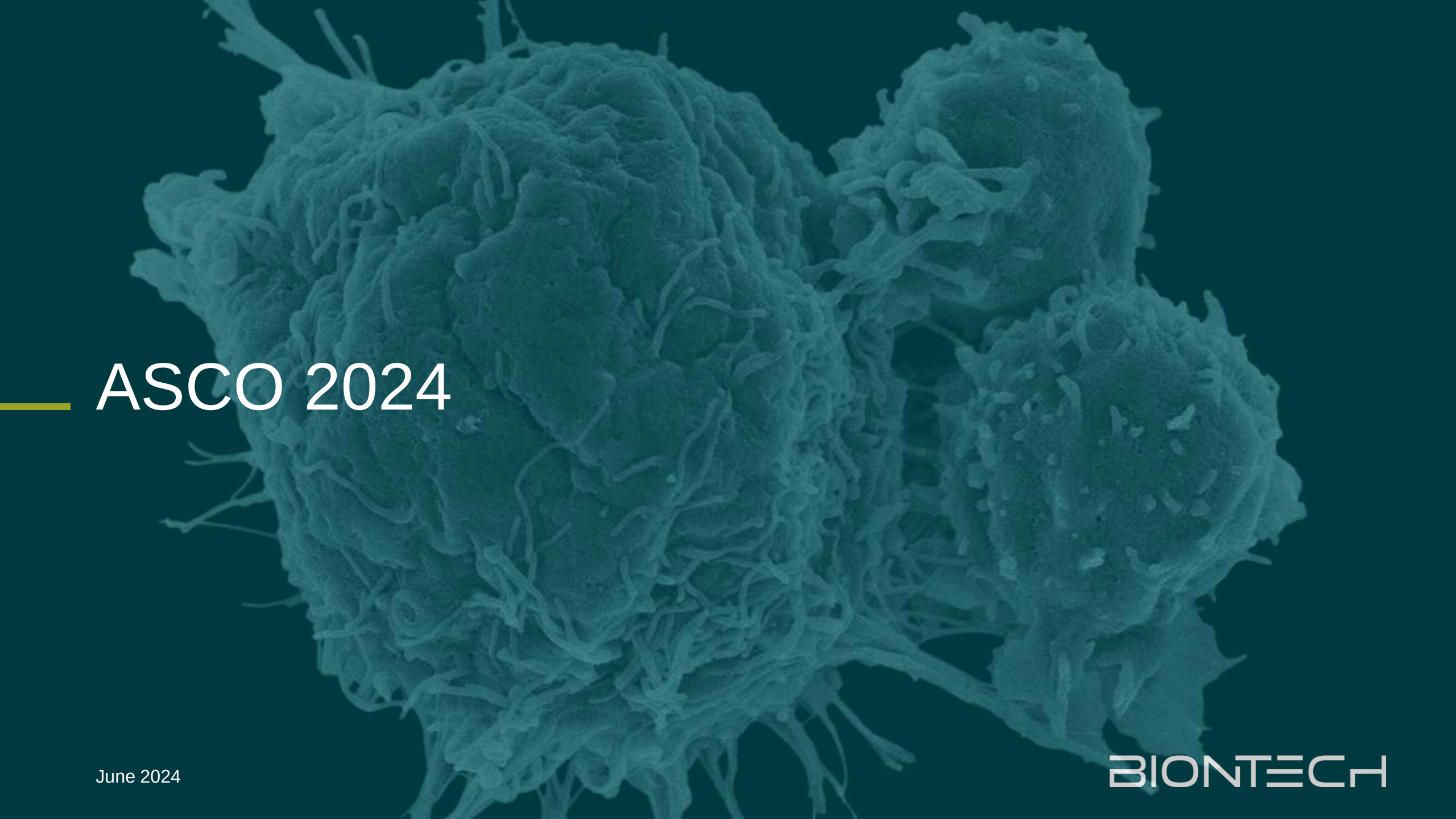


ASCO 2024

June 2024

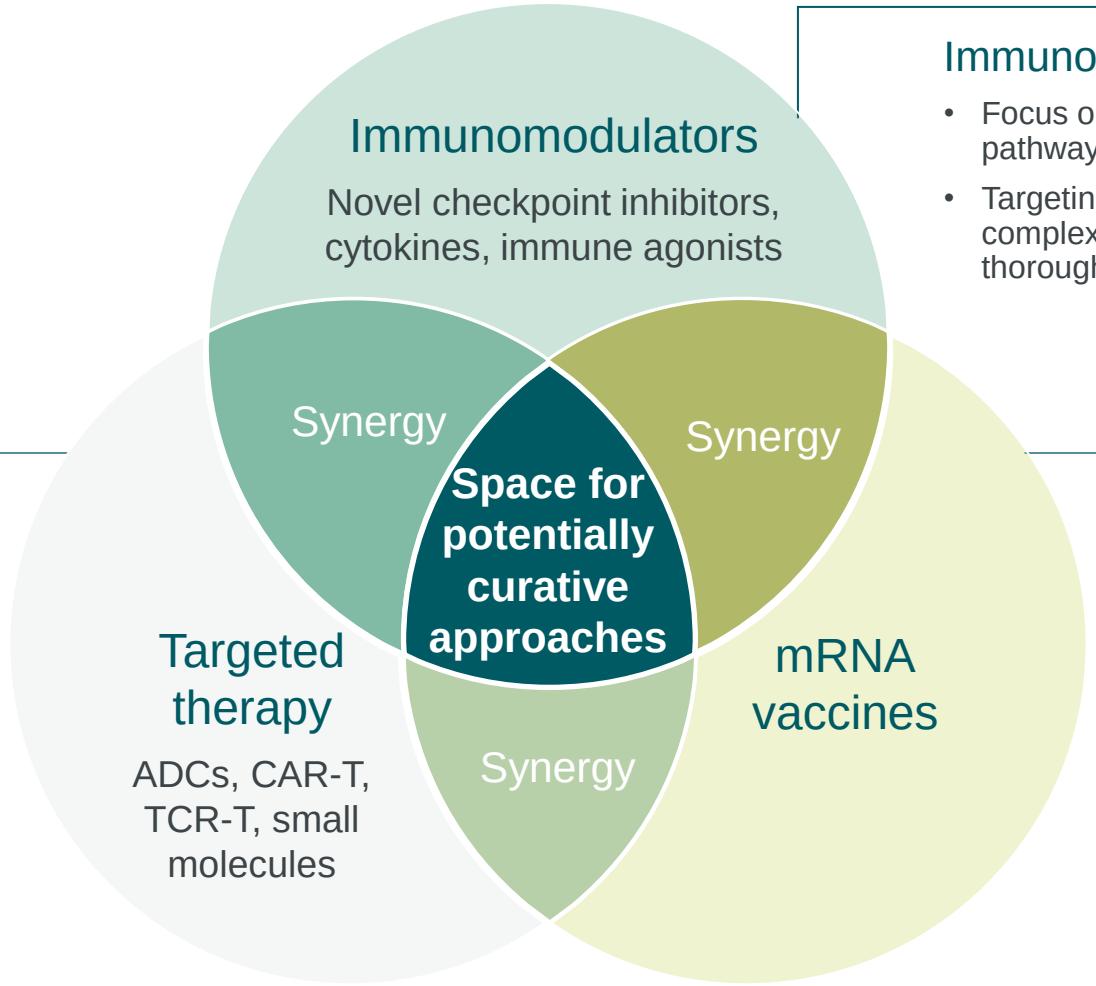
BIONTECH

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: the initiation, timing, progress, and results of BioNTech's research and development programs, including BioNTech's current and future preclinical studies and clinical trials, including statements regarding the 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; the targeted timing and number of additional potentially registrational trials, and the registrational potential of any trial BioNTech may initiate; and BioNTech's collaboration and licensing agreements. 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, 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 presentation, 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; future commercial demand; competition related to BioNTech's 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; 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 product candidates, if approved; BioNTech's ability to manage its development and expansion; 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 March 31, 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.

Towards a Potentially Curative Approach to Cancer: Differentiated Combinations



Immunomodulators

- Focus on the most relevant and crucial IO pathways
- Targeting different complementary players in the complex cancer immunity cycle may promote a thorough and durable anti-tumor effect

Targeted therapy

- Potent and precise therapies could rapidly reduce tumor burden
- Designed to have clinical efficacy across the entire disease continuum including late lines

mRNA cancer vaccines

- Could eliminate polyclonal residual disease with individualized vaccines for potential long-term impact
- Polyspecific activity by targeting multiple antigens at once

ADC = antibody-drug conjugate; CAR-T = chimeric antigen receptor-T-cell ; TCR-T = T-cell receptor engineered T-cell; IO = immuno oncology.

BIONTECH

Our Multi-Platform Immuno-Oncology Pipeline Today

Phase 1	Phase 1/2	Phase 2	Phase 3
BNT116 Adv. NSCLC	**BNT142** (CD3xCLDN6) Multiple CLDN6-pos. adv. solid tumors	**BNT111**[2] aPD(L)1-R/R melanoma, + cemiplimab	**BNT316/ONC-392 (gotistobart)**[4] (CTA-4) anti-PD-1/PD-L1 experienced NSCLC
Autogene cevumeran/BNT122[1] Multiple solid tumors	**BNT151** (IL-2 variant) Multiple solid tumors	**BNT113** 1L rel./met. HPV16+ PDL-1+ head and neck cancer, + pembrolizumab	**BNT323/DB-1303**[5] (HER2) HR+/HER2-low met. breast cancer
BNT152 + BNT153 (IL-7, IL-2) Multiple solid tumors	**BNT211** (CLDN6) Multiple solid tumors	**BNT116**[2] 1L adv. PD-L1 ≥ 50% NSCLC, + cemiplimab	**BNT323/DB-1303**[5] (HER2) PLANNED HER2-expressing rec. endometrial cancer
BNT221 Refractory metastatic melanoma	**BNT311/GEN1046**[3] (acasunlimab; PD-L1x4-1BB) Multiple solid tumors	**Autogene cevumeran/BNT122**[1] 1L adv. melanoma, + pembrolizumab	
BNT321 (sLea) Metastatic PDAC	**BNT312/GEN1042**[3]* (CD40x4-1BB) Multiple solid tumors	**Autogene cevumeran/BNT122**[1] Adj. ctDNA+ stage II or III CRC	
BNT322/GEN1056[3] Multiple solid tumors	**BNT313/GEN1053**[3] (CD27) Multiple solid tumors	**Autogene cevumeran/BNT122**[1] Adj. PDAC, + atezolizumab + mFOLFIRINOX	
BNT326/YL202[6] (HER3) Multiple solid tumors	**BNT314/GEN1059**[3] **(**EpCAMx4-1BB) Multiple solid tumors	**BNT311/GEN1046**[3] (acasunlimab; PD-L1x4-1BB) R/R met. NSCLC, +/- pembrolizumab	
	BNT316/ONC-392 (gotistobart)[4] (CTA-4) mCRPC, + radiotherapy	**BNT316/ONC-392 (gotistobart)**[4] (CTA-4) Plat.-R. ovarian cancer, + pembrolizumab	
	BNT316/ONC-392 (gotistobart)[4] (CTA-4) Multiple solid tumors		
	BNT321 (sLea) adjuvant PDAC, +mFOLFIRINOX		
	BNT323/DB-1303[5] (HER2) Multiple solid tumors		
	BNT324/DB-1311[5] (B7H3) Multiple solid tumors		
	BNT325/DB-1305[5] (TROP2) Multiple solid tumors		
	BNT411 (TLR7) Multiple solid tumors		

Legend

- mRNA
- Cell therapy
- Next generation IO
- ADCs
- Small molecules

1. Partnered with Genentech, member of Roche Group; 2. Partnered with Regeneron; 3. Partnered with Genmab; 4. Partnered with OncoC4; 5. Partnered with DualityBio; 6. Partnered with MediLink Therapeutics.
*Two phase 1/2 clinical trials in patients with solid tumors are ongoing in combination with immune checkpoint inhibitor +/- chemotherapy.
NSCLC = non-small cell lung cancer; mCRPC = metastatic castration resistant prostate cancer; HPV = human papillomavirus; PDAC = pancreatic ductal adenocarcinoma; CRC = colorectal cancer; CLDN = claudin; IL = interleukin; 1L = first line; R/R = relapsed/refractory; HER2/HER3 = human epidermal growth factor 2/3; sLea = sialyl Lewis A antigen; TROP2 = trophoblast cell-surface antigen 2, EpCAM = epithelial cell adhesion molecule; ctDNA = circulating tumor DNA; PD-1 = programmed cell death protein 1; PD-L1 = programmed cell death-ligand 1; CD = cluster of differentiation; 4-1BB = CD137; CTA-4 = cytotoxic T-lymphocyte-associated protein 4; mFOLFIRINOX = modified folinic acid-fluorouracil-irinotecan-oxaliplatin; TLR7 = toll-like receptor 7; ADC = antibody-drug conjugate; IO = immuno oncology.

