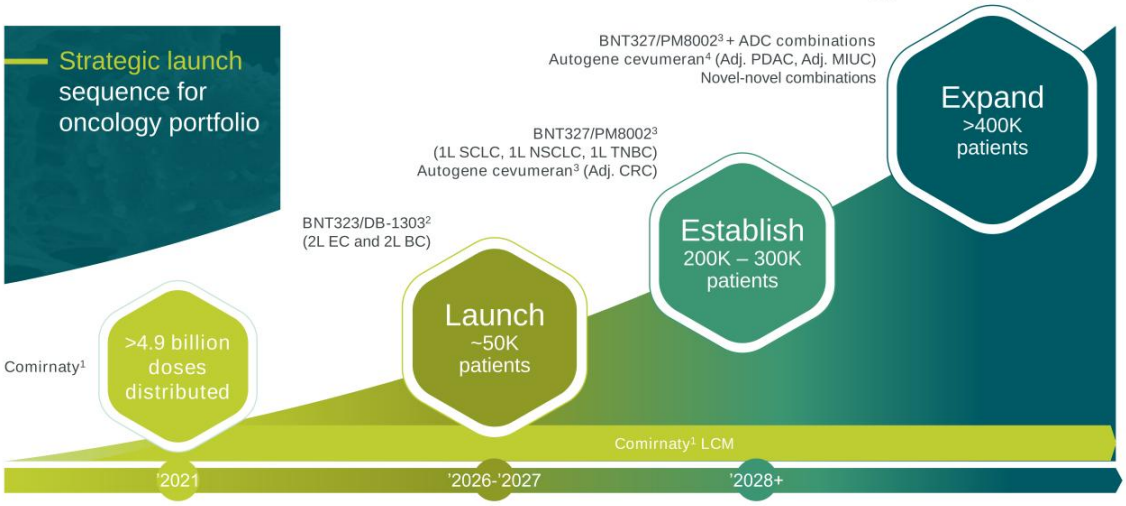
Building a Patient-Centric Commercialization Model to Support the Establishment of Individualized mRNA Cancer Therapies

End-to-End capabilities orchestration required



BIONTECH

BioNTech is in Transition to a Multi-Product Commercial Oncology Company



Partnered with: 1. Pfizer; 2. DualityBio; 3. Biotheus; 4. Genentech, a member of the Roche Group; Patient numbers sourced from DRG; LCM = Lifecycle Management.

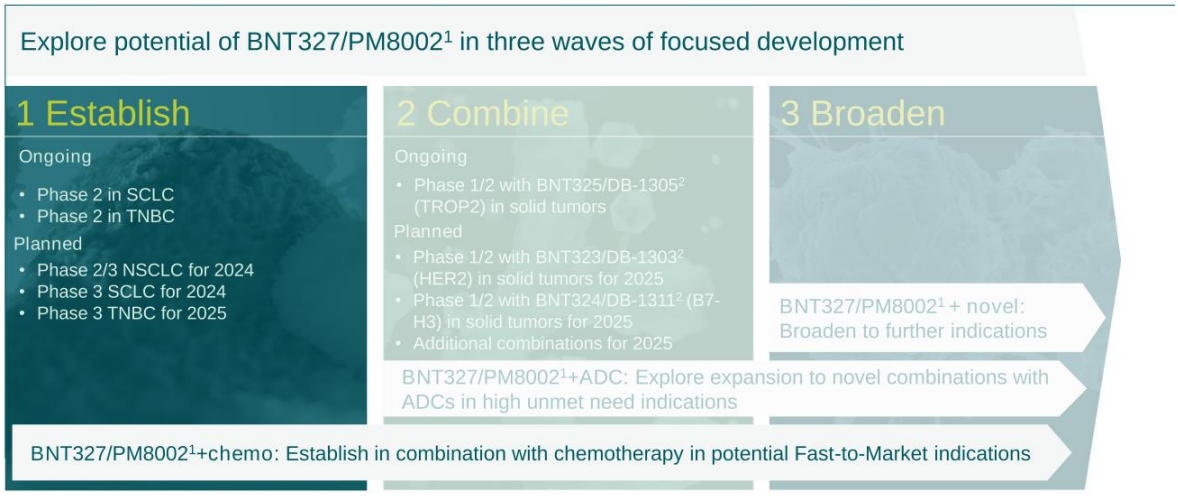
BIONTECH

4

BNT327 Clinical Development Strategy

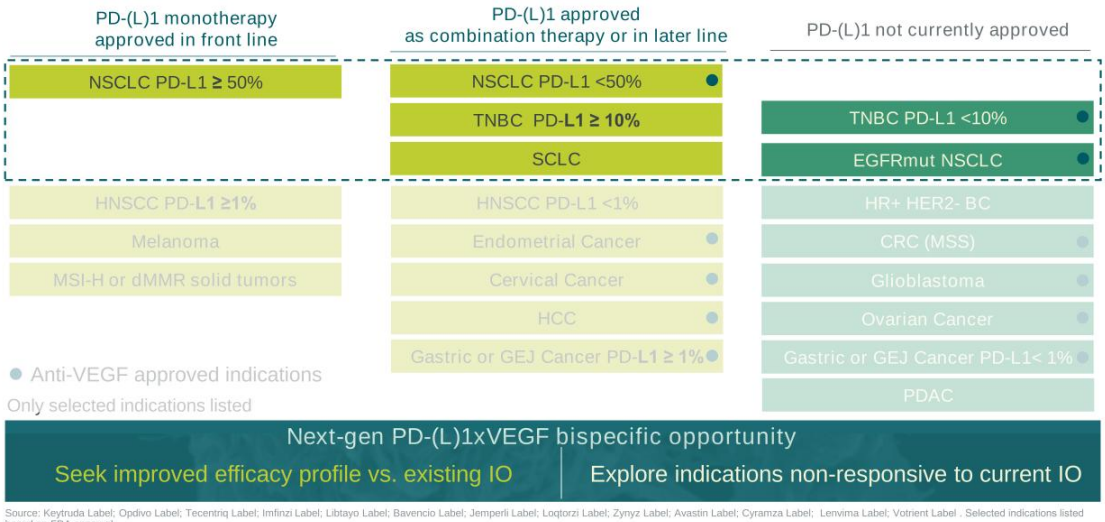
Prof. Ilhan Celik, M.D.
VP Clinical Development

Accelerating Global Clinical Development Program for BNT327/PM8002[1]



Partnered with: 1. Biotheus; 2. DualityBio.

Next-generation Bispecific Can Potentially Expand the Reach of IO Therapy



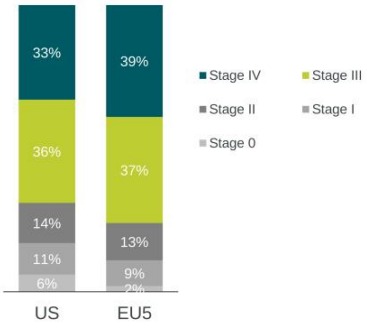
Source: Keytruda Label; Opdivo Label; Tecentriq Label; Imfinzi Label; Libtayo Label; Bavencio Label; Jemperli Label; Loqtorzi Label; Zynyz Label; Avastin Label; Cyramza Label; Lenvima Label; Votrient Label . Selected indications listed based on FDA approval.

BIONTECH

TNBC Patients Face Poor Outcomes Due to Limited Therapeutic Options

2030 U.S., EU4, U.K. TNBC incidence[1] **~65k**

BC staging distribution [2]



Treatment outcomes vary based on PD-L1 levels in 1L TNBC

	PD-L1 CPS < 10 (~ 55%)[3,4]	PD-L1 CPS ≥ 10 (~ 45%)[3,4]
mOS	Chemo: 15.0 mos (KN-355) [4]	Pembro + chemo: 23.0 mos (KN-355) [4]
4-year OS	Chemo: ~ 15 – 20% (KN-355) [4]	Pembro + chemo: ~ 25 – 30 % (KN-355) [4]
5-year survival Stage IV[2]	10%	

1.Incidence from SEER (US); Zentrum für Krebsregisterdaten (DE); Globocan (ES); Sante Publique (FR); AIOM (IT); Cancer Research UK 2. CancerMPact® 2024 Treatment Architecture EU5 and US 3.Danziger N, et al, . Variable Landscape of PD-L1 Expression in Breast Carcinoma as Detected by the DAKO 22C3 Immunohistochemistry Assay. Oncologist. 2023 Apr 6;28(4):319-326. 4. Cortes, J, et al. Pembrolizumab plus Chemotherapy in Advanced Triple-Negative Breast Cancer. N. Engl. J. Med. 2022, 387, 217–226.

BIONTECH

BNT327/PM8002[1] in Combination with Nab-Paclitaxel for 1L Metastatic TNBC

Phase 1b/2 (NCT05918133)

Y. Meng et al. Presented at ESMO 2024. Presentation 384MO

Key inclusion criteria

- Age 18-75 years with life expectancy ≥ 12 weeks
- Histologically or cytologically confirmed unresectable adv. or met. ER, PR, HER-2 negative TNBC
- No prior systemic therapy despite taxane in (neo)adj. settings, ≥ 12 months
- ≥ 1 measurable lesion (RECIST 1.1)
- ECOG PS 0-1
- Adequate organ function

n=60 → BNT327/PM8002[1] + Nab-paclitaxel

Treatment continued until
Disease progression
or
Unacceptable toxicity

Key endpoints

Primary endpoints: ORR per RECIST1.1, safety (NCI-CTCAE v5.0)
Secondary endpoints: PFS, DCR, OS

Benchmark comparator data for 1L TNBC by PD-L1 expression level

Indication	Benchmark regimen	ORR	mPFS	mOS	Benchmark Study
TNBC (CPS <10)	Chemo	35%	5.6 mo	15.0 mo	KEYNOTE-355[2,3]
TNBC (CPS ≥10)	Pembro + Chemo	62%	9.7 mo	23.0 mo	KEYNOTE-355[2]

1. Partnered with Biotheus; 2. J. Cortes et al, Pembrolizumab plus chemotherapy in advanced triple-negative breast cancer, N. Engl. J. Med. 387 (2020) pp 217-226; 3. Obtained from subgroup analysis.

BIONTECH

BNT327/PM8002[1]: Safety Profile Appears Manageable in 1L TNBC

Phase 1b/2 (NCT05918133)

Y. Meng et al. Presented at ESMO 2024. Presentation 384MO

Safety Overview (N=42)	n (%)
All TRAEs	42 (100)
Grade ≥3 TRAEs	24 (57.1)
SAEs	10 (23.8)
TRAE leading to dose interruption	27 (64.3)
TRAE leading to dose reduction	7 (16.7)
TRAEs leading to treatment discontinuation	2 (4.8)
irAE	15 (35.7)
Grade ≥3 irAE	4 (9.5)

TRAEs of Interest (N=42)	All grades, n (%)	Grade ≥ 3, n (%)
Neutrophil count decreased	36 (85.7)	13 (31.0)
White blood cell count decreased	32 (76.2)	10 (23.8)
Anaemia	32 (76.2)	2 (4.8)
Proteinuria	24 (57.1)	2 (4.8)
Hypertriglyceridaemia	18 (42.9)	4 (9.5)
Epistaxis	17 (40.5)	0
Aspartate aminotransferase increased	11 (26.2)	2 (4.8)
Alanine aminotransferase increased	10 (23.8)	1 (2.4)
Hypertension	8 (19.0)	2 (4.8)

Observed TRAEs are known safety signals of PD-(L)1 / VEGF-A targeting therapies plus chemotherapy and resulted in low discontinuation rate

1. Partnered with Biotheus.

BIONTECH

BNT327/PM8002[1] in Combination with Chemo Shows Clinically Meaningful Efficacy in 1L TNBC Irrespective of PD-L1 Status

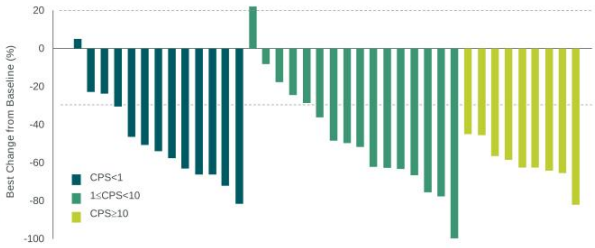
Phase 1/2b (NCT05918133):

Y. Meng et al. Presented at ESMO 2024. Presentation 384MO

Data update at SABCS December 11, 2024

Variable	ITT*	PD-L1 CPS<1	PD-L1 **1≤CPS<10**	PD-L1 **CPS≥10**
Population (n)	42	13	16	9
ORR % (95% CI)	78.6 (63.2, 89.7)	76.9 (46.2, 95.0)	68.8 (41.3, 89.0)	100.0 (66.4, 100.0)
cORR % (95% CI)	73.8 (58.0, 86.1)	76.9 (46.2, 95.0)	56.3 (29.9, 80.3)	100.0 (66.4, 100.0)
DCR % (95% CI)	95.2 (83.8, 99.4)	100.0 (75.3, 100.0)	93.8 (69.8, 99.8)	100.0 (66.4, 100.0)
mPFS (Mo), (95%CI)	13.5 (9.4, --)	NR (5.7, --)	14.0 (7.2, --)	10.8 (5.5, 13.5)

For the ITT population, mDoR 11.7 mos; mOS was not reached



Benchmark comparator data for 1L TNBC by PD-L1 expression level

Indication	Benchmark regimen	ORR	mPFS	mOS	Benchmark Study
TNBC (CPS <10)	Chemo	35%	5.6 mo	15.0 mo	KEYNOTE-355[2]
TNBC (CPS ≥10)	Pembro + Chemo	62%	9.7 mo	23.0 mo	KEYNOTE-355[2]

1. Partnered with Biotheus; 2. Cortes, J, et al. N. Engl. J. Med. 2022. SABCS = San Antonio Breast Cancer Symposium.
*PD-L1 testing was not done in 4 patients (not shown). ORR: 75.0% and mPFS 14.0 months.