BIONTECH

BioNTech at ASCO 2024

Modality	Program	Abstract #	Type	Abstract title	Date, time & location
Protein-based therapeutics	**BNT311/ GEN1046 (acasunlimab)**	2533	Poster	Acasunlimab (DuoBody-PD-L1x4-1BB) alone or in combination with pembrolizumab (pembro) in patients (pts) with previously treated metastatic non-small cell lung cancer (mNSCLC): initial results of a randomized, open-label, phase 2 trial	• Onsite Poster Display • Saturday, 1 June 2024 (9:00 AM – 12:00 PM) • Session: Developmental Therapeutics – Immunotherapy • Location: Hall A, Poster Board 12
	BNT327/ PM8002	5524	Poster	Efficacy and Safety of PM8002, a Bispecific Antibody Targeting PD-L1 and VEGF-A, as a Monotherapy in Patients with Solid Tumors: Clinical Data from Advanced Cervical Cancer and Platinum-resistant Recurrent Ovarian Cancer Cohorts	• Onsite Poster Display • Monday, 3 June 2024 (9:00 AM – 12:00 PM) • Session: Gynecologic Cancer • Location: Hall A, Poster Board 395
	BNT327/ PM8002	8533	Poster	A Phase Ib/IIa Trial to Evaluate the Safety and Efficacy of PM8002, a Bispecific Antibody Targeting PD-L1 and VEGF-A, as a Monotherapy in Patients with advanced NSCLC	• Onsite Poster Display • Monday, 3 June 2024 (1:30 PM – 4:30 PM) • Session: Lung Cancer – Non-small Cell Metastatic • Location: Hall A, Poster Board 397
	BNT326/ YL202	3034	Poster	YL202/BNT326, a HER3-targeted ADC, in patients with locally advanced or metastatic non-small cell lung cancer and breast cancer: Preliminary results from a first-in human phase I trial	• Onsite Poster Display • Saturday, 1 June 2024 (9:00 AM – 12:00 PM) • Session: Developmental Therapeutics – Molecularly Targeted Agents and Tumor Biology • Location: Hall A, Poster Board 179
mRNA therapeutics and vaccines	**Autogene cevumeran (BNT122, RO7198457)**	3526	Poster	Preliminary results correlating post-operative ctDNA status with disease-free survival in Stage II (high risk) / III Colorectal Cancer Patients in the BNT000-001 epidemiology study	• Onsite Poster Display • Saturday, 1 June 2024 (1:30 PM – 4:30 PM) • Session: Gastrointestinal Cancer – Colorectal and Anal • Location: Hall A, Poster Board 189
Cell therapies	**BNT211**	5038	Poster	Real-world evidence of overall survival (OS) and treatment patterns of patients (pts) with testicular germ cell tumors (DCT) receiving palliative chemotherapy in the United States	• Onsite Poster Display • Sunday, 2 June 2024 (9:00 AM – 12:00 PM) • Session: Genitourinary Cancer – Prostate, Testicular, and Penile • Location: Poster Board 356

1

BNT311/GEN1046 (acasunlimab)

Acasunlimab (DuoBody-PD-L1x4-1BB) Alone or in Combination with Pembrolizumab in Patients with Previously Treated Metastatic Non-Small Cell Lung Cancer: Initial Results of a Randomized, Open-Label Phase 2 Trial

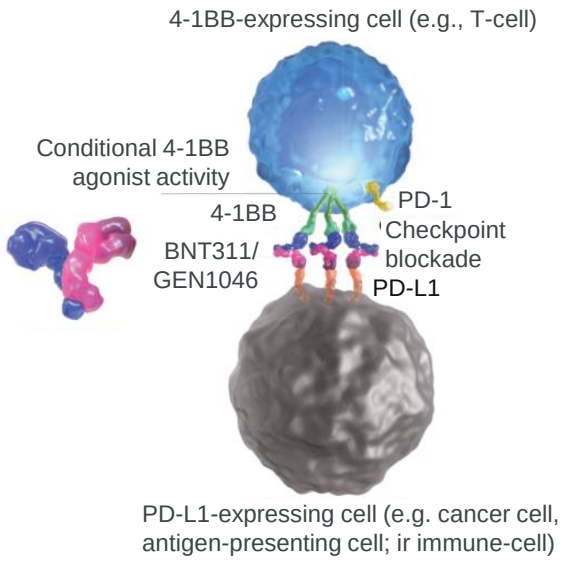
Joachim Aerts, Erasmus MC, Rotterdam, Netherlands, et. al., ASCO 2024, Poster #2533

BIONTECH

BNT311/GEN1046 (acasunlimab)[1]: a Bispecific Antibody to Combine Checkpoint Blockade and Conditional T-Cell Co-Stimulation in Multiple Solid Tumors

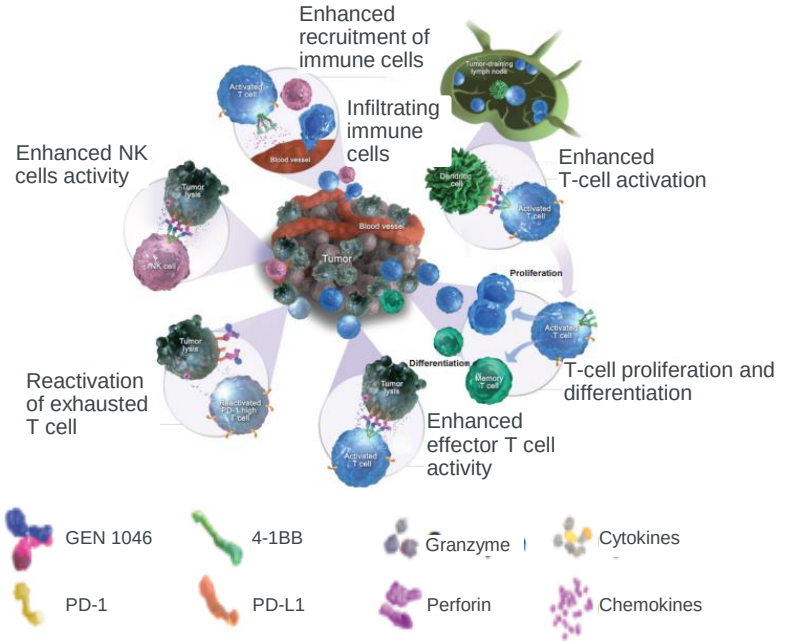
Inert Fc, dual targeted 4-1BB co-stimulation that is conditional on PD-L1 binding

BNT311/GEN1046 (acasunlimab) binding affinity:
K_D PD-L1: 0.16 nmol/L,
4-1BB: 0.15 nmol/L



Muik A, et al. *Cancer Discov* 2022; 12:1248−1345.

Novel mechanism that enhances T- and natural killer cell functions



Background information:

- Most patients with mNSCLC without actionable gene alterations have **limited treatment options** following progression on first-line checkpoint inhibitor-containing therapy[2]
- **Single-agent chemotherapy** remains the main second-line treatment option, despite **limited effectiveness** (docetaxel ORR: 13–17%; median OS <10 months) and **considerable toxicity** [3-5]
- Preclinical PK/PD findings suggest that **combining acasunlimab with additional PD-1 blockade may further potentiate and prolong anti-tumor activity** by allowing optimal 4-1BB engagement and more complete blockade of PD-1 signaling[6-8]

1. Partnered with Genmab; 2. Insa A, et al. *Crit Rev Oncol Hematol.* 2022;169:103538. **3.** Ahn MJ, et al. *Ann Oncol*. 2023;34:S1305-6; **4.** Borghaei H, et al. *Ann Oncol*. 2024;35:66-76; 5.Horn L, et al. *J Clin Oncol*. 2017;35:3924-33. **6.** Bajaj G, et al. *J Immunother Cancer*. 2021;9:A821, **7.** Blum J, et al. *J Immunother Cancer*, 2022;10(suppl 2):A1253.,**8.** Capello M, et al. *Cancer Res*. 2023;83(suppl 7):3283. Fc = fragment crystallizable region; PD–L1 = programmed cell death ligand 1; PD-1 = programmed cell death protein 1; NK = natural killer; mNSCLC = metastatic non-small cell lung cancer; ORR = objective response rate; OS = overall survival, 4-1BB = CD137, PK/PD = pharmacokinetics/pharmacodynamics.

BIONTECH

BNT311/GEN1046 (acasunlimab)[1]: Phase 2, Randomized, Open-Label Trial in Patients with Previously Treated mNSCLC (NCT05117242)

Key inclusion criteria

Age ≥ 18 years

mNSCLC with disease progression after ≥ 1 prior anti-PD-L1 treatment

Confirmed PD-L1 expression

ECOG PS 0-1

Adequate hematologic and renal/hepatic function

N=126*

Randomization stratified by PD-L1 expression and histology

BNT311/GEN1046 (acasunlimab)*
100 mg IV Q3W cycles 1-2, then 500 mg, IV, Q6W

*Enrollment discontinued in Dec 2023

BNT311/GEN1046 (acasunlimab) 100 mg IV + pembrolizumab,**
200 mg, IV, Q3W

** Enrollment discontinued in Feb 2024

BNT311/GEN1046 (acasunlimab)*
100 mg IV + pembrolizumab, 400 mg, IV, Q6W

Treatment continued until

- Progressive disease, unacceptable toxicity, or other reason for discontinuation, or
- ≤ 35 doses (Q3W) or ≤ 18 doses (Q6W) of pembrolizumab

Key endpoints

Primary: ORR by RECIST v1.1 per investigator

Secondary: DOR, PFS, OS, AEs and laboratory abnormalities

Selected exploratory endpoints: PK, biomarkers

Dosing:

*Following safety run-in for combination regime cohorts, up to 40 centrally PD-L1 pts per arm; pts were randomized to three arms

Please note: Not powered for inter-arm comparison

Aim of current analysis:

Evaluate safety and efficacy of BNT311/GEN1046 (acasunlimab)[1] in recurrent (non-small cell) lung cancer

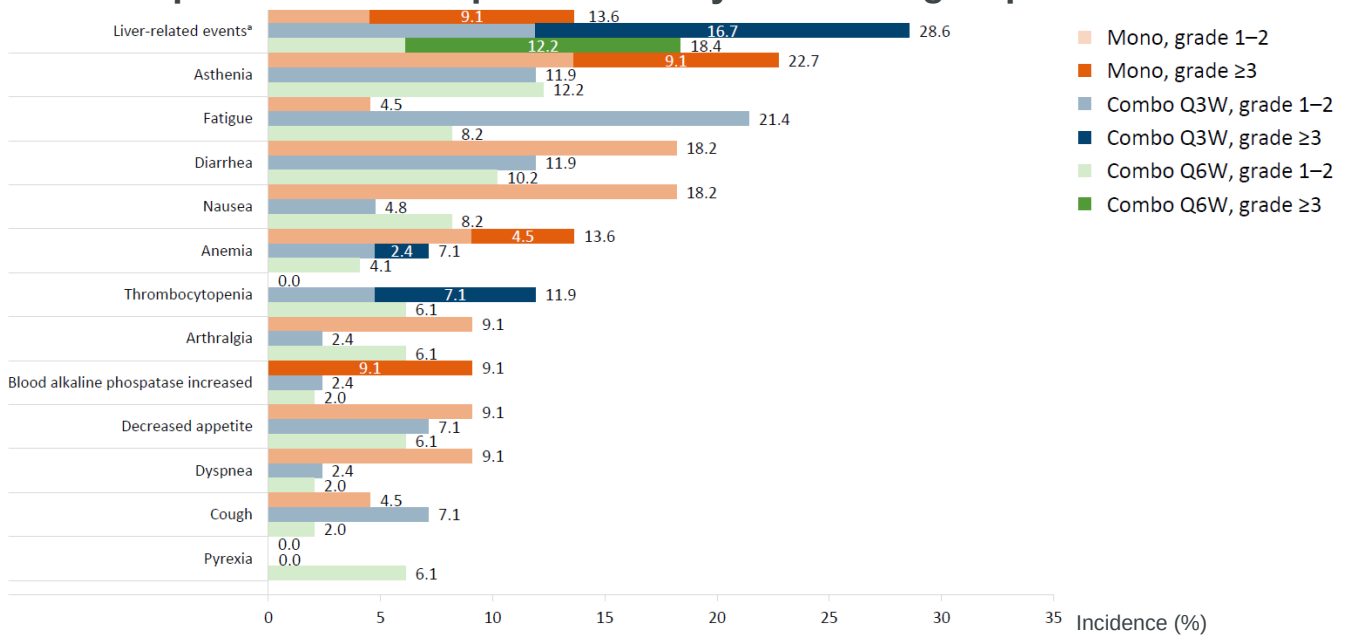
1. Partnered with Genmab. mNSCLC = metastatic non-small cell lung cancer; PD-L1 = programmed cell death ligand 1; ECOG PS = Eastern Cooperative Oncology Group performance status scale; IV = intravenously; QXW = every X weeks; ORR = overall response rate; RECIST = Response Evaluation Criteria in Solid Tumors; DOR = duration of response; PFS = progression-free survival; OS = overall survival; AE = adverse event; PK = pharmacokinetics.

BNT311/GEN1046 (acasunlimab)[1]: Well Manageable Treatment in All Three Arms, with Numerically Lower AE Incidence when Combined with Pembro Q6W

Phase 2 study (NCT05117242): Safety profile

Aerts, J. et al. presented at ASCO 2024. Poster #2533.

TRAEs reported in ≥5% of patients in any treatment group[2]



Liver-related events emerging as a prominent AE that is manageable with steroids and/or Tx delay

Data cutoff: March 22, 2024. One grade 5 TRAE (immune mediated hepatitis) was observed in the acasunlimab + pembro Q3W arm.

a. Liver related events include alanine aminotransferase increased, aspartate aminotransferase increased, gamma-glutamyltransferase increased, hypertransaminasemia, hepatitis, and immune-mediated hepatitis. Mono, acasunlimab monotherapy; combo Q3W, acasunlimab + pembro Q3W; combo Q6W, acasunlimab + pembro Q6W.

1. Partnered with Genmab. AE = adverse event; pembro = pembrolizumab; QxW = every X weeks; TRAE = treatment related adverse events.

BNT311/GEN1046 (acasunlimab)[1]: Demonstrated Encouraging Activity - Numerically Highest mDOR and 12-Mo OS when Combined with Pembro Q6W

Phase 2 study (NCT05117242): Anti-tumor activity (PD-L1+ subset)

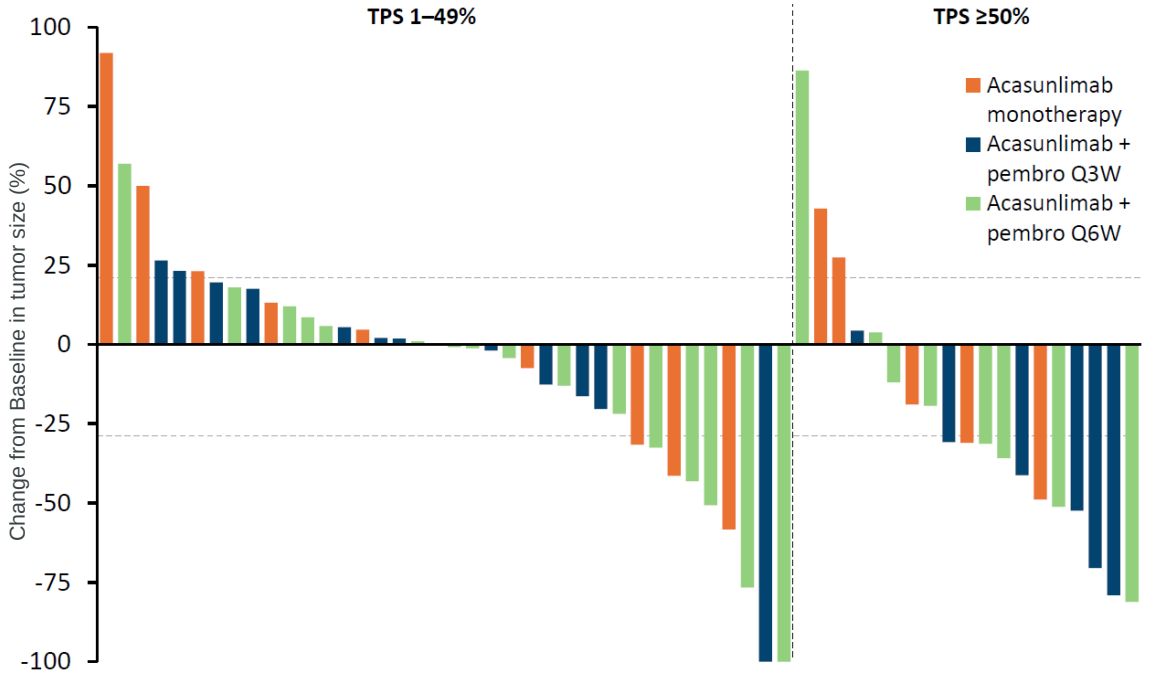
Aerts, J. et al. presented at ASCO 2024. Poster #2533.