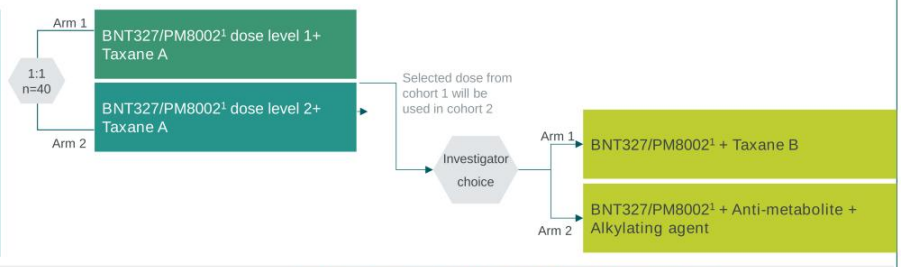
BIONTECH

BNT327/PM8002[1] Phase 2 in Combination with Chemotherapy for 1L/2L Triple Negative Breast Cancer

BNT327-02 (NCT06449222)

Key inclusion criteria

- Histologically confirmed, Ia/ mTNBC
- 1L or 2L
- If recurrent, stage I-III BC, at least 6 months has elapsed between completion of treatment with curative intent
- ECOG PS 0,1



Key endpoints

Primary endpoints: ORR per RECIST v1.1 and safety according to NCI-CTCAE v5.0

Benchmark comparator data for 1L TNBC by PD-L1 expression level

Indication	Benchmark regimen	ORR	mPFS	mOS	Benchmark Study
TNBC (CPS <10)	Chemo	35%	5.6 mo	15.0 mo	KEYNOTE-355[2]
TNBC (CPS ≥10)	Pembro + Chemo	62%	9.7 mo	23.0 mo	KEYNOTE-355[2]

Phase 3 trial planned for 2025

1. Partnered with Biotheus 2. Cortes, J, et al. N. Engl. J. Med. 2022..

BIONTECH

BNT327/PM8002[1] in Combination with Chemotherapy for EGFR-mutated, post-TKI NSCLC

Phase 2 study of BNT327/PM8002[1] + carbo/pem in EGFRm NSCLC post EGFR TKI (NCT05756972)

Adapted from Wu YL et al. Presented at ESMO 2024. Mini oral 1255MO.

Inclusion criteria

- Age ≥ 18 years
- Nonsquamous Stage IIIB/C and IV NSCLC ineligible for surgery or local therapy
- EGFR sensitizing mutation
- Failure of EGFR-TKI treatment(s)
- No other prior systemic therapy than EGFR-TKIs
- Asymptomatic/stable brain metastasis allowed

N=64

BNT327/PM8002[1] + Carboplatin + Pemetrexed
4 cycles

BNT327/PM8002[1] + Pemetrexed
Maintenance

Treatment continued until
Disease progression
or
Up to 2 years

Key endpoints

Primary endpoint: ORR per RECIST v1.1

Benchmark comparator data for 2L+ EGFR-mutated NSCLC

Status	Benchmark regimen	ORR	mPFS	mOS	Benchmark study
Current SoC	Chemo	29.0%	4.2mo	15.3mo	MARIPOSA-2[2]
Recent Approval	Amivantamab + chemo	53.0%	6.3mo	17.7mo	MARIPOSA-2[2]

1. Partnered with Biotheus; 2. https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/761210s004lbl.pdf (accessed on 13Nov2024)

BIONTECH

Safety Profile of BNT327/PM8002[1] + Chemotherapy in Patients with EGFRm NSCLC after Progressing on Prior EGFR TKI

Phase 2 study of BNT327/PM8002[1] + carbo/pem in EGFRm NSCLC post EGFR TKI (NCT05756972)

Adapted from Wu YL et al. Presented at ESMO 2024. Mini oral 1255MO.

Safety Overview, TRAE, (n=64)		n (%)
Any		63 (98.4)
Grade ≥3		39 (60.9)
SAE		11 (17.2)
Leading to interruption of BNT327/PM8002		20 (31.3)
Leading to discontinuation of	only BNT327/PM8002	4 (6.3)
	only chemotherapy	4 (6.3)
	BNT327/PM8002 and chemotherapy	1 (1.6)
Leading to death*		1 (1.6)
Any-grade immune-related		26 (40.6)
Grade ≥3 immune-related		4 (6.3)
Grade ≥3 VEGF-related (hypertension/elevated blood pressure, proteinuria, epistaxis, hemoptysis)		7 (10.9)

TRAEs of Interest (N=64)	All grades, n (%)	**Grade ≥ 3, n (%)**
White blood cell count decreased	48 (75.0)	9 (14.1)
Anaemia	47 (73.4)	6 (9.4)
Neutrophil count decreased	44 (68.8)	19 (29.7)
Platelet count decreased	37 (57.8)	6 (9.4)
Alanine aminotransferase increased	34 (53.1)	1 (1.6)
Aspartate aminotransferase increased	31 (48.4)	1 (1.6)
Proteinuria	25 (39.1)	1 (1.6)
Gamma-glutamyltransferase increased	24 (37.5)	5 (7.8)
Lymphocyte count decreased	24 (37.5)	7 (10.9)
Hypertension	13 (20.3)	5 (7.8)

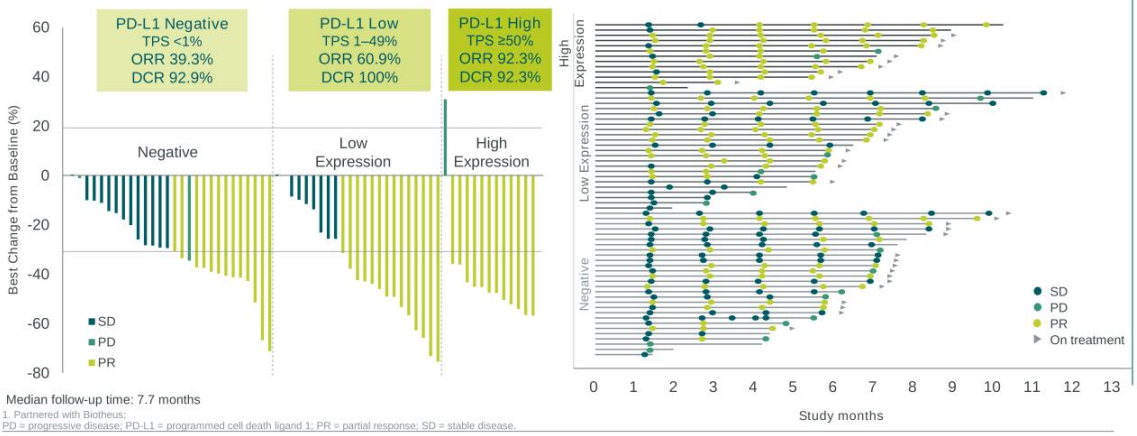
Observed TRAEs are known safety signals of PD-(L)1 / VEGF-A targeting therapies plus chemotherapy and resulted in low discontinuation rate

1. Partnered with Biotheus; *TRAE leading to death: 1 case of pneumonia.

BNT327/PM8002[1] in Combination with Chemo Shows Clinically Meaningful Efficacy in EGFRm NSCLC Irrespective of PD-L1 Status

Phase 2 study of BNT327/PM8002[1] + carbo/pem in EGFRm NSCLC post EGFR TKI (NCT05756972)

Adapted from Wu YL et al. Presented at ESMO 2024. Mini oral 1255MO.



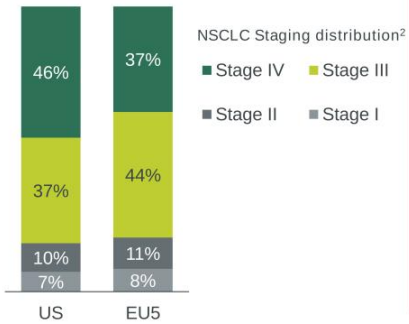
Median follow-up time: 7.7 months

1. Partnered with Biotheus;
PD = progressive disease; PD-L1 = programmed cell death ligand 1; PR = partial response; SD = stable disease.

BIONTECH

Non-Small Cell Lung Cancer is One of the Highest Incidence Cancers Globally[1]

2030 U.S., EU4, U.K. NSCLC incidence[1] **~415k**



Treatment outcomes vary based on histology and PD-L1 levels in 1L NSCLC patients without actionable genomic alterations

	Non-squamous (~ 70%)[3]	Squamous (~ 30%)[3]
PD-**L1 ≥ 50%** (~ 25 - 30%)[4,5]	5-year OS: 30% (KN-189)[6]	5-year OS: 23% (KN-407)[7]
PD-L1 1 - 49% (~ 30 - 40%)[4,5]	5-year OS: 20% (KN-189)[6]	5-year OS: 21% (KN-407)[7]
PD-L1 < 1% (~ 30 - 40%)[4,5]	5-year OS: 10% (KN-189)[6]	5-year OS: 11% (KN-407)[7]

1. Globocan – Cancer Tomorrow. 2. CancerMPact® 2024 Treatment Architecture EU5 and US; Note that 5-year survival reported includes all comer NSCLC population ie including with actionable genetic alterations. 3. Ganti AK, et al. Update of Incidence, Prevalence, Survival, and Initial Treatment in Patients With Non-Small Cell Lung Cancer in the US. JAMA Oncol. 2021 Dec; 4. Mansour MSI et al PD-L1 Expression in Non-Small Cell Lung Cancer Specimens: Association with Clinicopathological Factors and Molecular Alterations. Int J Mol Sci. 2022 Apr 19;23(9):4517; 5. Saez de Gordoa, K. et al. PD-L1 Expression in Non-Small Cell Lung Cancer: Data from a Referral Center in Spain. Diagnostics 2021, 11, 1452; 6. Garassino MC, et al. Pembrolizumab Plus Pemetrexed and Platinum in Nonsquamous Non-Small-Cell Lung Cancer: 5-Year Outcomes From the Phase 3 KEYNOTE-189 Study. J Clin Oncol. 2023 Apr 10;41(11):1992-1998; 7. Silvia Novello et al., Pembrolizumab Plus Chemotherapy in Squamous Non–Small-Cell Lung Cancer: 5-Year Update of the Phase III KEYNOTE-407 Study. JCO 41, 1999-2006(2023).

BIONTECH

BNT327/PM8002[1]: Phase 1/2 Dose Expansion Trial with Monotherapy in 1L NSCLC

Phase 1b/2a (NCT05918445): Safety across all 3 NSCLC cohorts

Wu, C. et al. presented at ASCO 2024. Poster #8533.

Key inclusion criteria

- Age ≥ 18 years with expected survival rate ≥ 12 weeks
- ECOG 0 to 1
- ≥ 1 measurable lesion (RECIST v1.1)

Cohorts*:

- Cohort 1 (n = 17): 1L NSCLC EGFR/ALK WT & PD-L1+ (TPS ≥1) w/o previous systemic treatment
- Cohort 2 (n = 36): EGFR-mutated NSCLC & failed prior EGFR-TKI treatment.
- Cohort 3 (n = 8): EGFR/ALK WT that failed anti-PD-(L)1 therapy and platinum-based chemotherapy regimens.

→ BNT327/PM8002[1] monotherapy 20 mg/kg Q2W →

Treatment continued until

Disease progression

or

Unacceptable toxicity

Key endpoints

Primary endpoints: ORR per RECIST v1.1 and safety according to NCI-CTCAE v5.0

Secondary endpoints: DoR, DCR, PFS per RECIST v1.1 and OS

Benchmark comparator data for 1L non-AGA NSCLC (PD-L1 all-comers)

Indication	Benchmark regimen	ORR	mPFS	mOS	Benchmark study
Non-Squamous	Pembro + chemo	48%	9.0 mo	22.0 mo	KEYNOTE-189[2]
Squamous	Pembro + chemo	62%	8.0 mo	17.2 mo	KEYNOTE-407[3]

* Additional cohorts are part of study NCT05918445 and not included in this presentation. 1. Partnered with Biotheus; 2. Garassino MC, et al. Pembrolizumab Plus Pemetrexed and Platinum in Nonsquamous Non-Small-Cell Lung Cancer: 5-Year Outcomes From the Phase 3 KEYNOTE-189 Study. J Clin Oncol. 2023 Apr 10;41(11):1992-1998; 3. Silvia Novello et al., Pembrolizumab Plus Chemotherapy in Squamous Non–Small-Cell Lung Cancer: 5-Year Update of the Phase III KEYNOTE-407 Study. JCO 41, 1999-2006(2023).

BIONTECH

BNT327/PM8002[1]: Monotherapy Safety Profile Appeared Manageable in 1L NSCLC

Phase 1b/2a (NCT05918445): Safety across all 3 NSCLC cohorts

Wu, C. et al. presented at ASCO 2024. Poster #8533.

Safety overview (n=61)	n (%)
All TRAEs	52 (85.2)
TRAE ≥3	12 (19.7)
irAEs	24 (39.3)
SAE	15 (24.6)
TRAE leading to dose discontinuation	5 (8.2)

Common TRAEs (n=61)	All grades, n (%)	Grade ≥ 3, n (%)
Proteinuria	33 (54.1)	3 (4.9)
Hypertension	15 (24.6)	6 (9.8)
Hypothyroidism	13 (21.3)	0
Hypoalbuminemia	12 (19.7)	0
Hypocalcemia	11 (18.0)	0
Anemia	9 (14.8)	1 (1.6)
Alanine aminotransferase increased	8 (13.1)	8 (13.1)

No Grade 4/5 TRAEs observed, most AEs were Grades 1-2

1. Partnered with Biotheus.

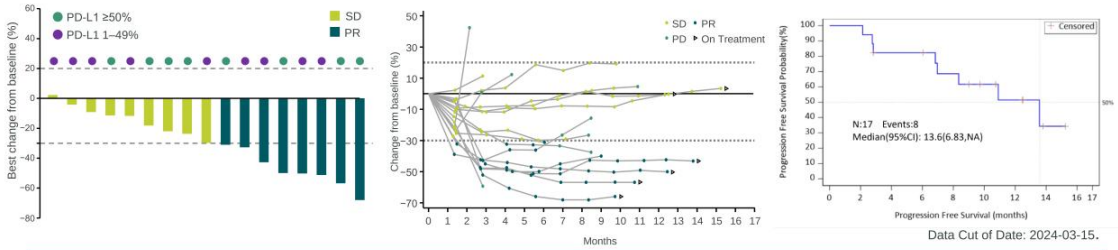
BNT327/PM8002[1] Monotherapy Efficacy in 1L NSCLC

Phase 1b/2a (NCT05918445): cohort 1, 1L NSCLC (EGFR & ALK WT)

Wu, C. et al. presented at ASCO 2024. Poster #8533.

Indication	Benchmark regimen	ORR	mPFS	mOS	Benchmark Study
1L NSCLC (PD-L1 ≥ 50%)	Pembro monotherapy	45%	7.7 mo	26.3 mo	KEYNOTE-024[2]

Waterfall/spider plots and Kaplan-Meier curves (PFS)



Data Cut of Date: 2024-03-15.

1L NSCLC mono tx (cohort 1, n=17): ORR 47%, DCR 100%, mPFS 13.6 months
Comparable ORR in PD-L1 1–49% (n=9) and PD-L1 ≥50% (n=8)

Phase 2/3 to initiate by YE 2024

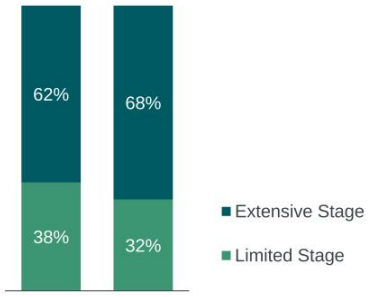
1. Partnered with Biotheus; 2. Reck, M. et al. NEJM 2016.

BIONTECH

Extensive-Stage Small Cell Lung Cancer is a High-Incidence Cancer with Poor Long-term Survival Rates

2030 U.S., EU4, U.K. SCLC incidence[1] **~60k**

SCLC Staging distribution[2]



High unmet need for ES-SCLC patients as long-term survival outcomes remain very poor

	Limited-Stage SCLC	Extensive-Stage SCLC
mOS	CRT: 25 – 30 mos (CONVERT)[3]	Atezo + chemo: 12.3 mos (IMPower133)[4,5]
24 mos OS	CRT: ~ 50% (CONVERT)[3]	Atezo + chemo: ~ 25% (IMPower133)[4,5]
5-year survival[2]	20%	3%

1.Incidence from: SEER data for diagnosed SCLC incidence in US; Cancer Research UK; Zentrum für Krebsregisterdaten; Sante Publique; AIOM; EPDATA.
2.Statistics from Dayen et al (2019); CancerMPact® Patient Metrics US & EU5, accessed February 2024. *Due to limited survival data in EU5, U.S. survival data is reported;
3.Walls, Gerard M. et al.Long-Term Outcomes After Concurrent Once- or Twice-Daily Chemoradiation in Limited-Stage Small Cell Lung Cancer: A Brief Report From the CONVERT TrialInternational Journal of Radiation Oncology, Biology, Physics, Volume 119, Issue 5, 1386 - 1390
4.L. Horn et al, First-line atezolizumab plus chemotherapy in extensive-stage small-cell lung cancerN. Engl. J. Med., 379 (2018), pp. 2220-2229
5.Stephen V. Liu et al., Updated Overall Survival and PD-L1 Subgroup Analysis of Patients With Extensive-Stage Small-Cell Lung Cancer Treated With Atezolizumab, Carboplatin, and Etoposide (IMpower133). JCO 39, 619-630(2021).

BIONTECH

BNT327/PM8002[1] in Combination with Paclitaxel for 2L SCLC

Phase 2 (NCT05879068)

Key Inclusion criteria

Patients with advanced SCLC who progressed after platinum-based chemotherapy with or without checkpoint inhibitors

- Age ≥ 18 years
- ECOG PS 0-1

n=99

Induction

BNT327/PM8002[1] + paclitaxel (5 cycles)

Maintenance

BNT327/PM8002[1]

Treatment continued until

Disease progression
or
withdrawal of consent
or
Unacceptable toxicity

Key endpoints

Primary endpoints: ORR per RECIST1.1, TRAEs incidence and severity

Secondary endpoints: DCR, DoR, PFS and OS

Benchmark comparator data for 2L+ SCLC

Status	Benchmark regimen	ORR	mPFS	mOS	Benchmark study
Current SoC	Chemo	29%	4.0 mo	7.6 mo	ATLANTIS[2]
Recent Approval	tarlatamab	40%	4.9 mo	14.3 mo	DeLLphi-301[3]

1. Partnered with Biotheus 2. Aix S.P. et al. Lancet Resp Med 2023. 3. Ahn M. et al. NEJM 2023.

BIONTECH

BNT327/PM8002[1] Combined with Paclitaxel Shows Acceptable Safety Profile in 2L SCLC

Phase 2 (NCT05879068)

Ying Cheng et al. Presented at ESMO 2023. Poster#1992P

Safety overview (n=48)	n (%)
All TRAEs	45 (93.8)
TRAE ≥3	30 (62.5)
SAE	16 (33.3)
TRAE leading to treatment discontinuation	1 (2.1)

TRAE **≥10% of patients**	All grades, n (%)	Grade ≥ 3, n (%)
Neutropenia	23 (47.9)	22 (45.9)
Leukopenia	23 (47.9)	12 (25.0)
Decreased platelet count	12 (25.0)	1 (2.1)
Anemia	11 (22.9)	0
Proteinuria	9 (18.8)	2 (4.2)
Pneumonitis	6 (12.5)	1 (2.1)*

*One grade 5 event due to pneumonitis

Observed TRAEs are known safety signals of PD-(L)1 / VEGF-A targeting therapies plus chemotherapy and resulted in low discontinuation rate (2.1%)

1. Partnered with Biotheus.

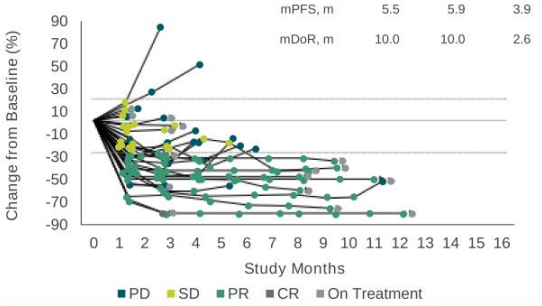
BNT327/PM8002[1] Combined with Paclitaxel Shows Efficacy in 2L SCLC

Phase 2 (NCT05879068)

Ying Cheng et al. Presented at ESMO 2023. Poster#1992P

- Received prior anti-PD-1/PD-L1 : ~46%

Efficacy Evaluation Population			
Response	ITT (n=36)	IO-naïve (n=22)	IO-treated (n=14)
mPFS, m	5.5	5.9	3.9
mDoR, m	10.0	10.0	2.6



Efficacy Evaluation Population			
Response	ITT (n=36)	IO-naïve (n=22)	IO-treated (n=14)
ORR, %	61.1	72.7	42.9
DCR, %	86.1	81.8	92.9

ORR for current SoC therapies in 2L+ SCLC ranges from 24-40% [2]

1. Partnered with Biotheus; 2. On-label ORR for topotecan (24%), lurbinectedin (35%), and tarlatamab (40%).

BIONTECH

BNT327/PM8002[1]: Phase 2 Dose Optimization in Combination with Chemotherapy for 1L/2L SCLC

BNT327-01 (NCT06449209)

Key Inclusion criteria

- Cohort 1: Untreated ES-SCLC or LS-SCLC with TFI≤6 months since last treatment
- Cohort 2 & 3: SCLC with disease progression after 1L platinum based CTx (w/wo IO) or 2L CTx

BNT327/PM8002[1] (dose level 1) + chemo

BNT327/PM8002[1] (dose level 2) + chemo

Treatment continued until

Disease progression

or

Intolerable toxicity

- Three cohorts based on previous treatment for patients and chemo option used to combine with BNT327/PM8002[1]
- Each cohort randomized to receive two different dose levels BNT327/PM8002[1] with chemo

Key endpoints

Primary endpoints: ORR per RECIST v1.1 and safety according to NCI-CTCAE v5.0

Secondary endpoints: DoR, DCR, PFS per RECIST v1.1 and OS

Benchmark comparator data for 1L ES-SCLC

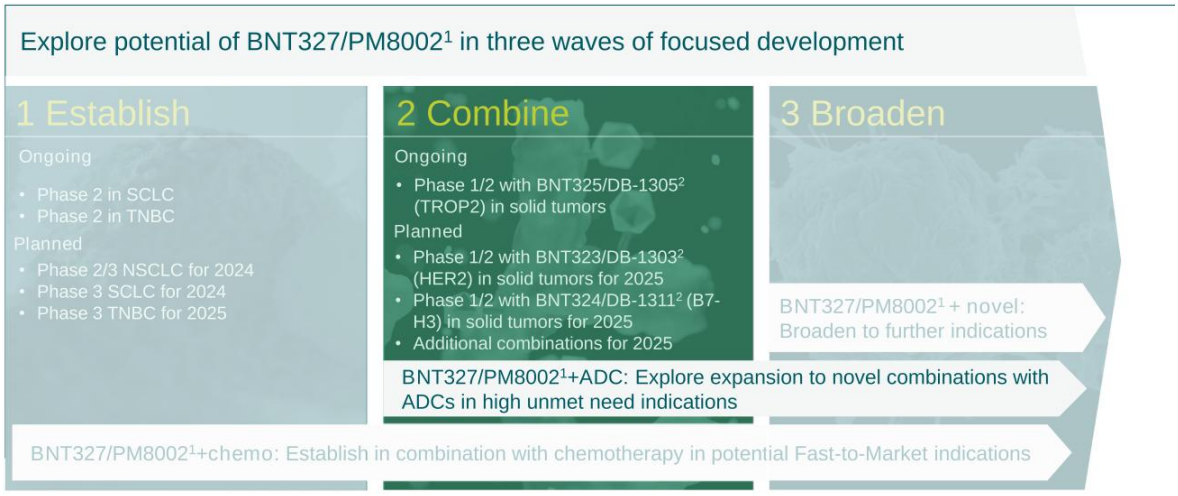
Benchmark regimen	ORR	mPFS	mOS	Benchmark study
Atezo + chemo	60%	5.2 mo	12.3 mo	IMPower133[2]

Phase 3 to initiate by YE 2024

1. Partnered with Biotheus; 2. L. Horn et al, First-line atezolizumab plus chemotherapy in extensive-stage small-cell lung cancerN. Engl. J. Med., 379 (2018), pp. 2220-2229.

BIONTECH

Accelerating Global Clinical Development Program for BNT327/PM8002[1]



Partnered with: 1. Biotheus; 2. DualityBio.

Well-Positioned in ADCs with Therapeutic Candidates Across Multiple Tumors

BNT323/DB-1303[1]

Targeting HER2, cleavable linker and topoisomerase I inhibitor

DAR: 8

Clinical status
- Ph3 in HR+HER2-low mBC
- Ph1/2 in multiple solid tumors

BNT324/DB-1311[1]

Targeting B7-H3, cleavable linker and topoisomerase I inhibitor

DAR: 6

Clinical status
- Ph1/2 in multiple solid tumors

BNT325/DB-1305[1]

Targeting TROP2, cleavable linker and topoisomerase I inhibitor

DAR: 4

Clinical status
- Ph1/2 in multiple solid tumors

BNT326/YL202[2]

Targeting HER3, cleavable linker allows for intracellular and extracellular release of topoisomerase I inhibitor

DAR: 8

Clinical status
- Ph1 in multiple solid tumors

Expression level by indication[3]

High
Medium / Low
Very low / None

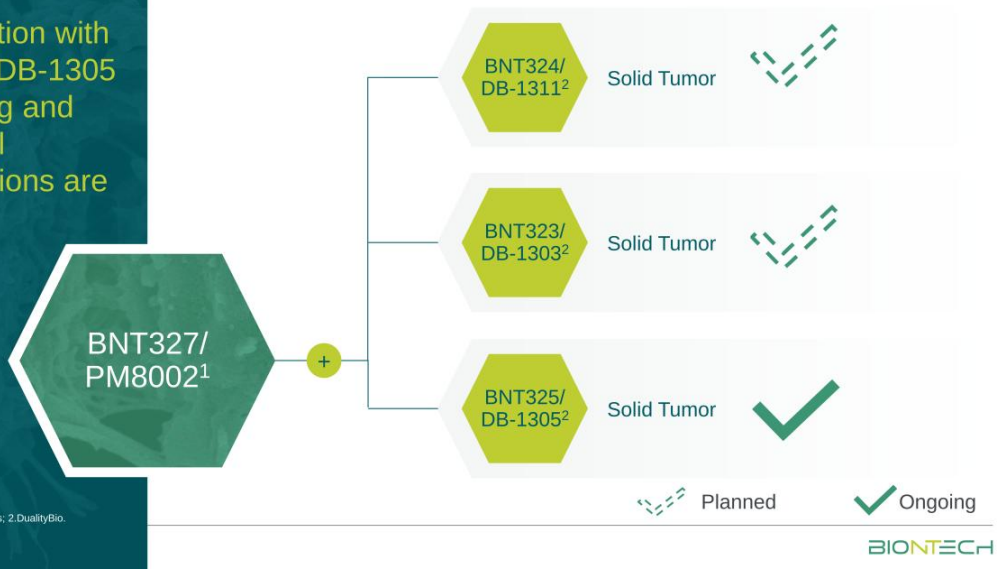
Target	NSCLC	SCLC	HER2+ BC	HR+ BC	TNBC	CRC	Gastric	Ovarian	PDAC	HNSCC	Prostate	Other high expression indications
HER2												Gynecologic
TROP2												
B7-H3												UC, EC
HER3												

1. Partnered with DualityBio; 2. Partnered with MediLink; 3. RNAseq data from AACR Project GENIE.

BIONTECH

BNT327/PM8002 + ADC Combinations are Planned or Ongoing

Combination with BNT325/DB-1305 is ongoing and additional combinations are planned



Partnered with 1. Biotheus; 2.DualityBio.