	Acasunlimab Monotherapy (n=16)	Acasunlimab + Pembro Q3W (n=22)[a]	Acasunlimab + Pembro Q6W (n=24)[b]
Unconfirmed ORR, % (95% CI)	31.3 (11.0–58.7)	20.8 (7.1–42.2)	29.6 (13.8–50.2)
Confirmed ORR, % (95% CI)	12.5 (1.6–38.3)	18.2 (5.2–40.3)	16.7 (4.7–37.4)
Confirmed DCR, % (95% CI)	50.0 (24.7–75.3)	59.1 (36.4–79.3)	75.0 (53.3–90.2)
Median DOR, mo (95% CI)	2.0 (1.6–NR)	5.2 (3.5–NR)	NR (NR–NR)
6-month PFS rate, % (95% CI)	0 (NA)	14 (3–31)	34 (13–56)
12-month OS rate, % (95% CI)	30 (9–54)	26 (6–52)	69 (43–85)

Data cutoff: March 22, 2024. Centrally confirmed PD-L1+ patients are shown.
a. n=24 for unconfirmed ORR.
b. n=27 for unconfirmed ORR.

Highest 6-month PFS (34%) when acasunlimab is combined with pembro Q6W

Anti-tumor activity by treatment group and best overall response[2]



Data cutoff: March 22, 2024. Centrally confirmed PD-L1+ patients with post-baseline scans are shown. Dashed lines indicate 20% and -30%

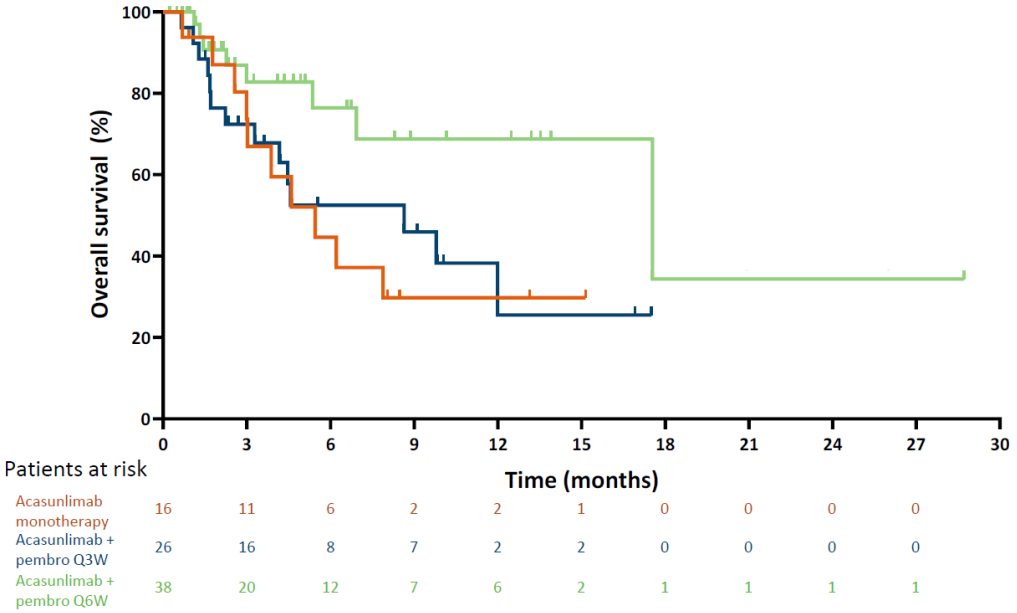
1. Partnered with Genmab. 2. Data cutoff: April 5, 2024. Centrally confirmed PD-L1+ patients with post-baseline scans are shown. Dashed lines indicate 20% and −30%.
PD-L1 = programmed cell death ligand 1; pembro = pembrolizumab; QxW = every X weeks; TPS = tumor proportion score; ORR = objective response rate; DCR = disease control rate; mDOR = median duration of response; PFS = progression free survival; Mo = month(s); OS = overall survival.; NR = not reached; CI = confidence interval; NA = not applicable.

BNT311/GEN1046 (acasunlimab)[1] Demonstrated Encouraging Preliminary Efficacy in Patients with Previously Treated mNSCLC

Phase 2 study (NCT05117242): Overall survival (PD-L1$^+$ subset)

Aerts, J. et al. presented at ASCO 2024. Poster #2533.

Kaplan-Meier Plot of OS in patients with PD-L1$^+$ mNSCLC[2]



Acasunlimab monotherapy
Median 5.5 months
(95% CI, 3.0–NR)

Acasunlimab + pembro Q3W
Median 8.6 months
(95% CI, 3.3–NR)

Acasunlimab + pembro Q6W
Median 17.5 months
(95% CI, 6.9–NR)

Acasunlimab + pembrolizumab Q6W resulted in a 12-months OS rate of 69% and a median OS of 17.5 months

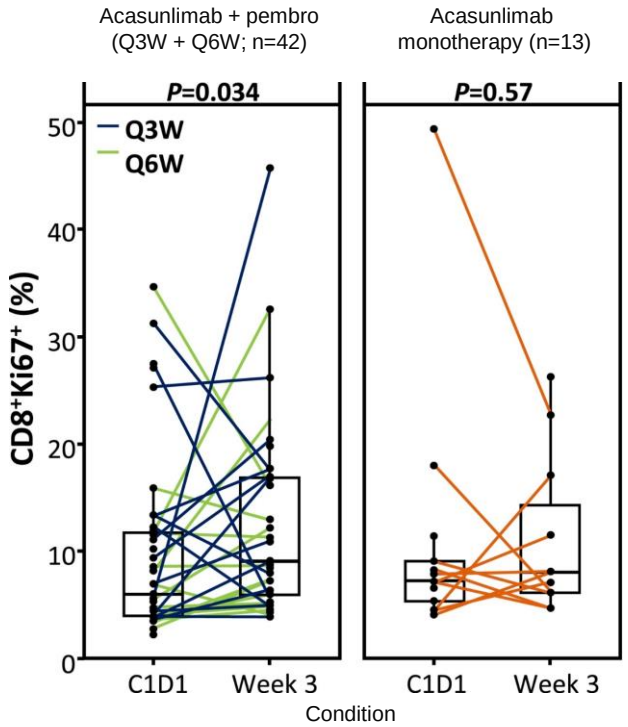
1.Partnered with Genmab; PD-L1 = programmed cell death ligand 1; mNSCLC = metastatic non-small cell lung cancer; pembro = pembrolizumab; QxW = every X weeks; DCR = disease control rate; OS = overall survival; CI = confidence interval; NR = not reached.
2. Data cutoff: May 1, 2024. Centrally confirmed PD-L1+ patients are shown.

BNT311/GEN1046 (acasunlimab)[1]: More Pronounced Proliferation of CD8+ Effector T-Cell Subsets in Combination with Pembro, in Line with Proposed MoA

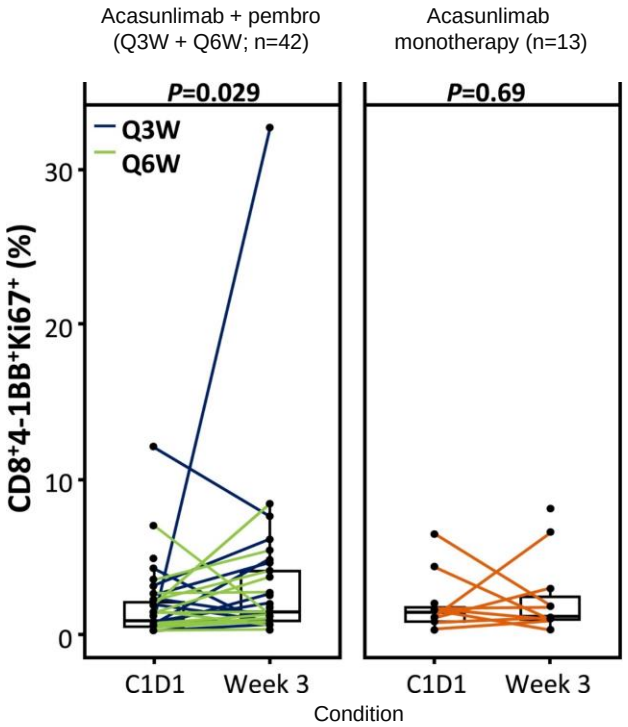
Phase 2 study (NCT05117242): On-treatment proliferation of CD8+ effector T-cells subsets in first cycle

Joachim Aerts et al. presented at ASCO 2024. Poster #2533.

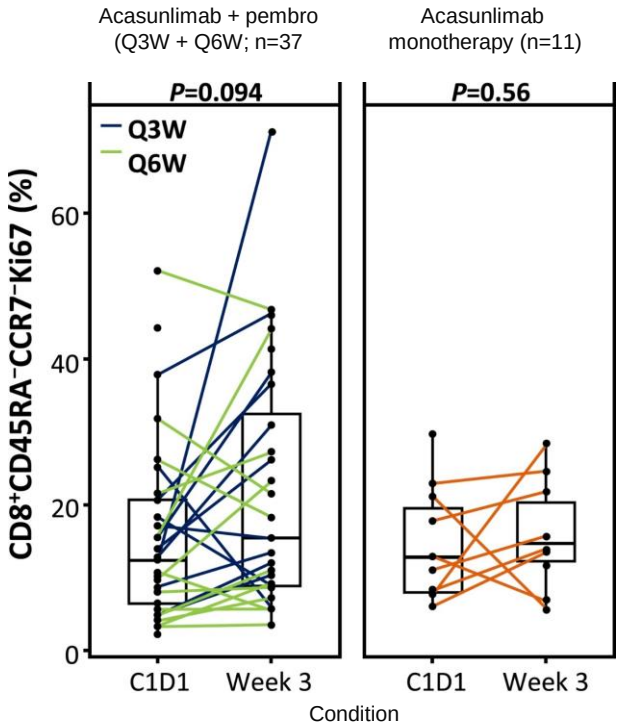
Proliferating CD8+ T-cells



Proliferating CD8+4-1BB+ T-cells



Proliferating CD8+ effector memory T-cells



1. Partnered with Genmab; CD = cluster of differentiation; ; pembro = pembrolizumab; QxW = every x weeks; 4-1BB = CD137; P = p-value; MoA = mode of action.
Based on flow cytometry analyses on viably frozen peripheral blood mononuclear cells (PBMCs); n values refer to number of patients at baseline.
Clinical data cutoff: March 22, 2024; translational data cutoff: March 20, 2024. Based on flow cytometry analyses on viably frozen peripheral blood mononuclear cells; n values refer to number of patients at baseline.

BNT311/GEN1046 (acasunlimab)[1] ASCO 2024 Data: Key Takeaway Messages

✓ **Safety Profile:** Adverse events of a combination of BNT311/GEN1046 (acasunlimab) + pembrolizumab were manageable, and no new safety signals were observed

✓ **Efficacy:** BNT311/GEN1046 (acasunlimab) + pembrolizumab combination showed encouraging efficacy in patients with PD-L1+ mNSCLC who had disease progression following ≥1 prior anti–PD-L1 treatment

- The Q6W regimen resulted in durable DCR (75%) and improved OS (median 17.5 months)
- Proliferation of CD8+ effector T-cell subsets was observed in the first cycle, with a more pronounced effect in patients receiving combination therapy

✓ **Outlook:** These results support further evaluation of BNT311/GEN1046 (acasunlimab) + pembrolizumab Q6W in patients with PD-L1+ mNSCLC

1. Partnered with Genmab. PD-L1 = programmed cell death ligand 1; mNSCLC = metastatic non-small cell lung cancer; QxW = every X wees; DCR = disease control rate; OS = overall survival; CD = cluster of differentiation.