BIONTECH

Time for a
15 minute
break

5

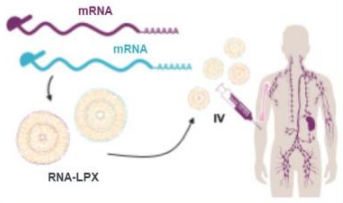
mRNA Cancer Vaccines

Prof. Özlem Türeci, M.D.
CMO and Co-founder

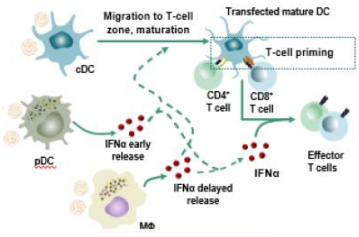
Michael Wenger, M.D.
VP, Clinical Development

Uridine-based mRNA-LPX Vaccines for Systemic Delivery and Induction of Potent Polyspecific Immune Responses Against Cancer Antigens

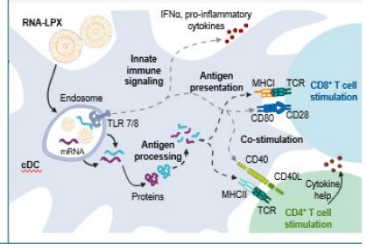
Uridine-based RNA in formulated LPX (RNA-LPX) and administered IV for preferential delivery to the APCs in spleen, lymph nodes and bone marrow



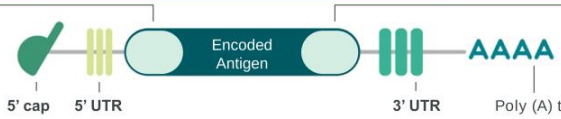
RNA-LPX is optimized for immune response stimulation



RNA-LPX combines targeted antigen delivery with stimulation of TLR-mediated IFNα immune response



Secretory signal peptide
for translocation of the nascent polypeptide chain into the endoplasmic reticulum



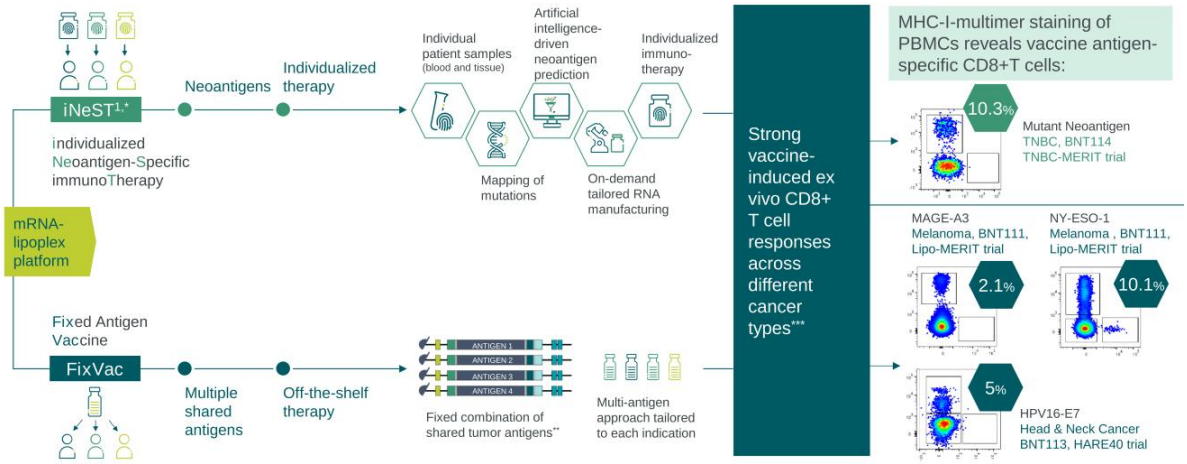
MITD (transmembrane and cytoplasmic domain of MHC class I)

5`cap, UTRs, poly(A) tail engineered for optimized stability and translational performance

Uridine chemistry for intrinsic adjuvanticity

BIONTECH

Full Exploitation of Cancer Vaccine Target Space



1. In collaboration with Genentech, a member of the Roche Group. ** Antigens vary across programs; *** T cell responses analyzed by ex vivo multimer staining analysis in blood.

BIONTECH

Multiple Clinical Trials Demonstrate Execution Across iNeST and FixVac Portfolio

Individualized vaccine: iNeST					FixVac		
Autogene cevumeran (BNT122/RO7198457) [1]					BNT111 [2]	BNT113	BNT116
Adjuvant			1L	R/R	R/R	1L	Multiple settings
MIUC Phase 2 + Nivolumab	CRC Phase 2 Monotherapy	PDAC Phase 2 + Atezolizumab	Melanoma Phase 2 + Pembrolizumab	Solid Tumors Phase 1 + Atezolizumab	Melanoma Phase 2 + Cemiplimab	HPV16+ HNSCC Phase 2 + Pembrolizumab	NSCLC Phase 1 & 2 Monotherapy, + Cemiplimab or CTx
Recruitment started	Recruitment ongoing Data presented from epi sub-study at ASCO 2024 and from biomarker sub-study at ESMO-GI 2024.	Recruitment ongoing Data presented from investigator-initiated Ph 1 trial at ASCO 2022 & AACR 2024 and published. (Rojas et al., Nature 2023)	Enrollment completed Ph 1 data on prototype vaccine published (Sahin et al., Nature 2017). Analysis of Ph 2 PFS as primary endpoint will be based on events and defined when reporting results.	Enrollment completed Data presented at AACR 2020. **Manuscript** accepted in Nature Medicine	Enrollment completed Positive topline data announced July 2024 Data presented from Ph 1 at multiple conferences incl. SITC 2021 and published. (Sahin et al., **Nature 2020)**	Recruitment ongoing Ph 2 data presented at multiple conferences incl. ESMO-IO 2022 Data from safety run-in of Ph 2 trial and Ph1/2 IIT presented at ESMO 2024.	Recruitment ongoing in Ph 2 in 1L NSCLC[2] Ph 1 trial ongoing. Data presented at SITC 2023, AACR 2024, and SITC 2024.

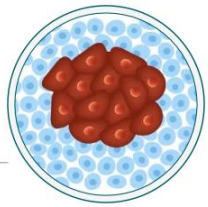
1. Partnered with Genentech, a member of the Roche Group; 2. In collaboration with Regeneron.

Evaluating Autogene Cevumeran[1] in the Adjuvant Treatment Setting for Cancers of High Unmet Need

Rationale for adjuvant setting

Low tumor mass with residual cancer cells

Resistance mechanisms and immune suppression not fully established



Healthier immune system and uncompromised T-cell function

Unmet medical need

Pancreatic Ductal Adenocarcinoma

69−75% relapse rate within 5 years after adjuvant therapy[2,3]

- Projected to be 2nd leading cause of cancer-related death (US) by 2030[4]
- 5-year survival rates after resection are ~10%[5]
- Largely CPI resistant due to low mutation burden [6]

Phase 1 trial completed and published
Randomized Phase 2 trial ongoing

Colorectal Cancer

20-35% relapse rate within 4 years after adjuvant therapy[7]

- 5-year survival rates of locoregional disease are ~70%[8]
- Median disease-free survival for ctDNA-positive, Stage 2 (high risk) and Stage 3 CRC post adjuvant chemotherapy: ≈ 11 months (Reinacher-Schick et al., ASCO 2024)

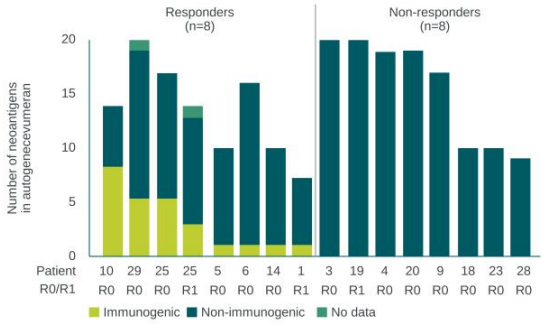
Randomized Phase 2 trial ongoing
Data update in late 2025/early 2026

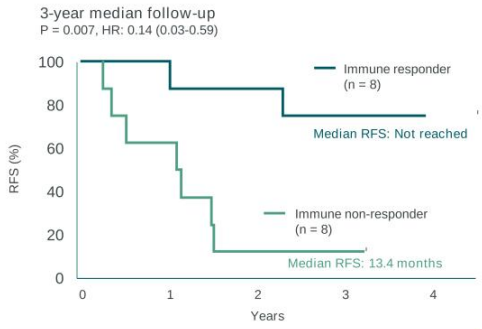
1. Partnered with Genentech, a member of the Roche Group; 2. Jones et al., JAMA Surgery 2019; 3. Conroy et al., JAMA Oncology 2022; 4. Rahib et al., JAMA Network Open 2021; 5. Bengtsson et al., Sci Rep 2020; 6. Kabacaoglu et al., Frontiers Immunol 2018; 7. André et al., JCO 2015; 8. NIH SEER cancer stat facts (Accessed October 30, 2024).

Response to Autogene Cevumeran[1] Correlates with Delayed PDAC Recurrence

Phase 1, investigator-initiated trial in resectable PDAC: 3-year follow-up data

Balachandran et al., AACR 2024. #CT025 & Rojas et al., Nature 2023.





At risk					
Responder	8	8	7	5	0
Non-responder	8	5	1	1	0

Half of all patients mounted neoantigen-specific de novo T cell responses against at least one vaccine neoantigen

1. Partnered with Genentech, a member of the Roche Group.

BIONTECH

Autogene Cevumeran[1] Investigated in a Phase 2 Randomized Trial vs SoC in Resected PDAC Patients

IMCODE003: Phase 2, open-label, multicenter, randomized trial (NCT05968326)

Key inclusion criteria

- Patients with resected PDAC
- No prior systemic anti-cancer treatment for PDAC
- No evidence of disease after surgery

Randomization

6-12 weeks after surgery

Screening Part A

Determine ≥5 neo-epitopes from blood and tumor samples for custom manufacture of autogene cevumeran

Screening Part B

Confirm patient eligibility

n=260
R 1:1

Treatment phases and dosing schedules

Patients are monitored at scheduled intervals until PDAC recurrence, occurrence of new cancers, or unacceptable toxicity.

- Autogene cevumeran[1] + atezolizumab + mFOLFIRINOX
- mFOLFIRINOX

Benchmark comparator data

Indication	Benchmark regimen	mDFS	mOS	5yr DFS	5yr OS	Benchmark study
Adjuvant PDAC	mFOLFIRINOX	21.4mo	53.5mo	26.1%	43.2%	PRODIGE 24[2]

Key endpoints

Primary: DFS

Secondary: DFS rates, OS, OS rates and safety

Status

- Recruitment ongoing

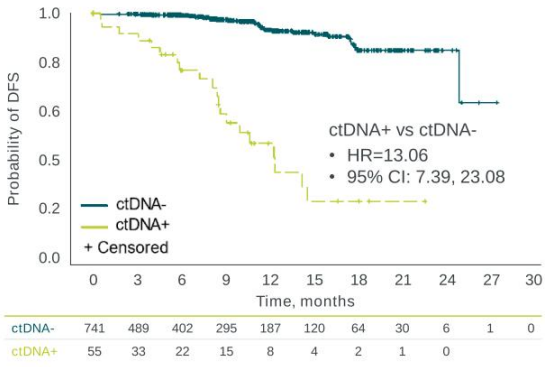
1. Partnered with Genentech, a member of the Roche Group; 2. Conroy et al,. JAMA Onc. 2022.

Post-Surgery ctDNA Positivity in CRC is Associated with Significantly Shorter DFS and Can Identify Patients at High Risk of Disease Recurrence

BNT000-001: A Multi-Site Epidemiological Study of ctDNA Status in Stage II/III CRC Patients After Resection and Prior to Adjuvant Chemotherapy (NCT04813627)

Reinacker-Schick. et al., ASCO 2024. Abstract #3526.

DFS in patients who were ctDNA+ vs ctDNA- post surgery[1]



ctDNA-	741	489	402	295	187	120	64	30	6	1	0
ctDNA+	55	33	22	15	8	4	2	1	0		

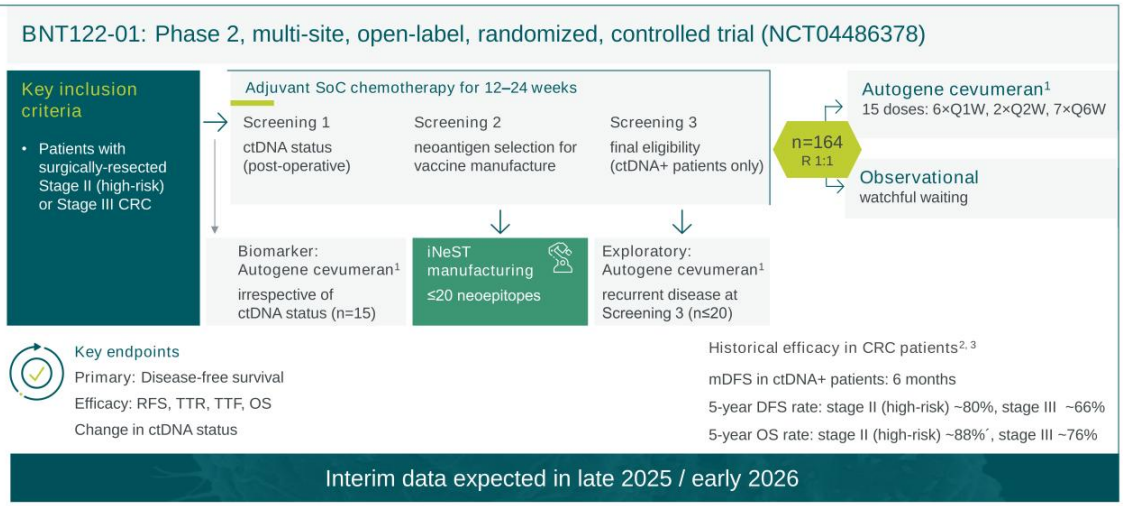
DFS rates at 12 and 18 months[1]

	ctDNA- (n=741)	ctDNA+ (n=55)*
Events, n (%)	31 (4.2)	20 (36.4)
Median DFS (IQR), months	Not reached (24.6, NR)	10.55 (7.2, 14.4)
12-month DFS rate (95% CI), %	93.2 (90.3, 96.2)	47.2 (31.9, 69.8)
18-month DFS rate (95% CI), %	84.9 (79.1, 91.2)	23.6 (10.6, 52.3)

1. Data cut off: 15 March 2024. Patients who transferred to BNT122-01 (n=56) were excluded from this analysis.

BIONTECH

Autogene Cevumeran[1] Investigated in a Phase 2 Randomized Trial vs. Watchful Waiting in Adjuvant Colorectal Cancer



1. Partnered with Genentech, a member of the Roche Group; 2. Kotani et al., Nature 2023, Nakamura et al., ESMO 2023; 3. André et al., J Clin Onc. 2015.