2 BNT327/PM8002

Efficacy and Safety of BNT327/PM8002, a Bispecific Antibody Targeting PD-L1 and VEGF-A, as a Monotherapy in Patients with Solid Tumors: Clinical Data from Advanced Cervical Cancer and Platinum-Resistant Recurrent Ovarian Cancer Cohorts

Lingying Wu, Department of Gynecologic Oncology, National Cancer Center/National Clinical Research Center for Cancer/Cancer Hospital, Chinese Academy of Medical Sciences and Peking Union Medical College, Beijing, China, et. al., ASCO 2024, Poster #5524

BIONTECH

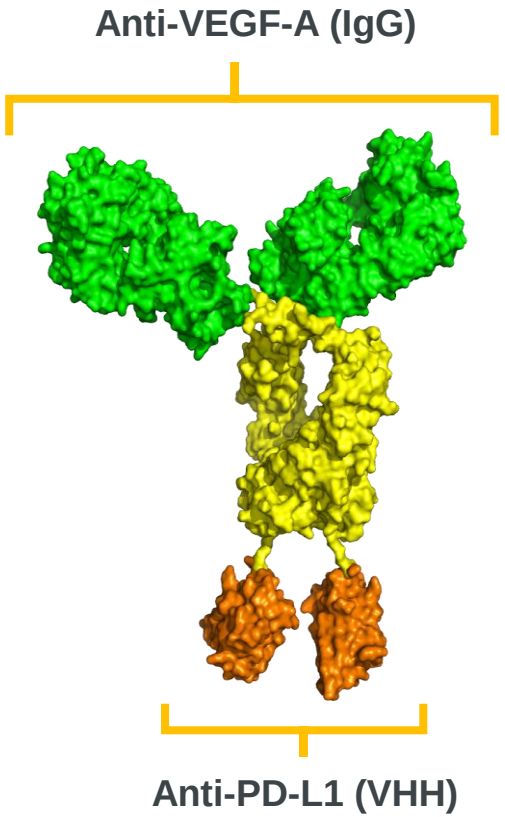
BNT327/PM8002[1] – A Next-Gen IO Agent that Combines Two Clinically Validated MoA

Dual blockade of PD-L1 and VEGF-A have been proven synergistic

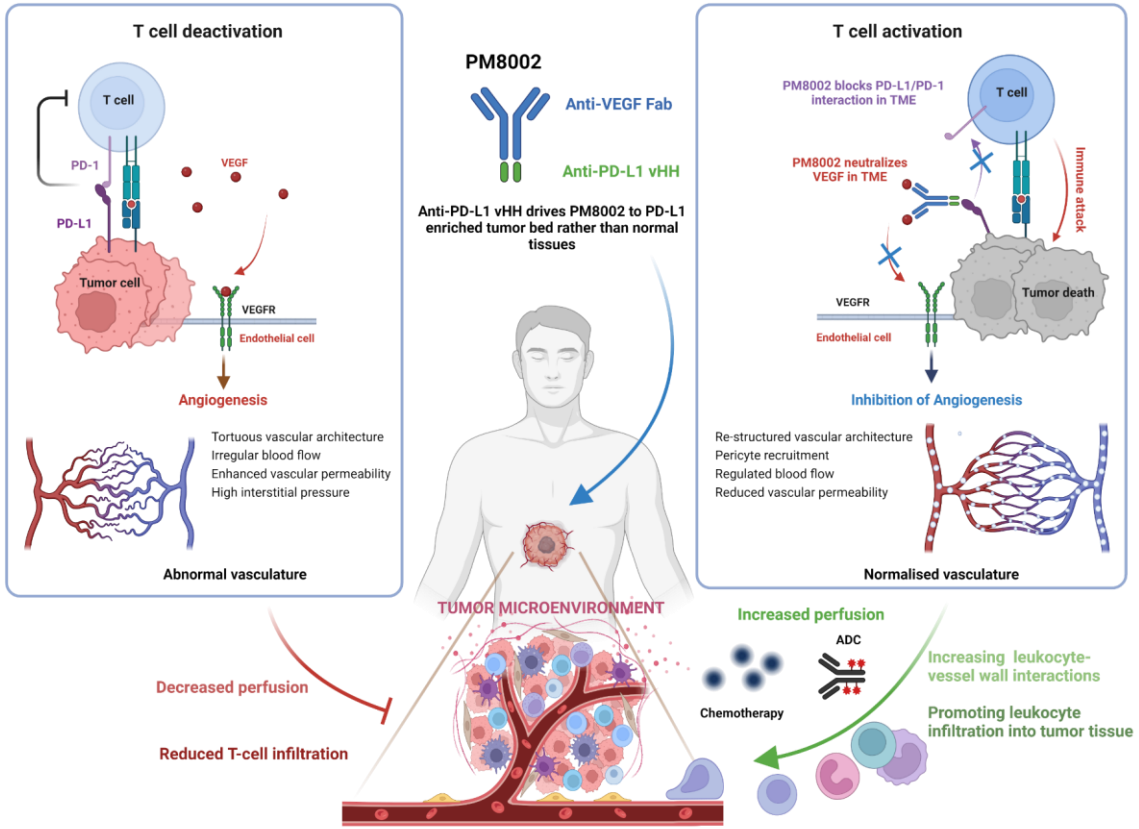
- Compelling profile with over 500 patients treated to date
- Monotherapy activity and synergy in combination therapy observed in early clinical studies
- Encouraging safety profile vs PD-L1 + VEGF inhibition or PD-1 alone

Protein binding activity (K_D) for human

- PD-L1: 5.5 nM
- VEGF-A: <0.4 nM



"Two in one" MoA synergies with ADCs

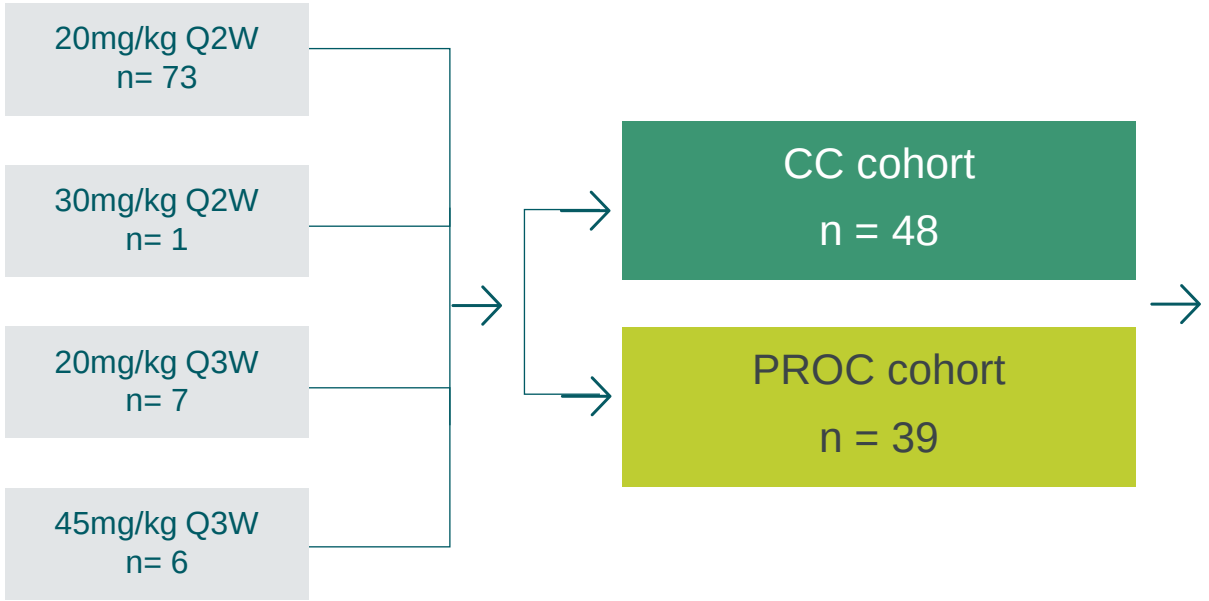


1. Partnered with Biotheus. IO = immuno oncology; MoA = Mode of Action; PD-1 = programmed cell death protein 1; PD-L1 = programmed cell death ligand 1; VEGF = vascular endothelial growth factor; VEGFR = VEGF receptor; ADC = antibody drug conjugate; TME = Tumor Microenvironment; IgG = immunoglobulin G; VHH = heavy chain variable.
The MoA graphic was generated by Biorender.com.

BNT327/PM8002[1]: Phase 1b/2a Open-Label Trial as Monotherapy in Patients with Advanced CC and PROC (NCT05918445)

Inclusion criteria

- Advanced or metastatic CC (≤ 2 prior treatment lines) and PROC (≤ 1 prior treatment line after platinum resistance)
- Age 18-75 years
- ECOG PS 0-1
- Adequate organ function
- Exclude evidence of significant bleeding and coagulation disorder or other significant bleeding risk



Treatment continued until

a) Disease progression

b) Intolerable toxicity

Key endpoints:

Primary endpoints: ORR per RECIST1.1

Secondary endpoint: DCR, PFS, safety

Aim of current analysis:

Evaluate safety and efficacy of BNT327/PM80021 as monotherapy in solid tumors

1. Partnered with Biotheus. Chinese Trial registration: ChiCTR2000040552.

CC = cervical cancer; PROC = platinum resistant ovarian cancer; ECOG PS = Eastern Cooperative Oncology Group performance status scale; QxW = every x weeks; ORR = objective response rate; RECIST = Response Evaluation Criteria in Solid Tumors; DCR = disease control rate, PFS = progression free survival.

BIONTECH

BNT327/PM8002[1]: Treatment Appeared Well Manageable

Phase 1b/2a study (NCT05918445): Safety profile

Wu, L. et al. presented at ASCO 2024. Poster #5524.

Overview of Treatment-Related Adverse Events

Categories	n (%)
All TRAEs	83 (95.4)
≥3 TRAEs	32 (36.8)
SAEs	29 (33.3)
irAEs	49 (56.3)
≥3 irAEs	7 (8.0)
TRAEs leading to discontinuation	13 (14.9)

Parameter TRAEs ≥ 15%	Grade, n (%)			
	All	3	4	5
Proteinuria	32 (36.8)	4 (4.6)	0	0
Hypertension	26 (29.9)	8 (9.2)	0	0
Hypothyroidism	21 (24.1)	0	0	0
Anemia	18 (20.7)	1 (1.1)	0	0
Thrombopenia	18 (20.7)	0	0	0
WBC count decrease	17 (19.5)	1 (1.1)	0	0
Hypoalbuminaemia	17(19.5)	0	0	0

- Proteinuria, hypertension, hypothyroidism and hematologic toxicities as most numerously observed TRAEs
- Limited TRAE-related treatment discontinuation (14.9%)

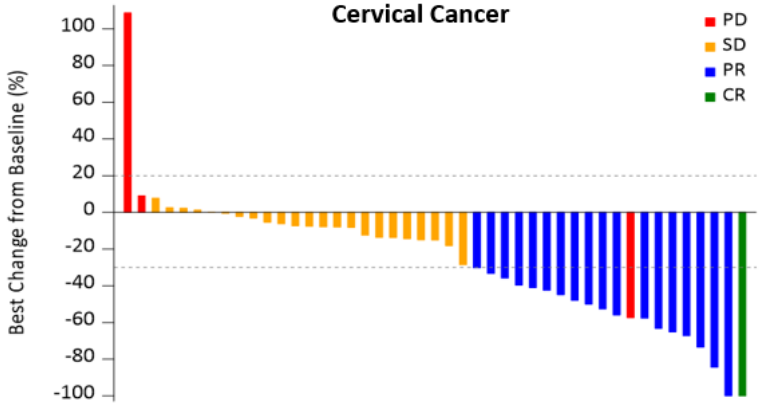
1. Partnered with Biotheus. WBC = white blood cell; TRAE = treatment-related adverse event; SAE = serious adverse event; irAE = immune-related adverse event.

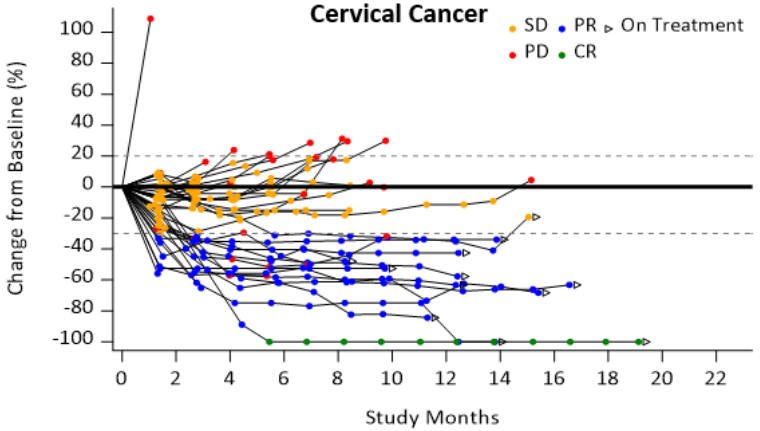
BNT327/PM8002[1] as Monotherapy Showed Encouraging Efficacy Signals in Patients with CC

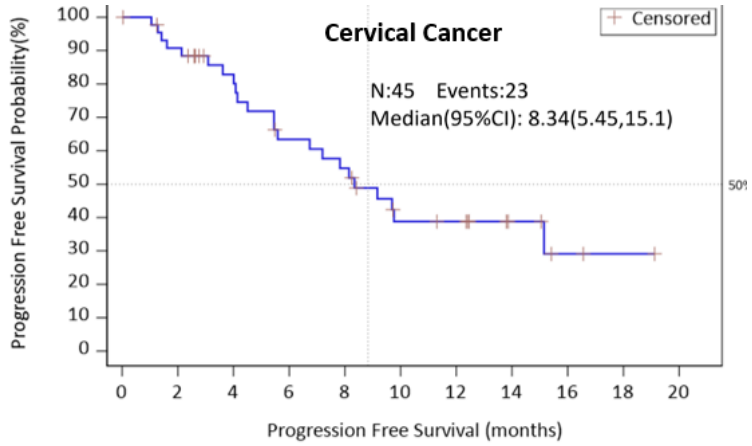
Phase 1b/2a study (NCT05918445): Efficacy signals CC

Wu, L. et al. presented at ASCO 2024. Poster #5524.

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







CC: N=45 | 1 CR | 18 PR | 23 SD | ORR was 42.2% and DCR 93.3% | ORR in patients with PD-L1-positive tumors 52.4%

mPFS was **8.3 months**

1. Partnered with Biotheus. CC = cervical cancer; PD = progressive disease; SD = stable disease; PR = partial response; CR = complete response; ORR = overall response rate; DCR = disease control rate; mPFS = median progression-free survival; CI = confidence interval; PD-L1 = programmed death-ligand 1.

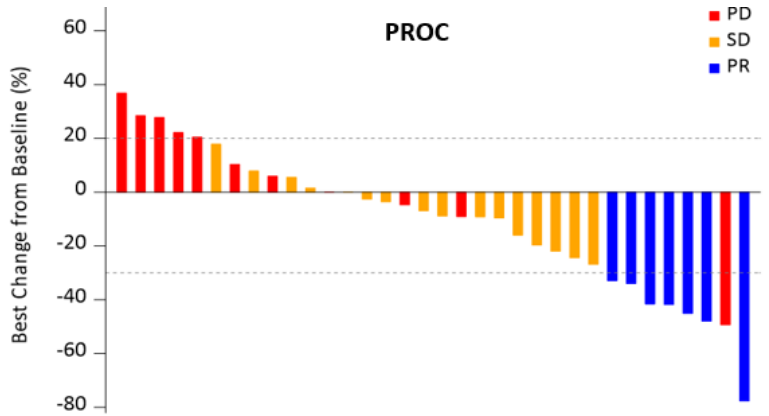
BIONTECH

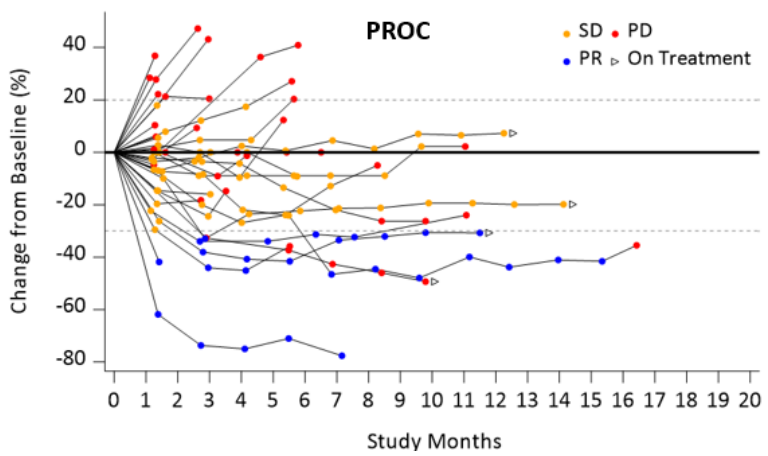
BNT327/PM8002[1] as Monotherapy Showed Encouraging Efficacy Signals in Patients with PROC

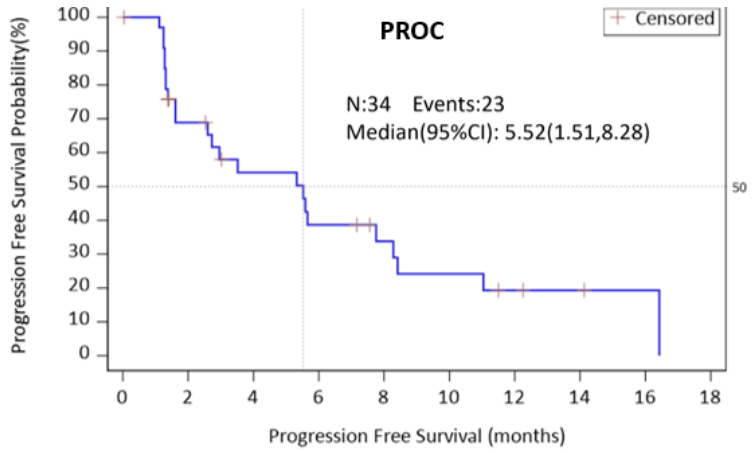
Phase 1b/2a study (NCT05918445): Efficacy signals PROC

Wu, L. et al. presented at ASCO 2024. Poster #5524.

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







PROC: N=34 | 7 PR | 16 SD | ORR of 20.6% and DCR of 67.7%

mPFS was **5.5 months**

1. Partnered with Biotheus. PROC = platinum-resistant ovarian cancer; PD = progressive disease; SD = stable disease; PR = partial response; CR = complete response; ORR = overall survival rate; DCR = disease control rate; mPFS = median progression-free survival; CI = confidence interval.

BIONTECH

BNT327/PM8002[1] ASCO 2024 Data: Key Takeaway Messages

Safety Profile: TRAEs occurred in 95.4% of patients (83/87) with ≥ Grade 3 TRAEs of 36.8% (32/87).

- Serious adverse events were observed in 33.3% (29/87) of patients
- Most common TRAEs were proteinuria, hypertension, hypothyroidism, anemia, thrombopenia, leukopenia and hypoalbuminaemia
- 14.9% (13/87) of patients discontinued BNT327/PM8002 treatment due to TRAEs

Efficacy: BNT327/PM8002[1] showed encouraging antitumor activity as monotherapy in previously treated patients with PROC or advanced CC

1. Partnered with Biotheus. TRAE = treatment related adverse events; PROC = platinum resistant ovarian cancer, CC = cervical cancer.

3 BNT327/PM8002

A Phase Ib/IIa Trial to Evaluate the Safety and Efficacy of PM8002/BNT327, a Bispecific Antibody Targeting PD-L1 and VEGF-A, as a Monotherapy in Patients with Advanced NSCLC

Chunjiao Wu, Jilin Cancer Hospital, Jilin, China, et. al., ASCO 2024, Poster #8533

BIONTECH

BNT327/PM8002[1]: Phase 1b/2a Open-Label Multiple Cohort, Dose Expansion Trial with BNT327/PM8002 as Monotherapy in Patients with Advanced NSCLC (NCT05918445)

Inclusion criteria

- Age ≥ 18 years with expected survival rate ≥ 12 weeks
- Malignant tumor confirmed by histology or cytology
- Toxicity of previous anti-tumor therapy has not been alleviated
- Adequate organ function
- ECOG 0 to 1
- ≥ 1 measurable lesion (RECIST v1.1.A)

Cohorts presented in this poster*:

Cohort 1 (n = 17)
1L NSCLC EGFR/ALK WT & PD-L1+ (TPS ≥ 1) w/o previous systemic treatment

Cohort 2 (n = 36)
EGFR-mutation NSCLS & failed prior EGFR-TKI treatment. Patients with T790 mutations received 3rd generation EGFR-TKIs

Cohort 3 (n = 8)
EGFR/ALK WT that failed anti-PD-1/L1 therapy and platinum-based chemotherapy regimens. 3 patients received anti-VEGF antibodies

PM8002 monotherapy
20 mg/kg
Q2W

Treatment continued until

Disease progression

or

Intolerable 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

Aim of current analysis:

Evaluate safety and efficacy of BNT327/PM80021 as monotherapy in patients with advanced NSCLC

* Additional cohorts are part of study NCT05918445 and not included in this presentation.
1. Partnered with Biotheus. NSCLC = non-small cell lung cancer; ECOG = Eastern Cooperative Oncology Group; EGFR = epidermal growth factor receptor; ALK = anaplastic large-cell lymphoma kinase; PD-L1 = programmed cell death ligand 1; TPS = tumor proportion score; TKI = tyrosine kinase inhibitor; VEGF = vascular endothelial growth factor; QxW = every x weeks; ORR = objective response rate; RECIST = Response Evaluation Criteria in Solid Tumors; DoR = duration of response; DCR = disease control rate; PFS = progression free survival; OS = overall survival; WT = wild type; NCI-CTCAE = National Cancer Institute Common Terminology Criteria for Adverse Events.

BNT327/PM8002[1]: Safety Profile Appeared Well Manageable

Phase 1b/2a study (NCT05918445): Safety

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

Overview of treatment-emergent adverse events

Categories	n (%)
All TRAEs	52 (85.2)
≥G3 TRAEs	12 (19.7)
irAEs	24 (39.3)
SAEs	15 (24.6)
TRAEs leading to discontinuation	5 (8.2)

- No Grade 4/5 TRAEs observed
- Most AEs were Grades 1-2 and related to laboratory value findings

	Grade, n (%)			
Common TRAEs	All	3	4	5
Proteinuria	33 (54.1)	3 (4.9)	0	0
Hypertension	15 (24.6)	6 (9.8)	0	0
Hypothyroidism	13 (21.3)	0	0	0
Hypoalbuminaemia	12 (19.7)	0	0	0
Hypocalcemia	11 (18.0)	0	0	0
Urinary tract infection	9 (14.8)	0	0	0
Anaemia	9 (14.8)	1 (1.6)	0	0
Hyponatraemia	9 (14.8)	0	0	0
Hypercholeresterolaemia	8 (3.1)	0	0	0
Alanine aminotransferase increased	8 (3.1)	8 (13.1)	0	0
Urinary occult blood positive	8 (3.1)	0	0	0
Blood creatinine increased	8 (3.1)	0	0	0
Gamma-glutamyltransferase increased	7 (11.5)	0	0	0
Weight decreased	7 (11.5)	0	0	0
Hyperglycaemia	7 (11.5)	0	0	0

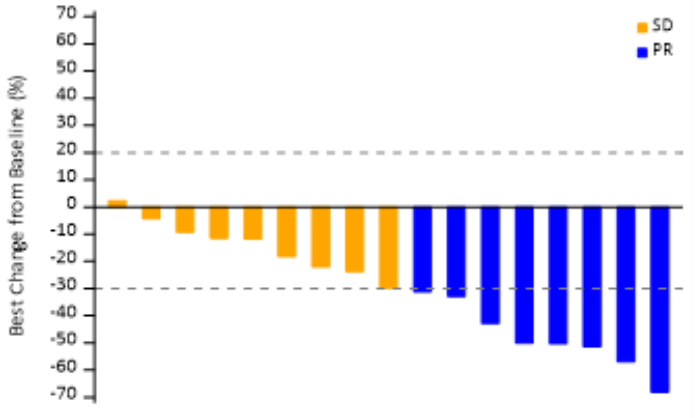
1. Partnered with Biotheus. TRAE = treatment related adverse event; irAEs = immune-related adverse event; SAE = serious adverse event.

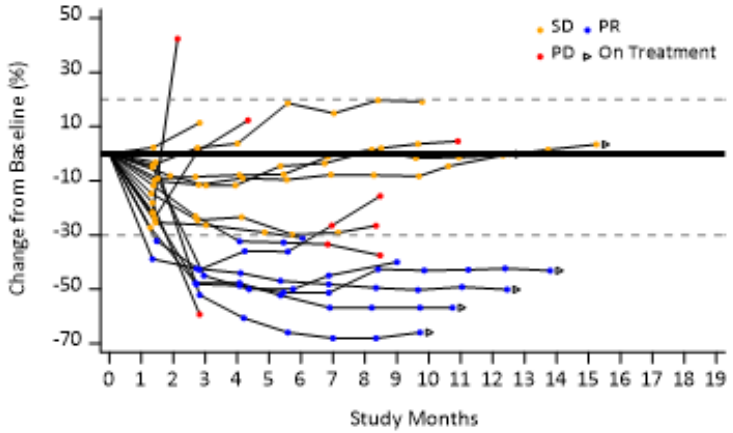
BNT327/PM8002[1]: Encouraging Anti-Tumor Activity

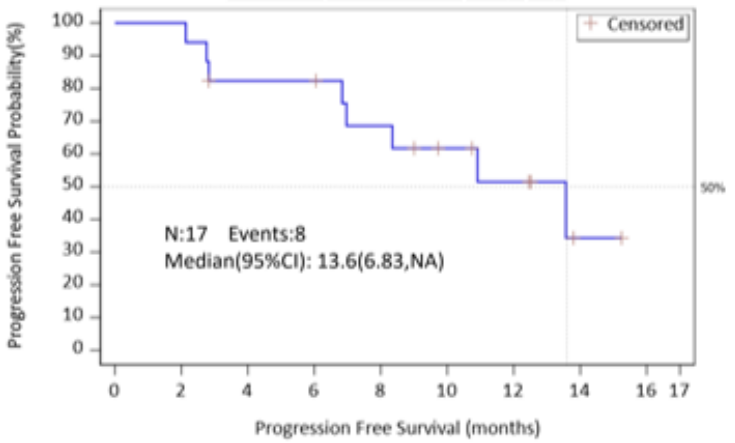
Phase 1b/2a study (NCT05918445): Efficacy signals, cohort 1

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

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







Cohort 1 (N=17): ORR was **47.1%** with a **DCR** of **100% |** 8 PR (7 confirmed PR) and 9 SD

mPFS was **13.6 months**

1. Partnered with Biotheus. ORR = objective response rate; DCR = disease control rate; mPFS = median progression free survival; SD = stable disease; PR = partial response; PD = progressive disease; CI = confidence interval; NA = not applicable.

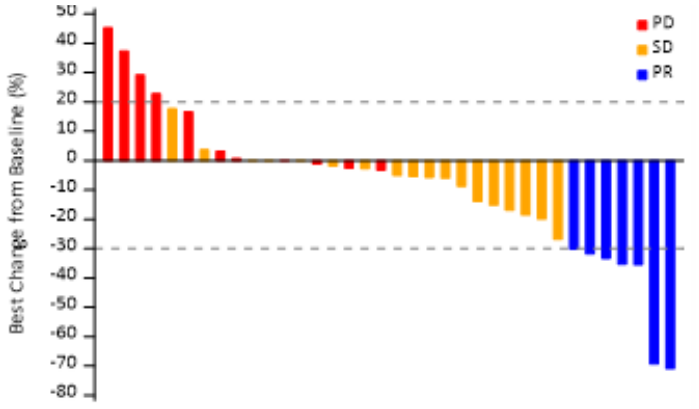
BIONTECH

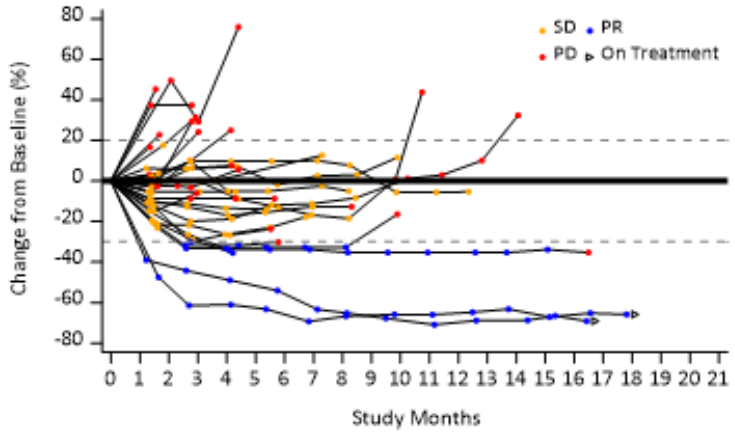
BNT327/PM8002[1]: Encouraging Anti-Tumor Activity

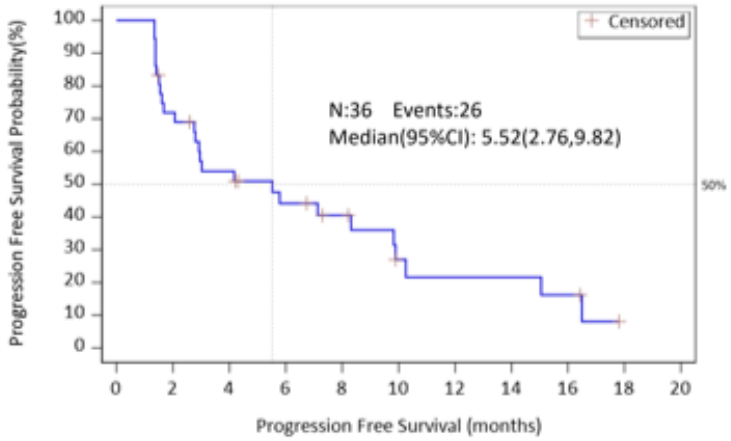
Phase 1b/2a study (NCT05918445): Efficacy signals, cohort 2

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

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







Cohort 2 (N=36): ORR was **19.4%** with a **DCR** of **69.4%**

mPFS was **5.5 months**

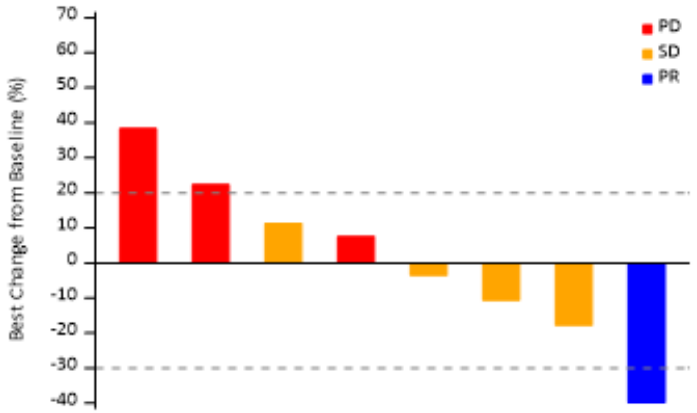
1. Partnered with Biotheus. ORR = objective response rate; DCR = disease control rate; mPFS = median progression free survival; SD = stable disease; PR = partial response; PD = progressive disease; CI = confidence interval; NA = not applicable.