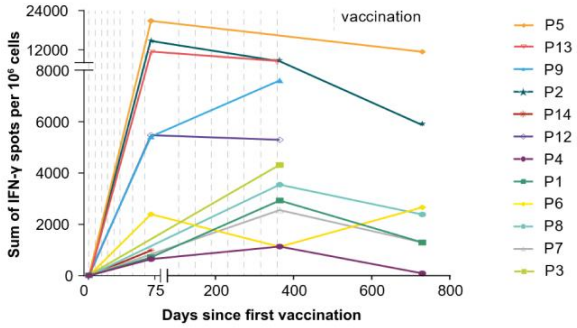
BIONTECH

Functional Vaccine-Induced T Cells are Long-Lived and Detected One Year After Last Vaccination with Autogene Cevumeran in all Evaluable Patients

Kinetics and persistence of T cell responses to vaccine-encoded neoantigens

Elez et. al., Biomarker sub-study results of Phase 2 trial (NCT04486378), ESMO-GI 2024.

Kinetics and durability of ex vivo T-cell responses in individual patients (n=12)



Data cut-off March 15, 2024

- Autogene cevumeran[1] induces T-cell responses in all patients
- Responses are polyepitopic: against a median of 3 vaccine-encoded neoantigens
- Almost all responses were detectable after 8 vaccinations.
- All 12 patients included in the immunogenicity analysis were disease-free at data cut-off

1. Partnered with Genentech, a member of the Roche Group.

BIONTECH

Autogene Cevumeran[1] Investigated in a Phase 2 Randomized Trial in Combination with Nivolumab in Adjuvant MIUC Patients

Medical need

Standard of care

Neoadjuvant chemotherapy, followed by cystectomy and for eligible patients this is followed by adjuvant treatment with an immune checkpoint inhibitor (ICI).

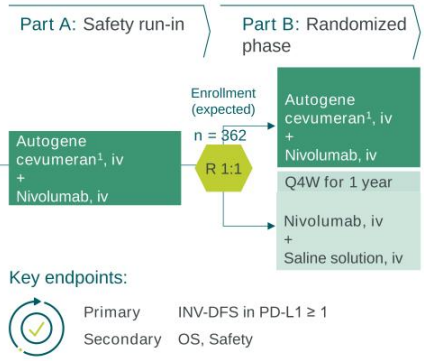
Unmet medical need

- Adjuvant ICI significantly increases disease-free survival in patients. Despite this, a significant number of patients will relapse in the first two years.[2]
- The 5-year survival among MIUC patients with distant metastasis has been reported to be about 8%.[3]

IMCODE004: Phase 2, multi-site, open-label, randomized, controlled trial (NCT06534983)

Inclusion criteria

- Age ≥ 18 years
- Histologically confirmed MIUC or upper urinary tract
- Surgical resection of MIUC of the bladder or upper tract without any adj. chemotherapy or radiotherapy
- Absence of residual disease or metastasis, confirmed by CT or MRI scans
- TNM classification of resected specimen is (y)pT3-4 or (y)pN+ and M0
- ECOG status 0 or 1



Trial currently recruiting

1. Partnered with Genentech, a member of the Roche Group.;2. Bajorin et al., 2021 NEJM; 3. American Cancer Society Cancer Facts and Figures 2024.

BIONTECH

Multiple Clinical Trials Demonstrate Execution Across iNeST and FixVac Portfolio

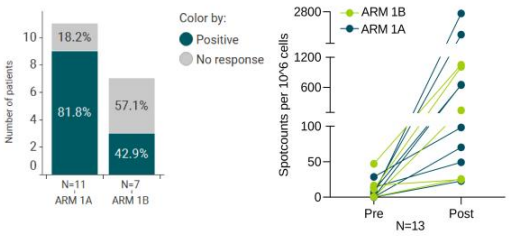
Individualized vaccine: iNeST[1]					FixVac		
Autogene cevumeran (BNT122/RO7198457)					BNT111[2]	BNT113	BNT116
Adjuvant			1L	R/R	R/R	1L	Multiple settings
MIUC Phase 2 + Nivolumab	CRC Phase 2 Monotherapy	PDAC Phase 2 + Atezolizumab	Melanoma Phase 2 + Pembrolizumab	Solid Tumors Phase 1 + Atezolizumab	Melanoma Phase 2 + Cemiplimab	HPV16+ HNSCC Phase 2 + Pembrolizumab	NSCLC Phase 1 & 2 Monotherapy, + Cemiplimab or CTx
Recruitment started	Recruitment ongoing Data presented from epi sub-study at ASCO 2024 and from biomarker sub-study at ESMO-GI 2024.	Recruitment ongoing Data presented from investigator-initiated Ph 1 trial at ASCO 2022 & AACR 2024 and published. (Rojas et al., Nature 2023)	Enrollment completed Data of prototype version Ph 1 published (Sahin et al., Nature 2017). Analysis of Ph 2 PFS as primary endpoint will be based on events and defined when reporting results.	Enrollment completed Data presented at AACR 2020. **Manuscript** accepted in Nature Medicine	Enrollment completed Positive topline data announced July 2024 Data presented from Ph 1 at multiple conferences incl. SITC 2021 and published. (Sahin et al., Nature 2020)	Recruitment ongoing Ph 2 data presented at multiple conferences incl. ESMO-IO 2022 Data from safety run-in of Ph 2 trial and Ph1/2 IIT presented at ESMO 2024.	Recruitment ongoing in Ph 2 in 1L NSCLC[2] Ph 1 trial ongoing. Data presented at SITC 2023, AACR 2024, and SITC 2024.

1. Partnered with Genentech, a member of the Roche Group; 2. In collaboration with Regeneron.

BNT113 Showed Consistent Immune Responses in Adjuvant and Advanced Disease in Multiple Studies

Vaccine induced T cell responses and consistent clonotype expansion observed in majority of patients

Ottensmeier, et. al. ESMO 2024.

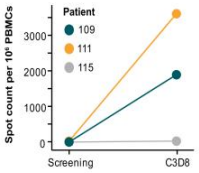


Ex vivo IFNγ ELISpot responses to E6 and/or E7 peptide pools

Vaccine-induced T cell count corresponded with volume of tumor reduction

Saba et. al. ESMO 2024

	Best vaccine response per patient, cell type and target, measured by **IFNγ** ELISpot ex vivo						BOR per RECIST v1.1	
	PepMix E6			PepMix E7				
Patient	CD4+	CD8+	Bulk PBMC	CD4+	CD8+	Bulk PBMC	BICR	Inv.
109							PD	SD
111							PR	PD
115							PD	PD



Normalized spot count of vaccine-induced T cells

BIONTECH

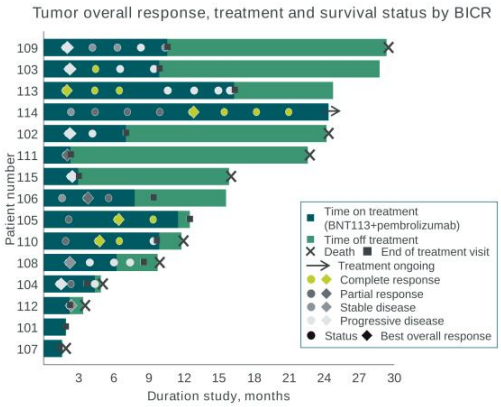
BNT113 Showed Activity with ORR[1] of 40% in PD-L1+ HPV16+ HNSCC Patients

Results from safety run-in of Phase 2 AHEAD-MERIT in 1L metastatic HNSCC (NCT04534205)

Saba et. al., ESMO 2024

Antitumor activity[2]	N=15
Unconfirmed ORR (BICR), %	40.0
CR, n	4
PR, n	2
Unconfirmed DCR (BICR), %	53.3
Unconfirmed ORR (investigator), %	33.3
Unconfirmed DCR (investigator), %	60.0
PFS by BICR	
Median (95% CI), months	3.9 (2.1–10.6)
6-month rate, %	42.3
12-month rate, %	14.1
18-month rate, %	14.1
PFS by investigator	
Median (95% CI), months	6.0 (2.3–10.4)
OS, median (95% CI), months	22.6 (9.8–NE)

Data cut-off: 24 June 2024



1. Assessed per blinded independent central review (BICR); 2. The efficacy analysis set was defined as all patients who received at least one dose of BNT113 (N=15).

BIONTECH

BNT113 in Combination with Pembrolizumab as 1L Treatment in Patients with R/R HPV16+ HNSCC Expressing PD-L1

Medical need

Standard of care

Pembrolizumab-based regimens are SoC for patients with PD-L1 CPS≥1, while platinum-based regimens are preferred for patients with PD-L1 CPS<0

Unmet medical need

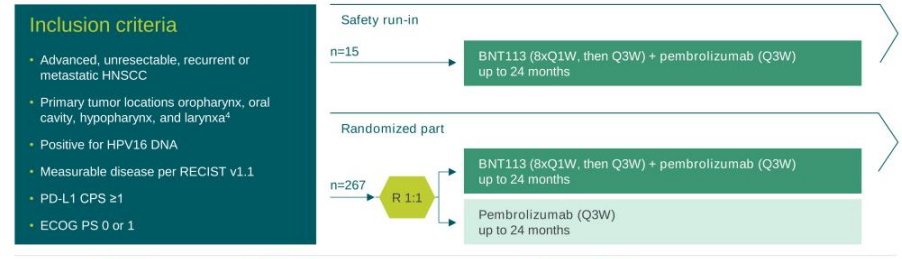
Up to 25% of patients with early-stage HPV16+ tumors will relapse within two years. [2]

5-year survival rates for patients with relapsed advanced HPV16+ tumors is 75%.[3]

AHEAD-MERIT: a Phase 2 controlled trial in 1L metastatic HNSCC (NCT04534205)

Inclusion criteria

- Advanced, unresectable, recurrent or metastatic HNSCC
- Primary tumor locations oropharynx, oral cavity, hypopharynx, and larynxa[4]
- Positive for HPV16 DNA
- Measurable disease per RECIST v1.1
- PD-L1 CPS ≥1
- ECOG PS 0 or 1



Endpoints	Safety run-in	Randomized part
Primary:	TEAEs; up to 27 months	OS, ORR; up to 48 months
Secondary:	ORR, DOR, DCR	INV-ORR, PFS, DCR, DOR, safety
Exploratory:	PFS, OS, biomarkers	

Benchmark comparator data for 1L HNSCC (~22% patients HPV16+)

Indication	Benchmark regimen	ORR	mPFS	mOS	Benchmark Study
1L HNSCC (CPS ≥1)	Pembrolizumab	19%	3.2 mo	12.3 mo	KEYNOTE-048[4]

1. Partnered with Genentech, a member of the Roche Group; 2. Gorphe et al., Radiother Onc 2022 3. Munoz-Bello et. Al, Cell 2024; 4. Harrington et. al., J Clin Oncol. 2023.

86

BNT116[1]-Induced T cell Responses Have Been Observed in NSCLC

Vaccine induced CD4+ and CD8+ T cell responses observed consistently

Öven BB, et. al., presented at AACR 2024. CT051

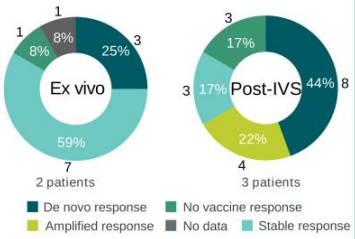
Best vaccine response per patient, cell type and target, measured by IFNγ ELISpot post-IVS													BOR
Patient	CLDN6		KK-LC-1		MAGE-A3		MAGE-A4		MAGE-C1		PRAME		Inv.
	$CD4^+$	$CD8^+$	$CD4^+$	$CD8^+$	$CD4^+$	$CD8^+$	$CD4^+$	$CD8^+$	$CD4^+$	$CD8^+$	$CD4^+$	$CD8^+$	
03-016				■						■			SD
03-013	■	■	■	■	■		■	■	■	■	■		PR
03-018		■		■	■					■			PR

■ Induced T cell response (ex vivo ELISpot) ■ No response (ex vivo ELISpot) ■ No response (ex vivo ELISpot)

Summary of vaccine responses measured post-IVS by IFNγ ELISpot and response per RECISTv1.1

De novo and vaccine-expanded T cell responses were observed across patients

Atmaca A, et. al., presented at SITC 2024. Poster 1486

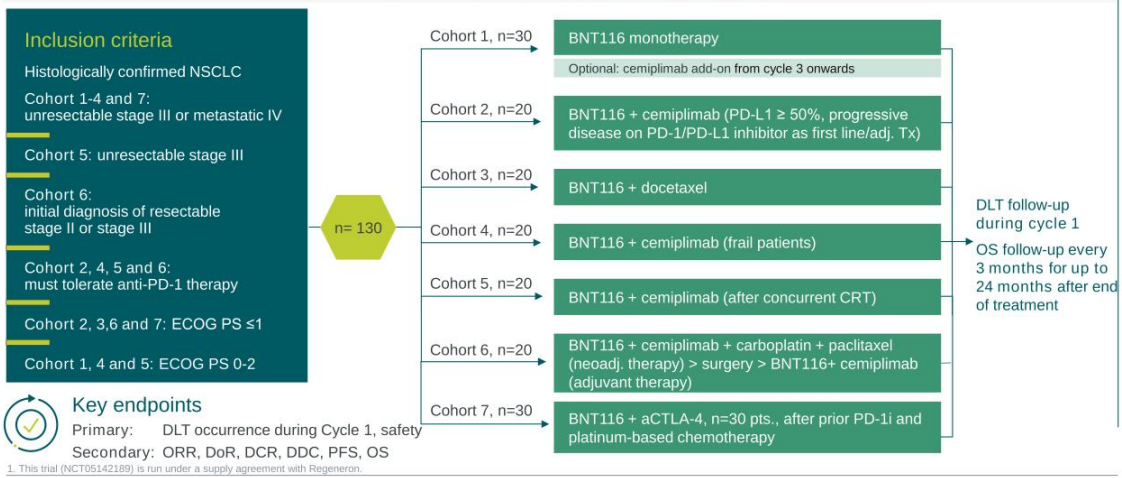


1. This trial (NCT05142189) is run under a supply agreement with Regeneron.

BIONTECH

Assessing BNT116's Potential in Multiple Combinations and Disease Settings[1]