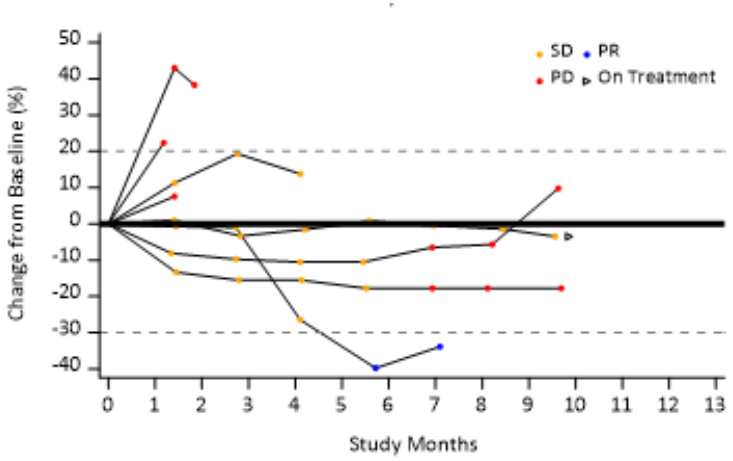
BNT327/PM8002[1]: Encouraging Anti-Tumor Activity

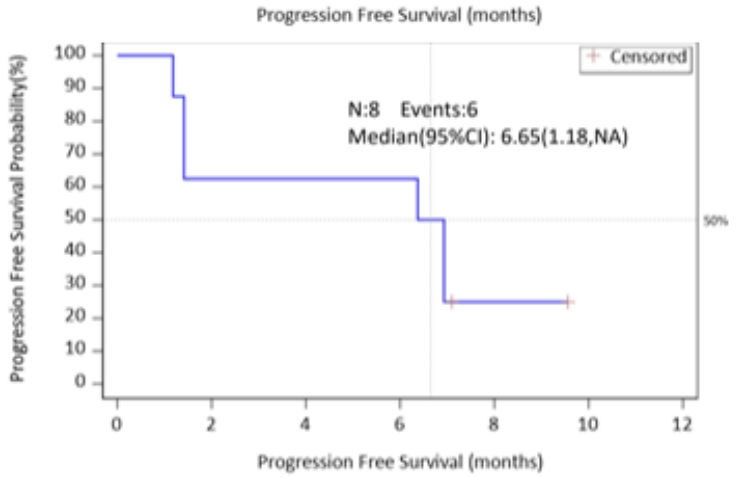
Phase 1b/2a study (NCT05918445): Efficacy signals, cohort 3

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

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







Cohort 3 (N=8): ORR was **12.5%** with a **DCR** of **62.5%**

mPFS was **6.7 months**

1. Partnered with Biotheus. ORR = objective response rate; DCR = disease control rate; mPFS = median progression free survival; SD = stable disease; PR = partial response; PD = progressive disease; CI = confidence interval; NA = not applicable.

BIONTECH

BNT327/PM8002[1] ASCO 2024 Data: Key Takeaway Messages

✓ **Safety Profile:** BNT327/PM8002[1] showed acceptable safety, with most adverse events of Grades 1-2 and no drug-related deaths

✓ **Efficacy:** BNT327/PM8002 showed encouraging anti-tumor activity in previously untreated advanced non-squamous NSCLC (EGFR/ALK WT & PD-L1+), patients with EGFR mutations who failed previous EGFR-TKI therapy, and advanced NSCLC patients who failed the combination of anti-PD-1/L1 and platinum-based chemotherapy

1. Partnered with Biotheus. NSCLC = non-small cell lung cancer; EGFR = epidermal growth factor; ALK = anaplastic lymphoma kinase; WT = wild type; PD-L1 = programmed cell death ligand 1; EGFR-TKI = Epidermal growth factor receptor tyrosine kinase inhibitor;

4 BNT326/YL202

YL202/ BNT326, a HER3-Targeted ADC, in Patients with Locally Advanced or Metastatic Non-Small Cell Lung Cancer and Breast Cancer: Preliminary Results from a First-in Human Phase 1 Trial

Ying Cheng, Department of Medical Oncology, Jilin Cancer Hospital, Changchun, China, et. al., ASCO 2024, Poster #3034

BNT326/YL202: An Investigational HER3-Targeted ADC, in Patients with Locally Advanced or Metastatic NSCLC and Breast Cancer

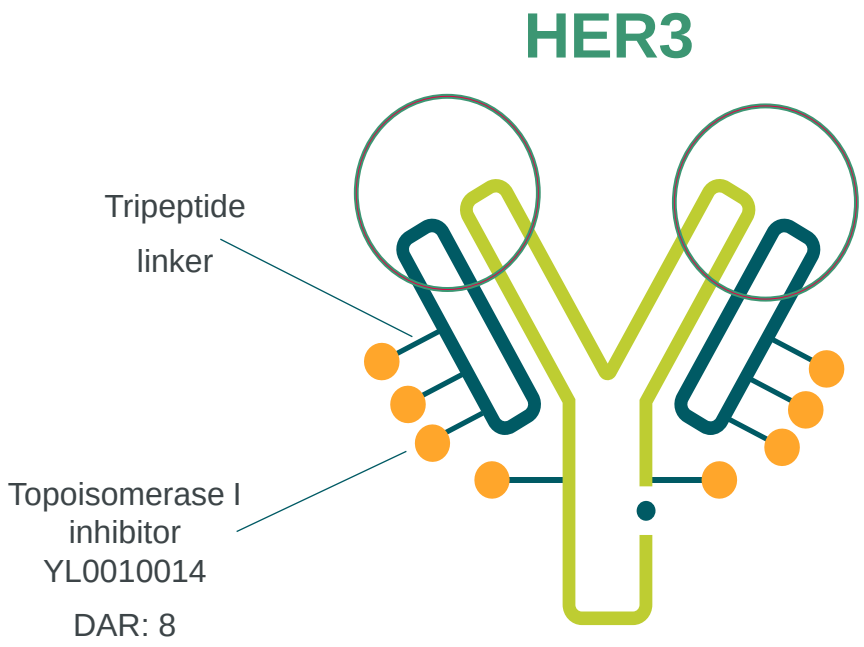
Background information:

HER3 is over-expressed in various cancers and can be further elevated after HER2/EGFR/endocrine targeting treatment

In preclinical studies, BNT326/YL202 demonstrated potent, dose-dependent antitumor activity in HER3-positive cell line- and patient-derived xenograft (CDX and PDX) mouse models[2]

BNT326/YL202 is a novel investigational antibody-drug conjugate (ADC) consisting of an anti-HER3 IgG1 monoclonal antibody linked to 8 molecules of YL0010014, a novel topoisomerase I inhibitor, via a tripeptide linker

The cleavable linker allows for intracellular and extracellular release of topoisomerase I inhibitor (YL0010014)



1.Partnered with MediLink Therapeutics; 2. Jian Xu, Qing Zong, Liang Zhu, Qigang Liu, Sasha Stann, Jiaqiang Cal. Cancer Res. 2023;83(7_Suppl):Abstract nr 563.
HER2/3 = human epidermal growth factor receptor 2/3; ADC = antibody-drug conjugate; NSCLS = non-small cell lung cancer; EGFR = epidermal growth factor receptor; IgG1 = immunoglobulin G1; PDX = patient-derived xenograft; CDX = cell line-derived xenograft; DAR = drug-to-antibody ratio.

BNT326/YL202[1]: Phase 1 Multi Center, Open-Label, FIH Dose Escalation Monotherapy Trial in Patients with Advanced NSCLC and BC (NCT05653752)

Key criteria

Exclusion

- Prior treatment with HER3-targeting agent
- Intolerant to prior treatment with topoisomerase I inhibitor or ADC-topoisomerase I inhibitor
- Undergone or expect major, non-diagnostic surgery with 4 weeks before first dose of study

Inclusion NSCLC

- Locally advanced/ metastatic disease
- EGFR-activating mutation (exon 19 deletion or L858R)
- Previous treatment with 3rd generation EGFR TKI, platinum-based CTx, and anti-PD-L1 antibody (US patients)
- ECOG PS of 0 to 2

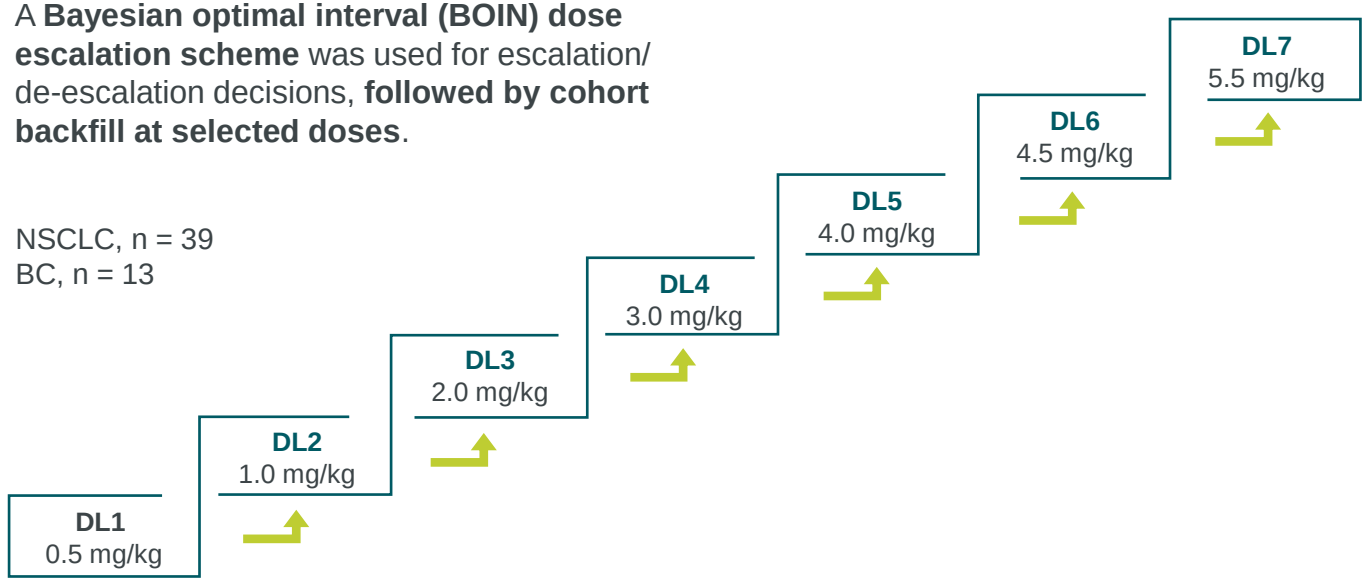
Inclusion BC

- Unresectable, locally advanced or metastatic disease
- HR+ and HER2- (IHC 0, 1+, 2+/ISH–)
- Previous treatment with endocrine therapy combined with CDK4/6 inhibitor and 1–2 lines of CTx
- ECOG PS of 0 to 2

Dose escalation (n=52):

A **Bayesian optimal interval (BOIN) dose escalation scheme** was used for escalation/ de-escalation decisions, **followed by cohort backfill at selected doses**.

NSCLC, n = 39
BC, n = 13



Key endpoints:

Primary endpoints: Safety and tolerability, determine MTD

Secondary endpoints: PK (ADC, AB, unconjugated payload); immunogenicity (presence of ADAs), tumor activity, evaluate RP2D

Exploratory endpoints: Expression level of HER3 in tumor tissue and its relationship with anti-tumor activity

Dosing:

IV, Q3W, 7 dose levels (DL)

Aim of current analysis:

Evaluate safety and tolerability and determine MTD of BNT326/YL202 as monotherapy in patients with NSCLC and BC

1. Partnered with MediLink Therapeutics. HER2/3 = human epidermal growth factor receptor 2/3; ADC = antibody drug conjugate; NSCLC = non-small cell lung cancer, BC breast cancer; EGFR = epidermal growth factor receptor TKI = tyrosine kinase inhibitor; CTx = chemotherapy; PD-L1 = programmed cell death ligand 1; ECOG PS = Eastern Cooperative Oncology Group performance status scale; HR = hormone receptor; FIH = first in human; DL = dose level; IV = intravenous; QxW = every x weeks; MTD = maximum tolerated dose; PK = pharmacokinetics; AB = antibody; ADA = anti-drug antibody; RP2D = recommended Phase 2 dose; IHC = immunohistochemistry; ISH = in-situ hybridization; CDK4/6 = cyclin-dependent kinase 4/6.

BIONTECH

BNT326/YL202[1]: Safety Profile was Consistent with its MoA

FIH Phase 1 study (NCT05653752): Safety

Cheng, Y. et al. presented at ASCO 2024. Abstract #3034.

Summary of treatment-related adverse events

System Organ Class/Preferred Term*	DL1 (N=3) n(%)	DL2 (N=4) n(%)	DL3 (N=7) n(%)	DL4 (N=10) n(%)	DL5 (N=18) n(%)	DL6 (N=10) n(%)	DL7 (N=3) n(%)	Overall (N=55) n(%)
Exposure cycles, median (range)	19.0 (2-20)	5.5 (1-11)	12.0 (4-14)	8.0 (3-11)	4.0 (1-6)	5.0 (1-8)	4.0 (3-5)	5.0 (1-20)
Any TRAEs, n (%)	2 (66.7)	4 (100)	6 (85.7)	10 (100)	18 (100)	10 (100)	3 (100)	53 (96.4)
TRAEs of CTCAE grades ≥3, n (%)	1 (33.3)	2 (50.0)	3 (42.9)	9 (90.0)	13 (72.2)	8 (80.0)	3 (100)	39 (70.9)
Any serious TRAEs, n (%)	0	1 (25.0)	1 (14.3)	4 (40.0)	9 (50.0)	7 (70.0)	2 (66.7)	24 (43.6)
TRAEs leading to:								
Dose reduction	0	0	0	6 (60.0)	10 (55.6)	7 (70.0)	1 (33.3)	24 (43.6)
Drug interruption	0	0	1 (14.3)	2 (20.0)	3 (16.7)	3 (30.0)	1 (33.3)	10 (18.2)
Drug withdrawal	0	0	0	0	3 (16.7)	0	1 (33.3)	4 (7.3)
Death	0	0	0	0	2 (11.1)	0	1 (33.3)	3 (5.5)

Most severe (Grade 3+) TRAEs were hematologic

1. Partnered with MediLink Therapeutics.

MoA = Mechanism of Action; TRAE = treatment-related adverse event; CTCAE = Common Terminology Criteria for Adverse Events; DL = dose level; FIH = first in human.

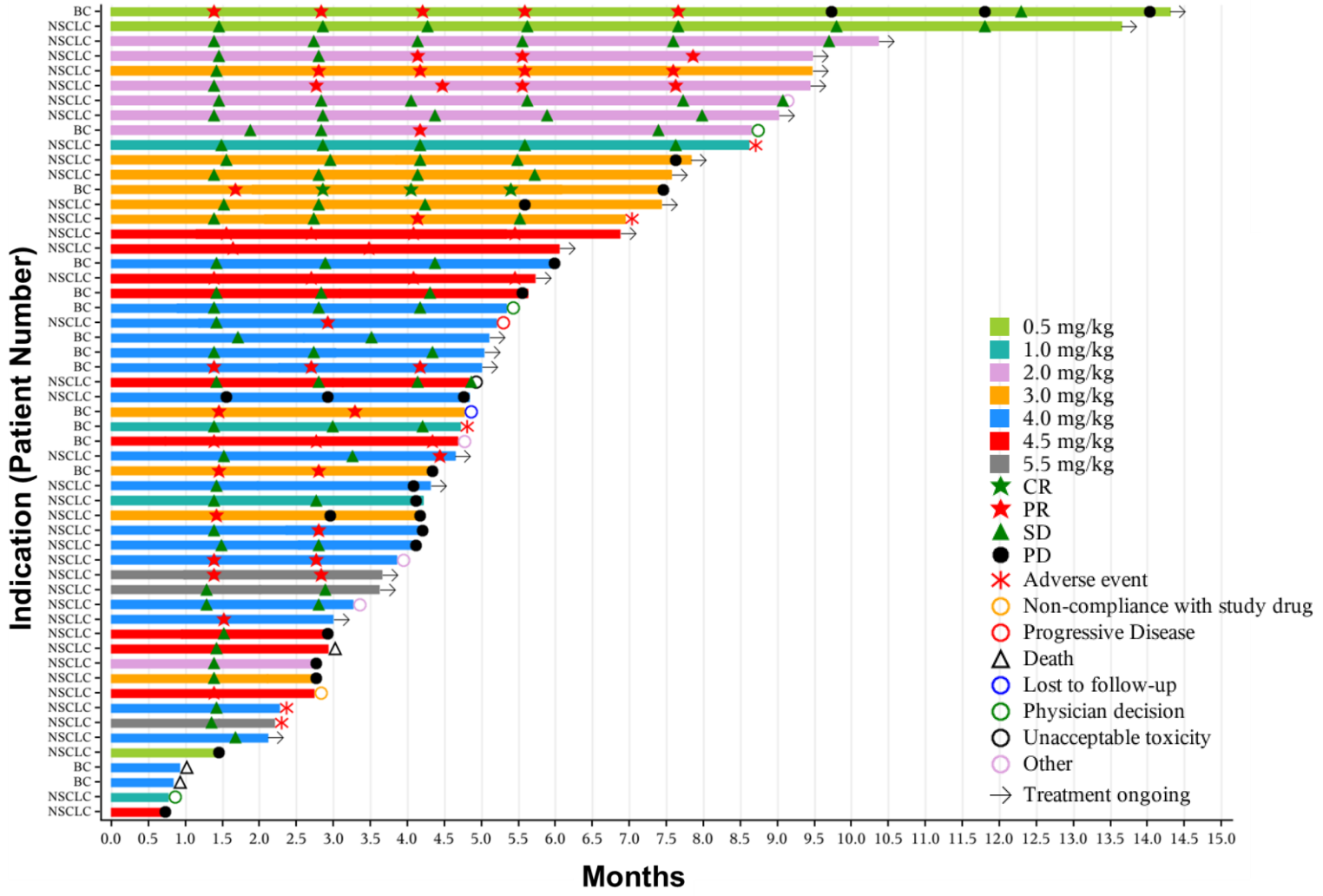
BIONTECH

BNT326/YL202[1]: Encouraging Activity and Near-Complete Disease Control in Patients with Advanced Disease

FIH Phase 1 study (NCT05653752):

Clinical activity, time on treatment and objective response by timepoint (N=55)

Cheng, Y. et al. presented at ASCO 2024. Abstract #3034.



Of 52 evaluable patients, ORR was 42.3% (n=22) and DCR was 94.2% (n=49), with responses seen beginning at 0.5 mg/kg

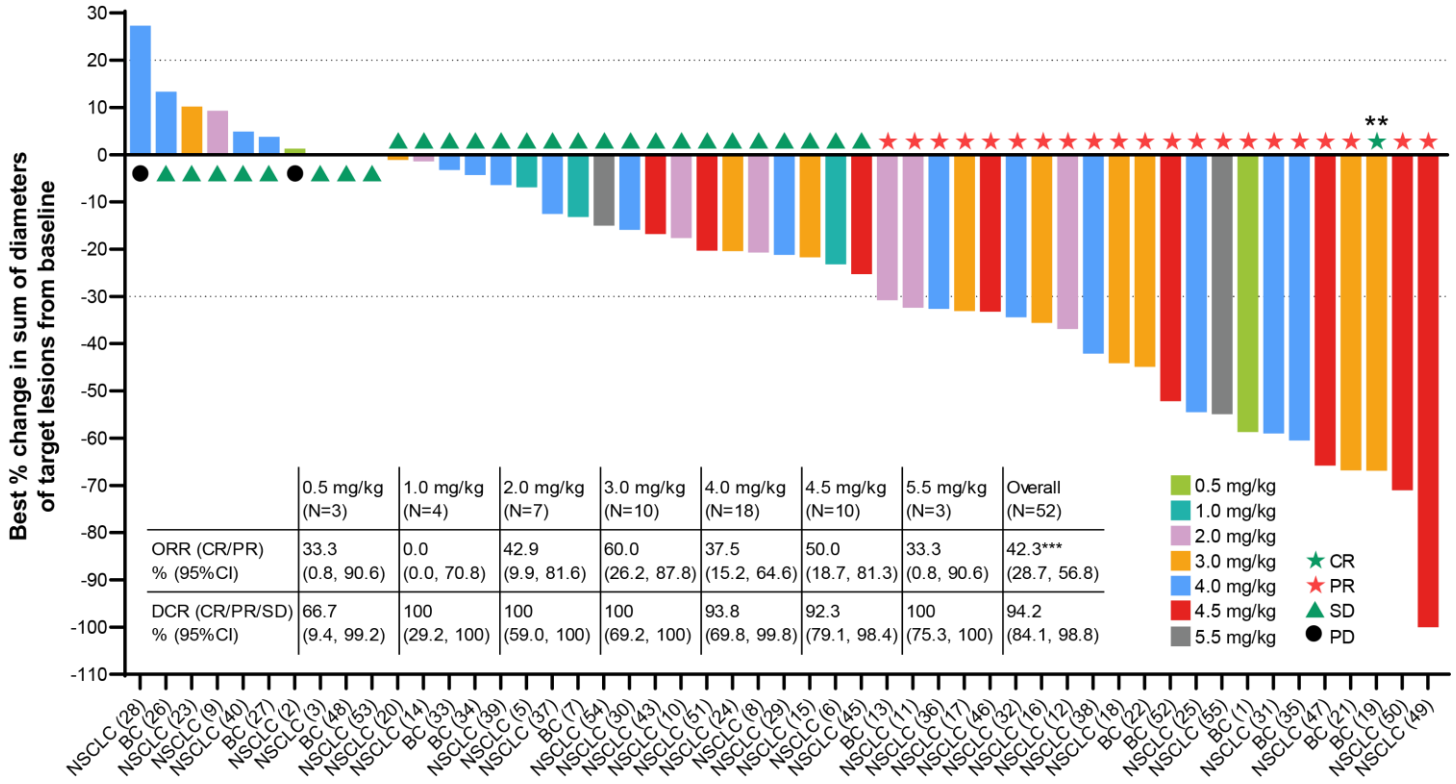
1. Partnered with MediLink Therapeutics. NSCLC = non-small cell lung cancer; BC = breast cancer; ORR = objective response rate; CR = complete response; PR = partial response; SD = stable disease; PD = progressive disease.

BIONTECH

BNT326/YL202[1]: Encouraging Activity and Near-Complete Disease Control in Patients with Advanced Disease

FIH Phase 1 study (NCT05653752): Clinical activity, best percent change from baseline in target lesion size (N=51*)

Cheng, Y. et al. presented at ASCO 2024. Abstract #3034.



1. Partnered with MediLink Therapeutics. NSCLC = non-small cell lung cancer; BC = breast cancer; DL = dose level; CR = complete response; PR = partial response; SD = stable disease; PD = progressive disease; FIH = first in human.
* One patient had non measurable target lesions at PD due to obstructive atelectasis induced by PD in non-target lesions and is therefore not presented in plot. ** CR occurred in patient with target lesion as lymph node that shrank to less than 10 mm. ***26.9% of patients had response confirmed on a subsequent scan.

BNT326/YL202[1] ASCO 2024 Data: Key Takeaway Messages

- **Safety:** The safety profile of BNT326/YL202[1] was consistent with its mechanism of action
- **Efficacy:** BNT326/YL202 demonstrated encouraging efficacy in heavily pretreated locally advanced/metastatic NSCLC and BC
  - Of 52 evaluable patients, ORR was 42.3% (n=22) and DCR was 94.2% (n=49), with responses seen at all dose levels
- **Outlook:** Further clinical development will focus on dose levels below 4.0 mg/kg, where the safety profile was manageable and promising clinical activity was observed

1. Partnered with MediLink Therapeutics. DL = dose level; NSCLC = non-small cell lung cancer; BC = breast cancer; ORR = objective response rate; DCR = disease control rate.

5 Autogene cevumeran (BNT122)

Preliminary Results Correlating Post-Operative ctDNA Status with Disease-Free Survival in Stage II (High Risk) / Stage III Colorectal Cancer Patients (BNT000-001 Epidemiology Study)

Anke C. Reinacher-Schick, Department of Hematology, Oncology and Palliative Care, St. Josef-Hospital, Ruhr-University Bochum, Germany, et. al.,
ASCO 2024, Poster #3526

BIONTECH

ctDNA Testing to Identify Patients with CRC at Risk of Recurrence after Curative Intent Surgery

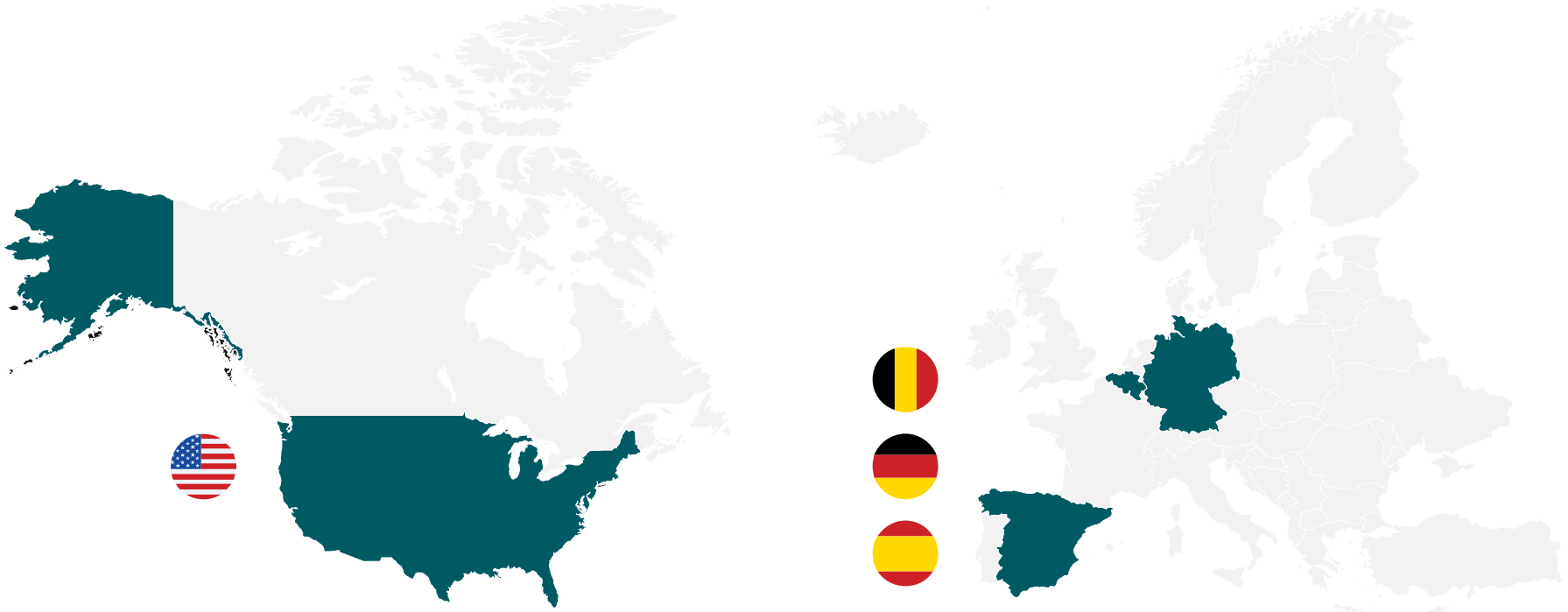
Background information:

Despite SOC surgical resection and adjuvant chemotherapy (AdCTx), disease recurrence in patients with Stage II (high risk) or Stage III CRC remains high[1]

Circulating tumor DNA (ctDNA) analysis post-surgery may help identify patients with minimal residual disease who are at risk of recurrence[2–4]

Recruitment is ongoing in 73 sites in the USA, Belgium, Germany, and Spain

In Germany, screening is performed with the support of the Colopredict registry study[5]