LuCa-MERIT-1: FIH, open-label, Phase 1 trial in NSCLC (NCT05142189)



Key endpoints

Primary: DLT occurrence during Cycle 1, safety

Secondary: ORR, DoR, DCR, DDC, PFS, OS

1. This trial (NCT05142189) is run under a supply agreement with Regeneron.

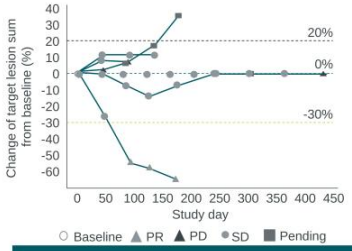
BIONTECH

BNT116 Has Shown Clinical Activity as Single Agent & in Combination with Chemo or anti-PD-1 in Advanced NSCLC in Phase 1 Trial[1]

BNT116 monotherapy plus cemiplimab add-on from cycle 3

Deme et al. SITC 2023

Progression after PD-(L)1 therapy, platinum-based chemotherapy, and one other systemic therapy

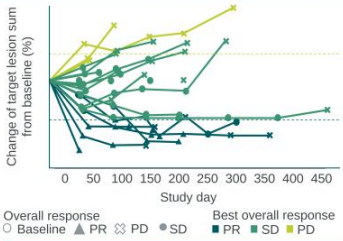


Combination therapy with BNT116+cemiplimab is active with DCR of 45% in heavily pre-treated lung cancer patients

BNT116 plus docetaxel

Öven et al. AACR 2024

Progression after PD-(L)1 therapy and platinum-based chemotherapy

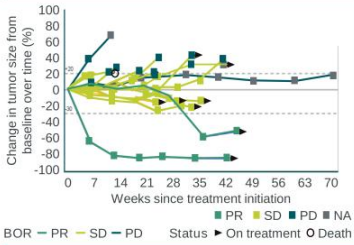


Combination therapy with BNT116 + docetaxel is active with an ORR of 30% and a DCR of 85% and mPFS of 4.4 months

BNT116 plus cemiplimab

Atmaca et al. SITC 2024

NSCLC with PDL1 TPS ≥50% that progressed after PD-(L)1 therapy as first-line or adjuvant therapy



Combination therapy with BNT116 + cemiplimab is active with an DCR of 80% and a mPFS of 5.5 months

1. This trial (NCT05142189) is run under a supply agreement with Regeneron.

BIONTECH

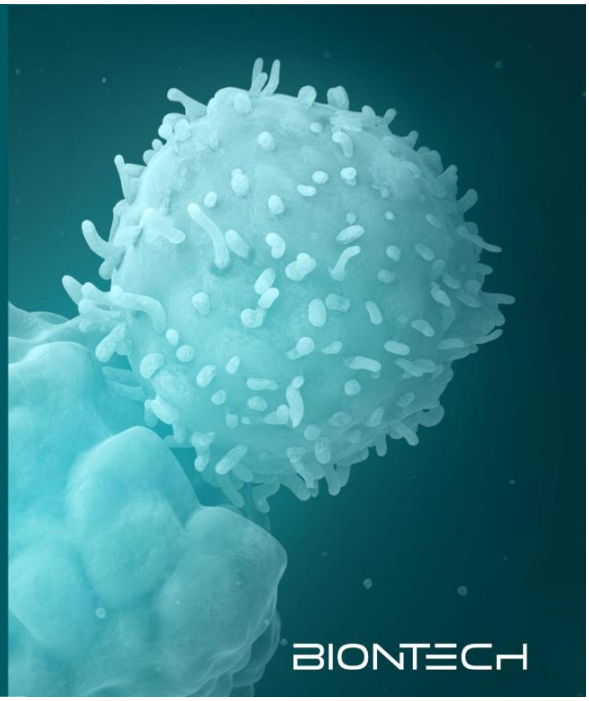
6

Select Targeted Therapies:

HER2-ADC BNT323
CLDN6 CART BNT211

Dr. Michael Wenger, MD
VP Clinical Research

Prof. Özlem Türeci, M.D.
CEO and Co-founder



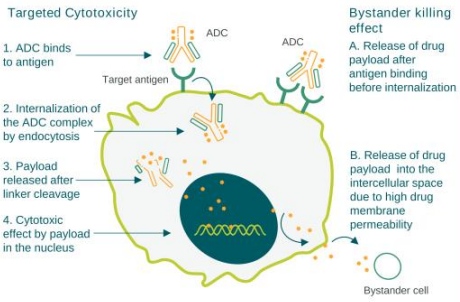
BNT323/DB-1303[1]: A HER2 ADC with a Potentially Differentiated Profile

BNT323/DB-1303[1] is a 3rd generation ADC

- A humanized anti-HER2 IgG1 monoclonal antibody
- A proprietary DNA topoisomerase I inhibitor
- A maleimide tetrapeptide-based cleavable linker

- Cysteine residue
- Linker-payload

Mode of action



Adapted from Coleman N.et al. npj Precis. Onc. 2023

Preclinical Data

Lin S. et al. Abstract #252. Presented at EORTC-NCI-AACR in 2022 & data on file.

- Superior in vitro plasma stability in human plasma
- Rapid systemic clearance in monkeys
- Potent anti-tumor effect in both HER2 positive and HER2 low tumor models with a wide therapeutic window
- Toxicity studies[2] in monkeys show favorable toxicity profile

Stable linker and fast clearance may contribute to the improved toxicity profile of BNT323/DB-1303[1]

1. Partnered with DualityBio; 2. DS-8201 is an in-house produced analog of trastuzumab deruxtecan.

BIONTECH

First-in-Human Trial with BNT323/DB-1303[1] in Patients with Advanced HER2-Expressing Solid Tumors

Phase 1/2a trial design (NCT05150691), multicenter, non-randomized, open-label

Moore K. et al. Presented at ASCO 2023. Abstract #3023

Key inclusion criteria

- Pretreated advanced or metastatic solid tumors
- HER2-positive or HER2-expressing cancers
- Previous systemic therapies
- ECOG PS 0-1

Part 1: Dose escalation (n=88 patients) → **Part 2a: Dose expansion cohorts (n=165 patients)**

(HER2 IHC 3+, IHC 2+, IHC 1+ or ISH +, or HER2 amplification and mutation by NGS)

- 12.0 mg/kg
- 10.0 mg/kg
- 8.0 mg/kg
- 7.0 mg/kg
- 6.0 mg/kg
- 4.4 mg/kg
- 2.2 mg/kg

RP2D/ MTD

(RP2D=8 mg/kg)

- Trastuzumab-treated HER2+ (IHC3+, IHC2+/ISH positive) gastric or GEJ adenocarcinoma, esophageal carcinoma and CRC
- **Both HER2 overexpression and HER2 low (IHC3+,2+,1+ or ISH positive) endometrial carcinoma**
- HR+/HER2 Low (IHC2+ /ISH negative, or IHC1+) breast cancer
- HER2+ (IHC3+, IHC2+/ISH positive) breast cancer
- NSCLC with activating HER2 mutation
- HER2+ or HR+/HER2-low breast cancer with treatment failure of trastuzumab deruxtecan (HER2+ BC; HR+/HER2-low BC)

Key endpoints

Safety, tolerability, pharmacokinetic, preliminary anti-tumor activity at the selected MTD/RP2D

Status

First patient in: Jan 2022
Trial ongoing

Phase 3 (NCT06018337) ongoing in chemo naïve 2L HR+ HER2 low breast cancer

1. Partnered with DualityBio.

BIONTECH

BNT323/DB-1303[1] Data Facilitates a Potential Path to Registration in HER2-Expressing Endometrial Cancer

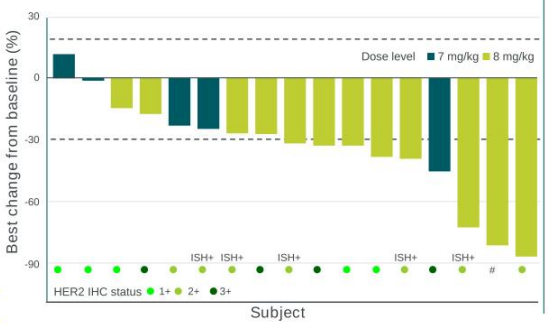
Phase 1/2a FIH study (NCT05150691): Clinical Efficacy

Moore K. et al. Presented at ESGO 2023. Abstract # 430

- HER2 tumor expression of IHC 1, 2 and 3+: 31%, 41% and 25%, respectively. Clinical response observed across HER2-expression levels, including IHC 1+
- Patients received median 2 lines of prior treatment. ~60% of patients had prior IO, ~38% prior anti-HER2 antibody
- Data cutoff: May 8, 2023

	Dose Escalation		Dose Expansion	
Response[a]	7 mg/kg (n=4)[b]	8 mg/kg (n=4)[b]	8 mg/kg (n=9)[b]	Total (n=17)[b]
Unconfirmed ORR, n (%)	2 (50)	4 (100)	4 (44)	10 (59)
Confirmed ORR, n (%)	1 (25)	3 (75)	0	4 (24)
Pending confirmation ORR, n (%)	1 (25)	1 (25)	4 (44)	6 (35)
Unconfirmed DCR, n (%)	4 (100)	4 (100)	8 (89)	16 (94)

[a] By investigator. [b] Response-evaluable subjects, which includes subjects with ≥1 postbaseline overall response.



Benchmark comparator data for 2L+ HER2+ Endometrial Cancer

Indication	Benchmark regimen	ORR	mPFS	mOS	Benchmark Study
Endometrial	T-DXd	57.5%	11.1 mo	26.0 mo	DESTINY-PanTumor02[2]

1. Partnered with DualityBio; 2. Meric-Bernstam F. et al. J Clin Oncol 2024.

BIONTECH

Phase 3 Study of BNT323/DB-1303[1] vs Chemotherapy in 2L+ HER2-expressing Endometrial Cancer

BNT323-01: (NCT06340568)

Key inclusion criteria

- Recurrent, metastatic endometrial cancer (including HER2 1+, 2+, or 3+ score on IHC by central testing)
- At least 1 prior line of platinum-based therapy (in any setting) and prior ICI (in any setting), up to three lines of prior therapy (excluding endocrine therapies)
- Measurable disease per RECIST v1.1
- ECOG PS 0 or 1

Key endpoints

Primary endpoints: PFS (BICR assessed)

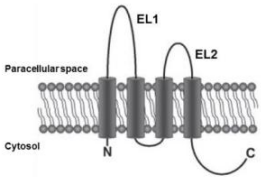
Benchmark comparator data for 2L+ Endometrial Cancer

Indication	Benchmark regimen	ORR	mPFS	mOS	Benchmark Study
Endometrial	Single-agent chemo	14.7%	3.8 mo	11.4 mo	KEYNOTE-775[2]

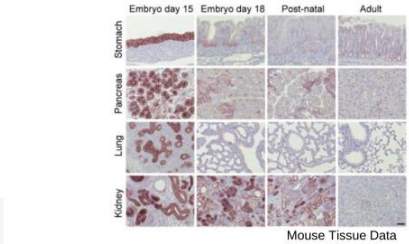
1. Partnered with DualityBio; 2. Makker V. et al. NEJM 2022.

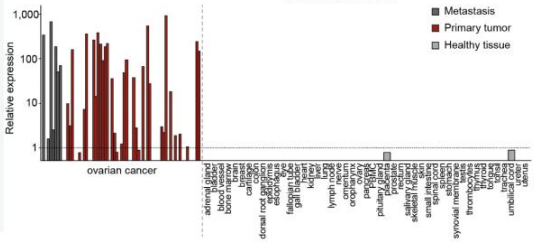
BIONTECH

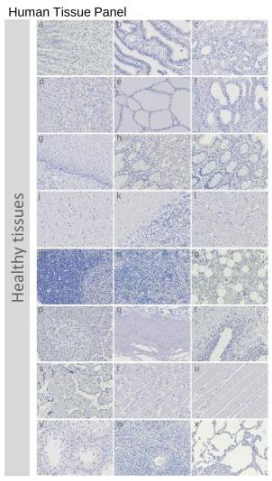
Claudin-6 (CLDN6) is a Carcinoembryonic Cell Surface Antigen



- Claudins are tight junction-associated tetraspanins with druggable extracellular loops
- Expressed exquisitely during organogenesis and not in healthy adult tissues
- Highly expressed in various cancer types with correlation to disease progression
- Cancer stem cell marker

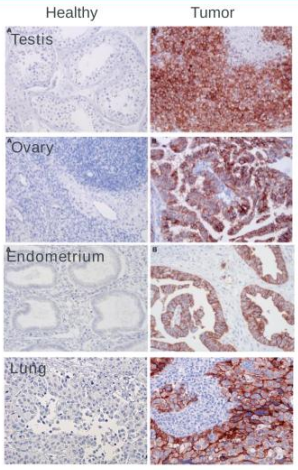






BIONTECH

CLDN6 is Expressed in High Medical Need Cancers Including Lung Cancer



Indication	CLDN6+	CLDN6high
Testicular Cancer*	93 %	90-93 %
Ovarian Cancer*	56 %	25-30 %
Uterine Cancer*	23 %	10-15 %
Lung Cancer**	11 %	2-5 %
Gastric Cancer***	9 %	2-5 %

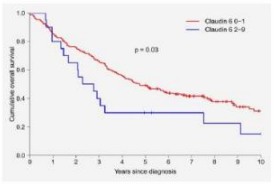
CLDN6^{high} = 50% of tumor cells expressing ≥2+ CLDN6 protein (IHC)

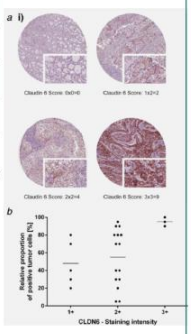
Reinhard et al., Science 2020

CLDN6 IHC staining of a TMA with 355 NSCLC

	tested	CLDN6+
Squamous CA	120	0
AdenoCA	195	20 (10%)
Large cell CA	40	3 (7.5%)
Total	355	23 (6.5%)

- No correlation with smoking history, Ki67+ status, tumor stage, WHO performance stage
- Negatively correlated with prognosis
- Correlated with TFF1+ status





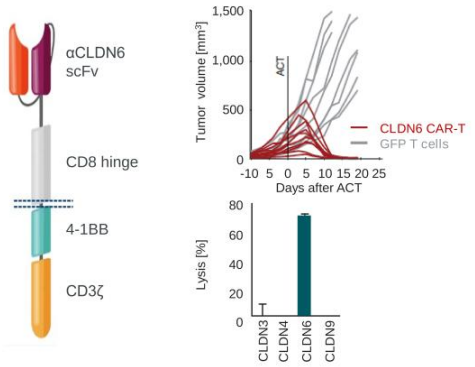
Micke et al., Int. J. Cancer 2014

BIONTECH

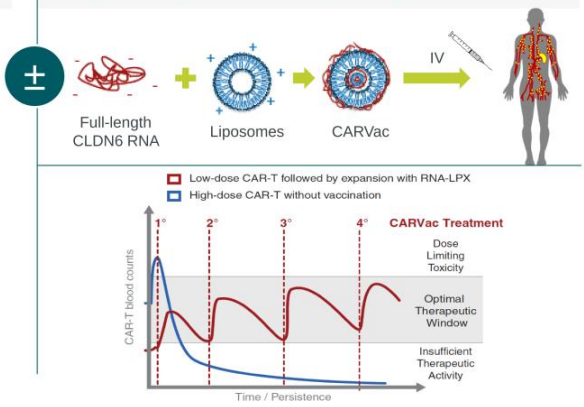
BNT211: A CLDN6 CAR-T-Cell Therapy + CLDN6-Encoding CARVac that Enhances Expansion and Persistence of the Infused CAR-T Cells

Potent 2nd generation CAR with high sensitivity and specificity

Reinhard K, et al. Science 2020, 367:446–453



Combined with CARVac (CAR-T cell amplifying RNA vaccine) to target APCs, Reinhard K, et al. Science 2020, 367:446–453; Kranz LM, et al. Nature 2016; 534:396–401



BIONTECH

BNT211 as Monotherapy or in Combination with Ribonucleic Acid Lipoplexes (RNA-LPX) in Patients with CLDN6-Positive Advanced Solid Tumors

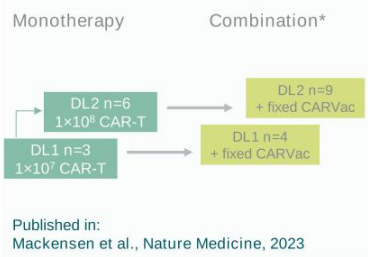
Phase 1, FIH, open-label, dose escalation study with expansion cohort to evaluate safety and efficacy of BNT211 with/without RNA-LPX in patients with CLDN6+ R/R solid tumors (NCT04503278)

Key inclusion criteria

- ≥50% tumor cells with CLDN 6 IHC 2+/3+ CLDN6 positivity (immunohistochemistry)
- Measurable disease per RECIST v1.1 or elevated tumor marker
- ECOG PS 0–1

ESMO 2022

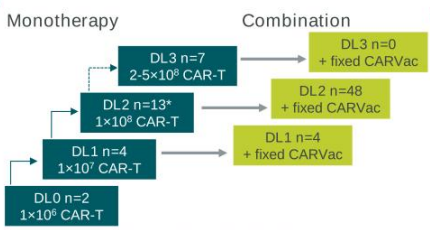
Part A: Manual product (n=22; completed)[1]



Published in:
Mackensen et al., Nature Medicine, 2023

ESMO 2023

Part B: Automated product (n=78; ongoing)[2]



*Three patients were treated at an optional de-escalation dose (DL 1.5=5×10⁷ cells) to further evaluate clinical safety and efficacy.

Key endpoints

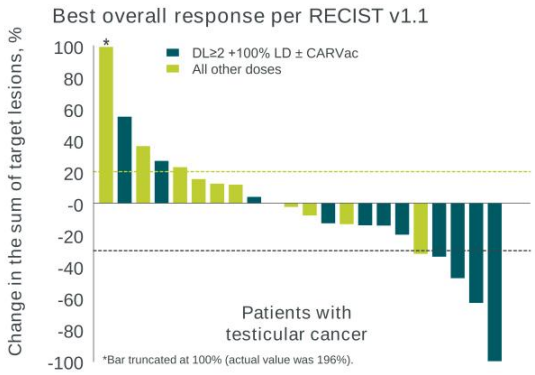
Primary:	Safety & tolerability, MTD, RP2D
Secondary:	ORR, DCR, DOR

1. Mackensen A, et al. Nature Med 2023;29:2844–2853; 2. Haanen JBAG, et al. Ann Oncol 2023;34 (suppl_2):S1281–S1282.

BIONTECH

BNT211-01: Overall Response Rate – Testicular Cancer

Overall ORR was 24%; at DL2 and DL3 ORR was 41.7%.
Two patients had a surgical complete response that lasted for over a year. Haanen et. al., ESMO 2024



Response[a]	Total (N=27)[b]
Evaluable patients, n	25
ORR, n (%) 95% CI (%)	6 (24.0) 8.6–42.3
DCR, n (%) 95% CI (%)	14 (56.0) 32.0–71.3

Response[a]	**DL≥2 +100% LD ± CARVac (N=14)[b,c]**
Evaluable patients, n	12
ORR, n (%) 95% CI (%)	5 (41.7) 12.8–64.9
DCR, n (%) 95% CI (%)	9 (75.0) 35.1–87.2

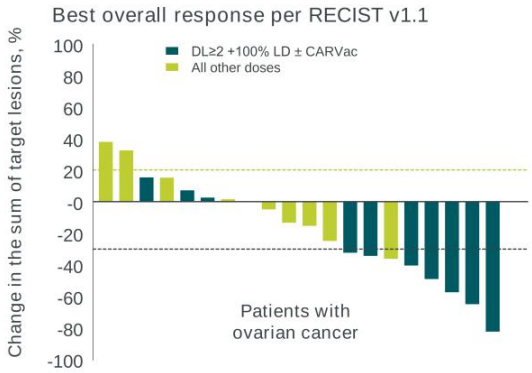
Data cut-off: May 16, 2024.

a. Includes tumor marker responses; b. Excludes patients who received an out-of-specification product; c. DL2=1×10^{9}; DL3=2–5×10^{9} CAR T cells.

BIONTECH

BNT211-01: Overall Response Rate – Ovarian Cancer

In the 24 evaluable patients across all dose levels, ORR was 33.3% and DCR was 75% - the same parameters when considered for Dose Level 2 and above were 58.3% and 83.3% respectively.
Haanen et. al., ESMO 2024



Response[a]	Total (N=30)[b]
Evaluable patients, n	24
ORR, n (%) 95% CI (%)	8 (33.3) 12.3–45.9
DCR, n (%) 95% CI (%)	18 (75.0) 40.6–77.3

Response[a]	**DL≥2 +100% LD ± CARVac (N=16)[b,c]**
Evaluable patients, n	12
ORR, n (%) 95% CI (%)	7 (58.3) 19.8–70.1
DCR, n (%) 95% CI (%)	10 (83.3) 35.4–84.8

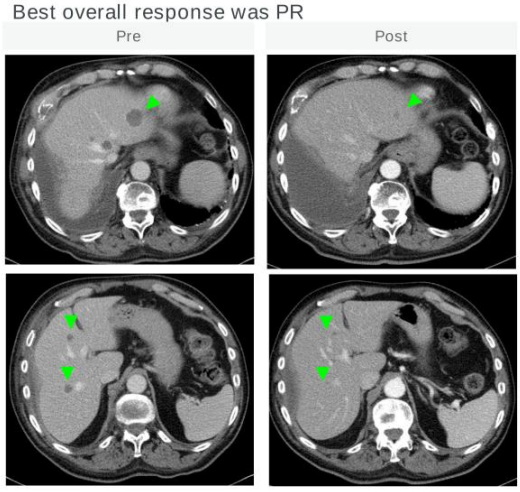
Data cut-off: May 16, 2024.

a. Includes tumor marker responses; b. Excludes patients who received an out-of-specification product; c. DL2=1×10^{6}; DL3=2–5×10^{6} CAR T cells.

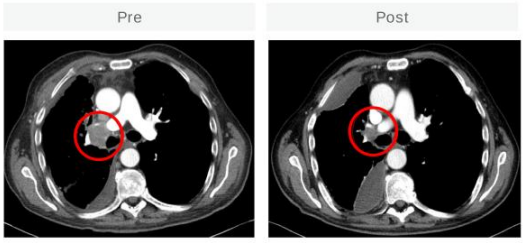
BIONTECH

Best Overall Response to CLDN6 CAR T+ CARVac in a Patient with NSCLC[1]

Best overall response was PR



- Patient with AGA-neg NSCLC, CLDN6+ (50% 2+/3+, 80% any positivity), IO-experienced,
- 2 previous treatment lines, former smoker
- Received CAR T + 5x CARVac



Target lesion size

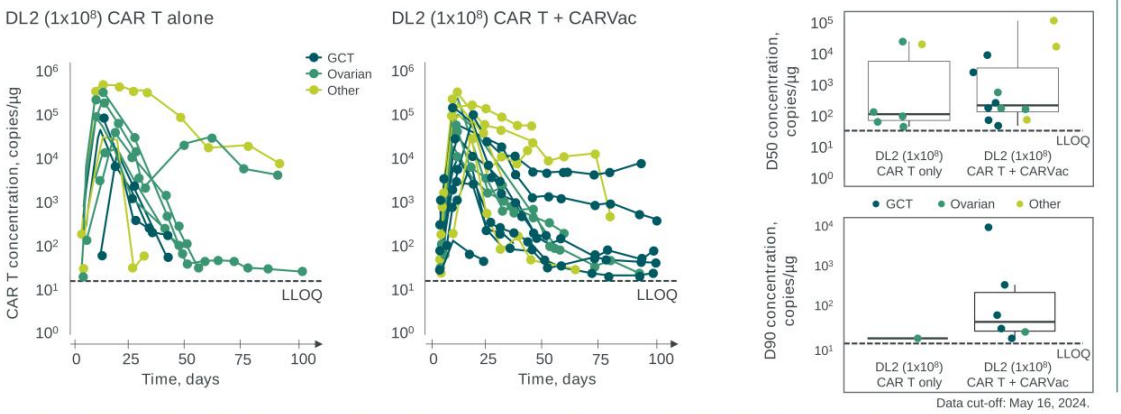
Screening	ACT	ACT + 1 Mo	ACT + 3 Mo
18 mm	53 mm	28 mm	12 mm
	+194%	-47%	-77%
		PR	PR

1. Data on file. Presented by U. Sahin at Lung Cancer Summit, NY, 2024

BIONTECH

CARVac Improves CAR T Persistence

Adding CARVac limits the decline and induces a plateau of CAR-T cells with robust and ongoing detection in patients[1] who received DL2+CARVac. Haanen et. al., ESMO 2024



Data cut-off: May 16, 2024.

1. At day 50, the proportion of patients with measurable CAR T > than the lower limit of quantification is 6 of 8 for CAR T alone and 12 of 12 for CAR T plus CARVac. At Day 90, 1/7 had detectable CAR T in the CAR T alone group vs 6/8 in the CAR T plus CARVac group.

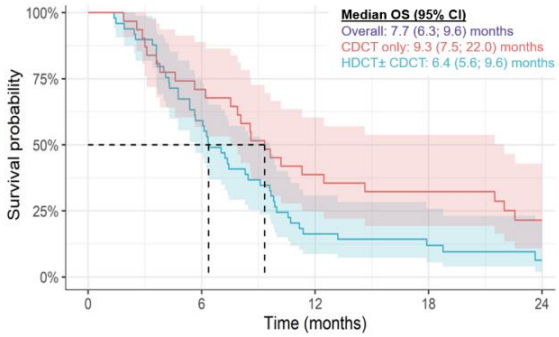
BIONTECH

mOS of 7.7 Months in Patients with R/R Testicular Germ Cell Tumors After Initiating Palliative Chemotherapy

Real-world evidence study: Results objective 1

Feldman, D. et al. ASCO 2024.

OS among patients with R/R testicular GCT receiving palliative chemotherapy exposure with sufficient follow-up time (N=80)



Time from the index date	0 month	6 months	12 months	24 months
Prior HDCT ± CDCT				
Pts at risk, N	49	29	8	2
Cumulative deaths, N	0	20	41	45
Survival probability, %	100.0	59.2	16.3	6.3
Prior CDCT only				
Pts at risk, N	31	22	12	6
Cumulative deaths, N	0	9	19	24
Survival probability, %	100.0	71.0	38.7	21.5

OS was assessed among 80 patients with R/R testicular GCT who had at least 12 months of follow-up time, which are a subgroup of patients identified for Objective 1 (N = 97).

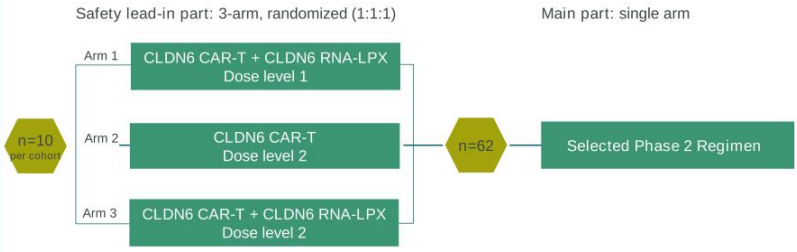
BIONTECH

BNT211 Pivotal Trial in Patients with R/R Testicular Germ Cell Tumors

BNT211-02 open-label, randomized Phase 2 study to evaluate safety and efficacy of BNT211 in adult patients with testicular or extragonadal germ cell tumors

Key inclusion criteria

- RECIST 1.1 or serum tumor markers
- Prior high dose chemo + autologous SCT or conventional dose chemo as salvage therapy
- ≥ 25% of tumor cells expressing CLDN6
- ECOG performance status 0-1
- Adequate organ function



Key endpoints

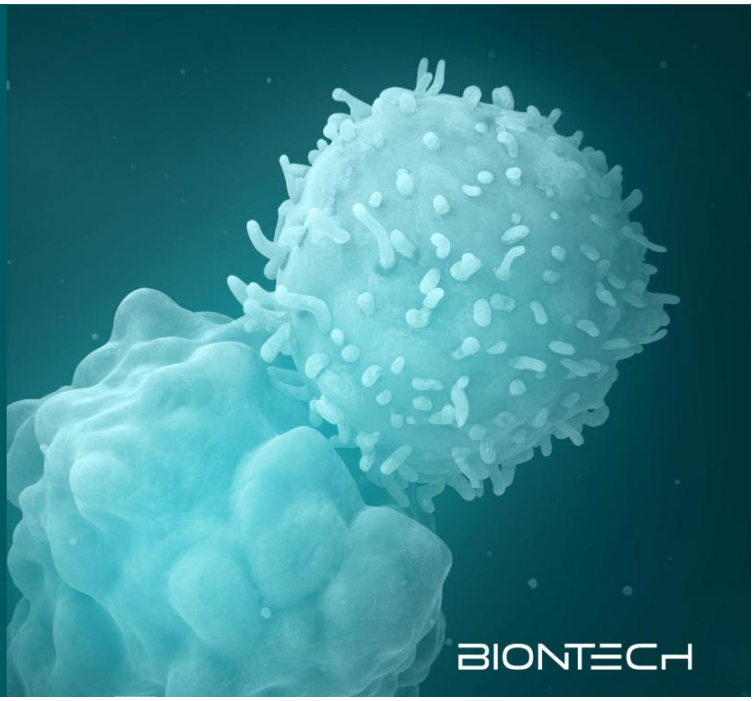
	Safety lead-in	Main part
Primary	Safety & tolerability, TEAEs, AESIs, serious/fatal TEAEs	ORR per RECIST1.1, reduction of serum tumor marker
Secondary	Efficacy (ORR, DCR, DOR), PK	PFS, OS, DOR, DCR, safety, PK, pharmacodynamics, immunogenicity

BIONTECH

7

Path to Value Creation

Ryan Richardson,
Chief Strategy Officer

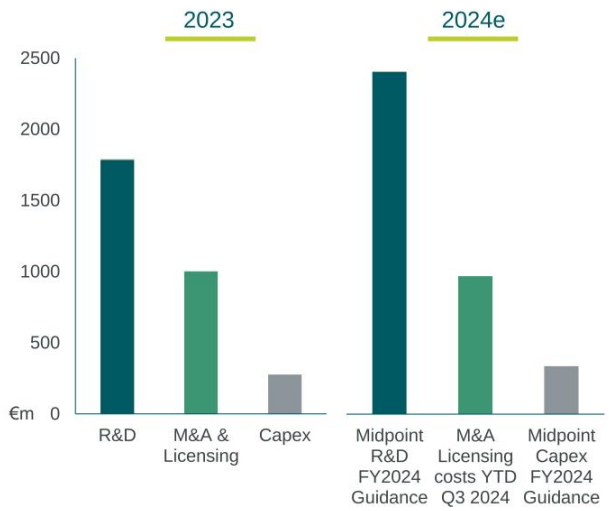


Progress in the Last Twelve Months Demonstrates the Strength of our Model and our Strategy

	2023 → 2024
COVID-19	Maintained leading market share (>50%)
Oncology Portfolio	7 Phase 2/3 trial starts >67% year-on-year increase in average quarterly patient enrollment in trials
Infectious Disease Vaccine Portfolio	Three Phase 1 trial starts
Corporate Development	Acquisitions of InstaDeep and Biotheus announced Six in-licensed molecules
Cash Balance	Grew cash balance from Q3 2023 to Q3 2024 (€17.0B to €17.8B[1])

1. Consists of cash and cash equivalents of €9,624.6 million, current security investments of €7,078 million and non-current security investments of €1,137.2 million, as of September 30, 2024, and does not include announced Biotheus acquisition considerations.

Our Capital Allocation Strategy Going Forward Will Continue to Focus on Value Creation



Outlook for 2025

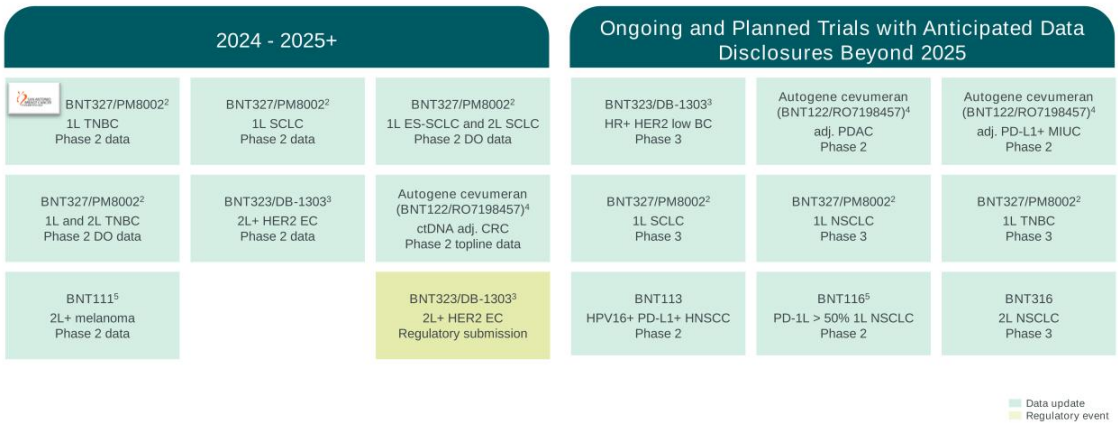
Strategically invest behind late-stage programs with transformational potential

Active portfolio management to create additional P&L headroom for pivotal trial investment

Expect to continue to benefit from interest income potential from strategic cash reserve

BIONTECH

Expected Potential Value Creating Milestones and Trials



Catalyst-rich upcoming period for mid- to late-stage pipeline to support company vision to achieve a diversified, cashflow-generating multi-product oncology portfolio by 2030

Partnered with: 1. Pfizer; 2. Biotheus; 3. DualityBio; 4. Genentech, member of Roche Group. 5. in collaboration with Regeneron; DO = Dose Optimization.

BIONTECH

Innovation Series 2024

THANK YOU

Contact us at investors@biontech.de

BIONTECH

Abbreviations (1)

n L	nth line	CRC	Colorectal cancer	FIH	First in human
AACR	American Association for Cancer Research	CRS	Cytokine release syndrome	Flu	Fludarabine
ACT	Adoptic cell transfer	CRT	Chemoradiation therapy	FPD	First patient dosed
ADC	Antibody-drug conjugate	CT	Computer tomography	GBM	Glioblastoma
adj.	Adjuvant	CTCAE	Common terminology criteria for adverse events	GC/GEJ	Gastric/Gastro-esophageal junction cancer
AE	Adverse event	ctDNA	Circulating tumor DNA	GCT	Germ cell tumor
AGA	Actionable oncogenic alteration	CTFI	Chemotherapy-free interval	GEJ	Gasto-esophageal junction
AI	Artificial intelligence	CTLA-4	Cytotoxic T-lymphocyte-associated protein 4	HCC	Hepatocellular carcinoma
ALK	Anaplastic large-cell lymphoma kinase	CTx	Chemotherapy	HDCT	High dose chemotherapy
APC	Antigen presenting cell	CXCL	Chemokine (C-X-C motif) ligand	HER2 (or 3)	Human epidermal growth factor receptor 2 (or 3)
ASCO	American Society of Clinical Oncology	Cy	Cyclophosphamide	HLA	Human leukocyte antigen
(m)BC	(metastatic) Breast cancer	DAR	Drug-antibody ratio	HLH	Hemophagocytic lymphohistiocytosis
BIRC	Blinded independent central review	DC	Dendritic cell	HNSCC	Head and neck squamous cell carcinoma
BL	Baseline	DCR	Disease control rate	HPV	Human papilloma virus
BOR	Best overall response	DDC	Duration of disease control	HR	Hazard ratio
BTC	Biliary tract cancer	DFS	Disease-free survival	HR	Hormone receptor
CAR	Chimeric antigen receptor	DL	Dose level	ICANS	Immune effector cell-associated neurotoxicity syndrome
CARVac	CAR T-cell amplifying RNA vaccine	DLT	Dose limiting toxicity	ICI	Immune checkpoint inhibitor
CnDn	Cycle n day n	dMMR	Deficient DNA mismatch repair	IDMC	Independent Data Monitoring Committee
CD	Cluster of differentiation	(m)DOR	Duration of response	IEC-HS	Immune effector cell-associated HLH-like syndrome
CDCT	Conventional dose chemotherapy	EC	Endometrial cancer	IFN	Interferon
cGMP	Current Good Manufacturing Practice	ECOG (PS)	Eastern Cooperative Oncology Group (performance status)	IgG	Immunoglobulin G
CI	Confidence interval	E2E	End to end	IHC	Immunohistochemistry
CICON	International Cancer Immunotherapy Conference	EGFR	Epidermal growth factor receptor	IIT	Investigator initiated trial
CLDN6	Claudin 6	ELISpot	Enzyme Linked Immuno Spot Assay	IL-x	Interleukin x
CMC	Chemistry, manufacturing and control	EORTC	European Organisation for Research and Treatment of Cancer	IND	Investigational new drug
COGS	Cost of goods sold	ER	Estrogen receptor	iNeST	Individualized NeoAntigen-Specific Therapy
CPD	Confirmed progression	ESMO	European Society for Medical Oncology	INV-	Investigator assessed
CPI	Checkpoint inhibitor	ESMO GI	European Society for Medical Oncology Gastrointestinal	IO	Immuno-oncology
CPS	Combined positive score	Fab	Fragment antigen binding	IPO	Initial public offering
CR	Complete response	FDA	U.S. Food and Drug Association	IQR	Interquartile range

Abbreviations (2)

irAE	Immune-related adverse event	NSCLC	Non-small cell lung cancer	SITC	Society of Immunotherapy of Cancer
ISH	in-situ hybridization	NY-ESO-1	New York esophageal squamous cell carcinoma-1	S&M	Sales and marketing
ITT	Intention to treat	OPEX	Operational expenditures	SoC	Standard of care
iv	Intravenously	(c)ORR	(Confirmed) objective response rate	SoD	Sum of diameters
IvS	in vitro stimulation	OS	Overall survival	TAA	Tunor-associated antigen
KK-LC-1	Kita-Kyushu lung cancer antigen 1	PBMC	Peripheral blood mononuclear cell	TAP	Transporter associated with antigen processing
LCM	Life cycle management	PD	Progressive disease	TC	Testicular cancer
LLOQ	Lower limit of quantification	PDAC	Pancreatic ductal adenocarcinoma	TCGA	The Cancer Genome Atlas
LD	Lymphodepletion	PD-(L)1	Programmed cell death protein (ligand) 1	TCR	T-cell receptor
LPX	Lipoplex	PFS	Progression-free survival	TEA	Tissue engineering acoustophoretic
m	Median	PK	Pharmacokinetics	TE(S)AE	Treatment-emergent (serious) adverse event
mAB	Monoclonal antibody	PoC	Proof of concept	TKI	Tyrosine kinase inhibitor
MAGE-A3	Melanoma antigen A3	PoT	Proof of technology	TLR	Toll-like receptor
MHC	Major histocompatibility complex	PR	Partial response	TME	Tumor microenvironment
MIUC	Muscle-invasive urothelial carcinoma	PR	Progesterone receptor	TNBC	Triple-negative breast cancer
MMR	Mismatch repair	PRAME	Preferentially expressed antigen in melanoma	TNF	Tumor necrosis factor
MΦ	Macrophage	PROC	Platinum-resistant ovarian cancer	TNM	Classification of malignant tumors (tumor-nodus-metastasis)
MoA	Mechanism of Action	PSOC	Platinum-sensitive ovarian cancer	TPS	Tumor proportion score
MPM	Malignant pleural mesothelioma	QxW	Every x week(s)	TRAE	Treatment-related adverse event
MRI	Magnetic resonance imaging	R	Randomized	Treg	Regulatory T cell
mRNA	Messenger ribonucleic acid	(ncc/cc)RCC	(Non-clear cell/clear cell) renal cell carcinoma	TRON	Helmholtz Institute for Translational Oncology
MSI-H (L)	High(low)-frequency microsatellite instability	R&D	Research and development	TROP2	Trophoblast cell-surface antigen 2
MSKCC	Memorial Sloan Kettering Cancer Center	RECIST	Response Evaluation Criteria in Solid Tumors	TTF	Time to treatment failure
MSS	Microsatellite stability	RFS	Recurrence-free survival	TTP	Time to progression
MTD	Maximum tolerated dose	RP2D	Recommended phase 2 dose	TTR	Time to response
NCI PRO-	National Cancer Institute Patient Reported Outcome	R/R	Relapsed/refractory	UC	Urothelial cancer
CTCAE	Common Terminology Criteria for Adverse Events	RT-qPCR	Real-time quantitative polymerase chain reaction	UICC	Union for International Cancer Control
NEN	Neuroendocrine neoplasm	SAE	Severe adverse event	UPD	Unconfirmed progression
NF-κB	Nuclear factor kappa B	(E/LS)SCLC	(Extensive/low stage) small cell lung cancer	VEGF(R)	Vascular endothelial growth factor (receptor)
NGS	Next generation sequencing	scFv	Single-chain variable fragment	VHH	Heavy chain variable
NR	Not reached	SD	Stable disease	WT	Wild type