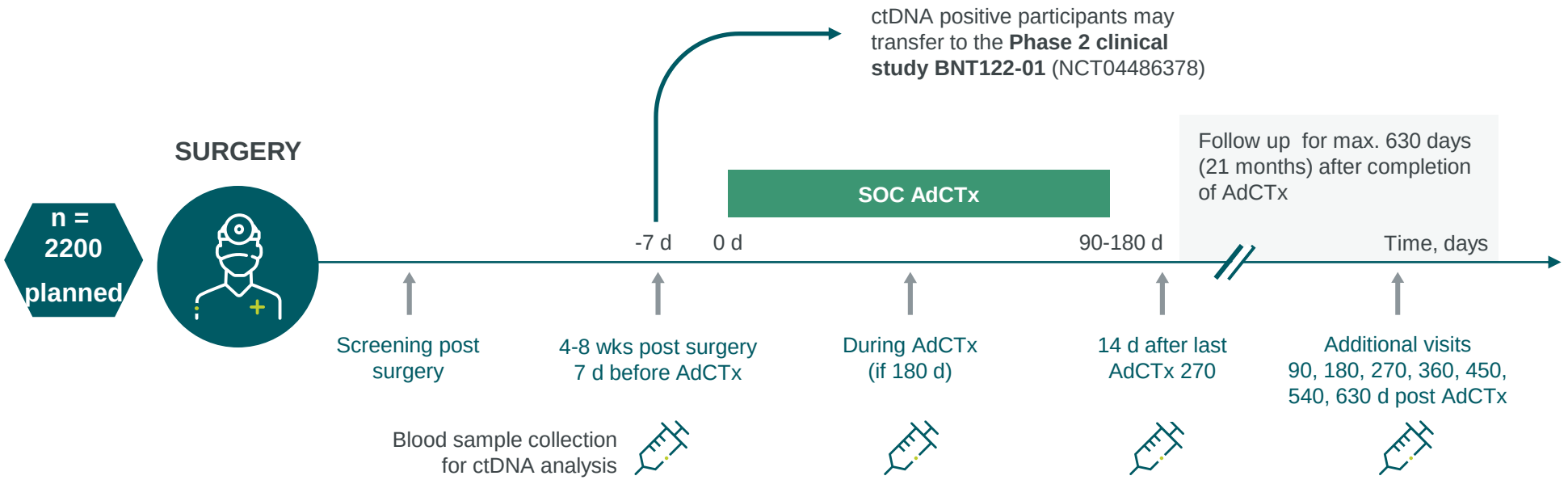
1. Yang L, et al. Nat Rev Clin Oncol 2024;21:67–79; 2. Henriksen TV, et al. Ann Oncol 2024;35(2):229–239; 3. Kotani D, et al. Nature Med 2023;29:127–134; 4. Grancher A, et al. Front Oncol 2022;12:973167; doi:10.3389/fonc.2022.973167; 5. Colopredict 2.0 PLUS (AIO-KRK-0413/ass). Available at https://www.aio-portal.de/studie/14--colopredict-plus-2-0.html
ctDNA = circulating tumor DNA; CRC = colorectal cancer; SOC = standard of care; AdCTx = adjuvant chemotherapy.

BIONTECH

BNT000-001: A Multi-Site Epidemiology Study to Underscore the Prognostic Value of Post-Operative ctDNA Positivity in Patients with Stage II or Stage III CRC (NCT04813627)

Inclusion criteria

- Stage II (high-risk) or Stage III CRC1
- Complete surgical resection (R0)
- Intention to receive SOC AdCTx within 8 weeks after surgery
- ECOG PS: 0 or 1



Study objectives:

Primary: Evaluate prevalence of ctDNA positivity post-surgery and prior to AdCTx

Secondary: Identify ctDNA+ participants for the Phase 2 study BNT122-01 (NCT04486378) that compares adjuvant autogene cevumeran to watchful waiting[2,3]

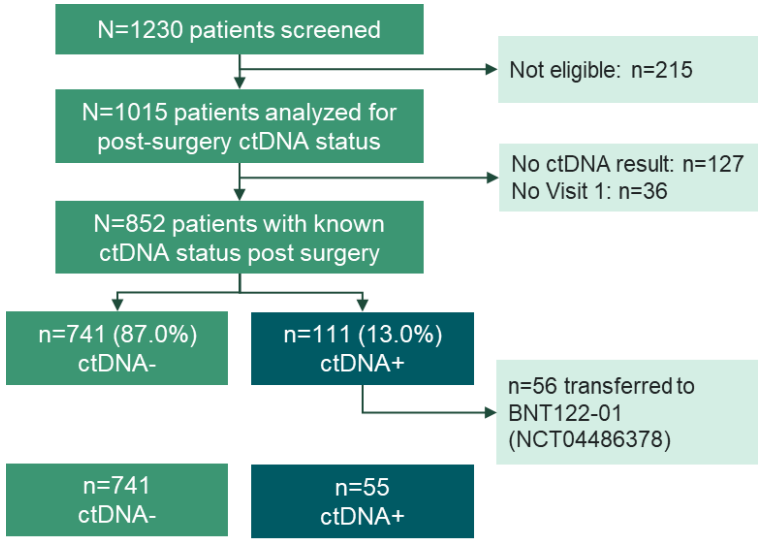
Exploratory: Assess predictive value of ctDNA for recurrence (prognostic value) and association of ctDNA positivity at different treatment time points

1. Amin MB, Greene FL, Edge SB (Eds.). AJCC cancer staging manual. 8th edition. Schweiz, Chicago, IL: Springer; AJCC American Joint Committee on Cancer. 2017. Available online at http://www.springer.com/;
2. Kopetz S, et al. J Clin Oncol 2022;40(16_suppl):TPS3641; doi:10.1200/JCO.2022.40.16_suppl.TPS3641; 3. ClinicalTrials.gov: NCT04486378. Available at: https://clinicaltrials.gov/study/NCT04486378.
ctDNA = circulating tumor DNA; CRC = colorectal cancer; SOC = standard of care; AdCTx = adjuvant chemotherapy; ECOG PS = Eastern Cooperative Oncology Group performance status scale; d = day(s).

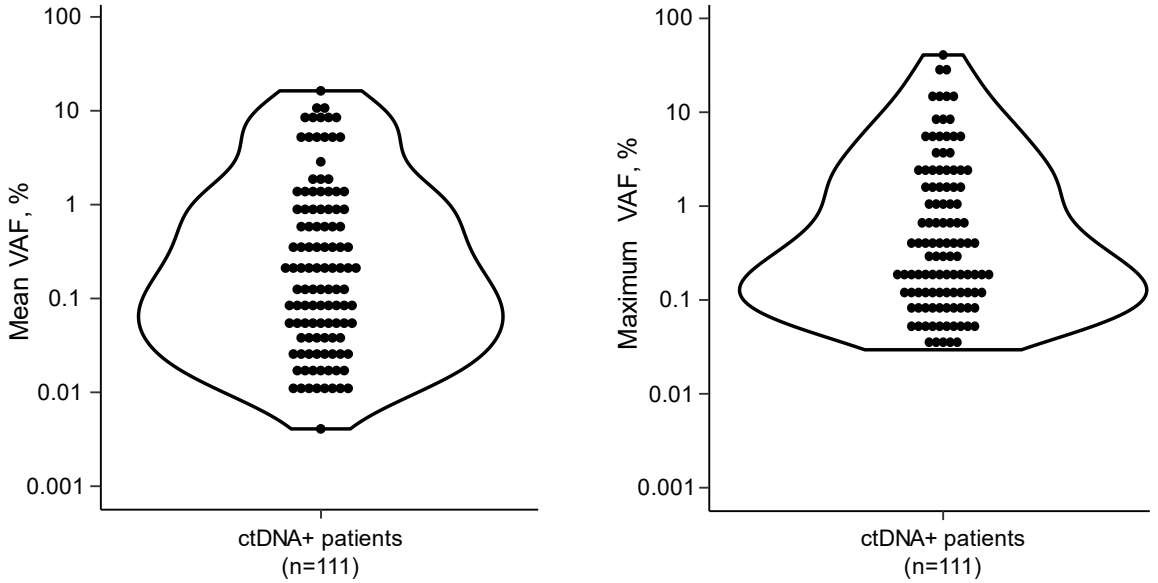
BNT000-001: 1,230* CRC Patients Screened to Identify ctDNA Status after Surgery

Epidemiology study (NCT04813627): Screening

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



VAF distribution in patients who were ctDNA+ post surgery**



Amongst 852 patients with known ctDNA status, 111 (13.0%) were ctDNA positive, with 56 transferred to the BNT122-01 study; remaining 55 patients were available for survival analysis

For ctDNA+ patients (n=111), mean VAF ranged from 0.004% to 16.0%

* As of March 15, 2024 **Data cut off: 15 March 2024.
ctDNA = circulating tumor desoxyribonucleic acid; CRC = colorectal cancer; VAF = variant allele frequency.

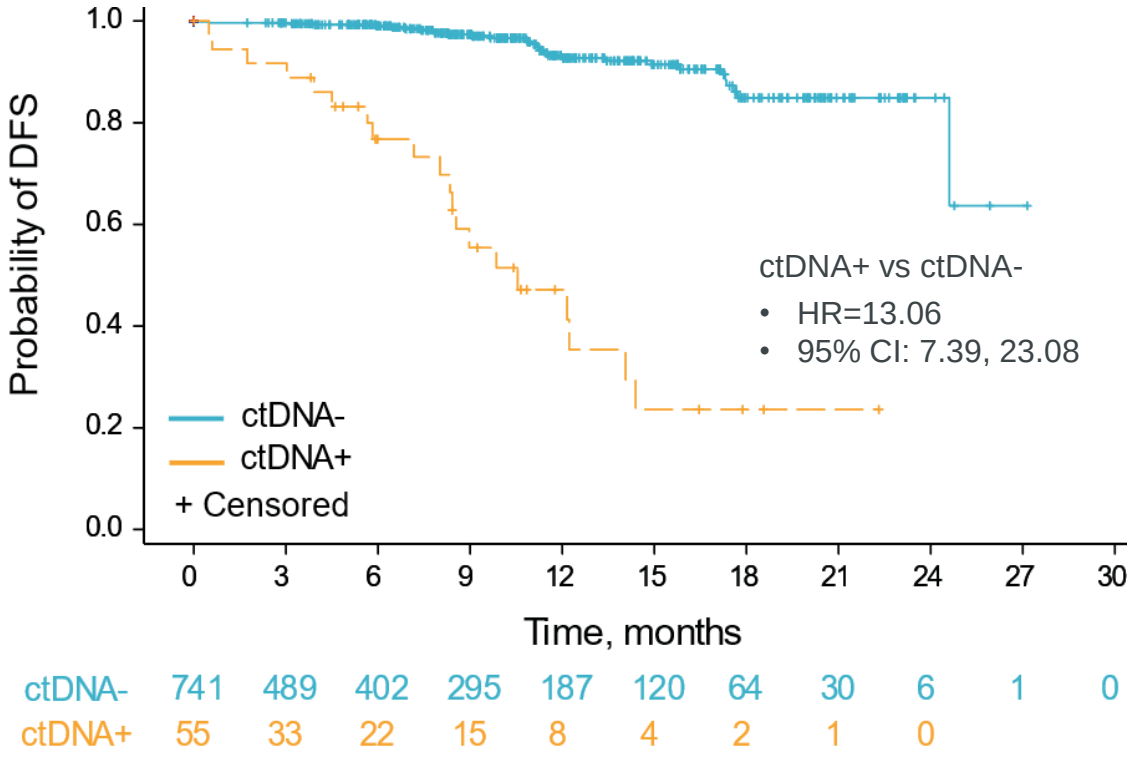
BIONTECH

Post-Surgery ctDNA Positivity was Associated with Significantly Shorter DFS

Epidemiology study (NCT04813627): Results

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

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



DFS rates at 12 and 18 months[2]

	ctDNA- (n=741)	ctDNA+ (n=55)*
Events, n (%)	31 (4.2)	20 (36.4)
Median DFS (IQR), months	NR (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)

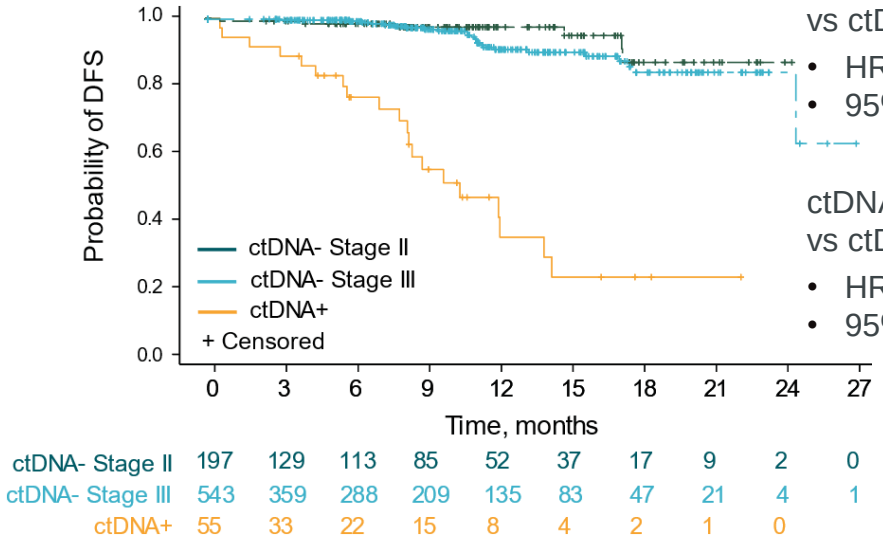
ctDNA = circulating tumor DNA; DFS = disease-free survival; HR = hazard ratio; CI = confidence interval; IQR = interquartile range; NR = not reached.
1. Data cut off: 15 March 2024. Patients who transferred to BNT122-01 (n=56) were excluded from these analysis. 2. Data cut off: 15 March 2024.Patients who transferred to BNT122-01 (n=56) were excluded from these analysis.

Patients with ctDNA+ Disease, Independent of Stage, had Shorter Median DFS than either ctDNA- Stage II or ctDNA- Stage III Subgroups

Epidemiology study (NCT04813627): Results subgroup analysis

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

DFS in ctDNA+ (Stage II/III) vs ctDNA- Stage II vs ctDNA- Stage III subgroups[1]



ctDNA+ (Stage II/III) vs ctDNA- Stage II

- HR=17.72
- 95% CI: 7.07, 44.44

ctDNA+ (Stage II/III) vs ctDNA- Stage III

- HR=11.63
- 95% CI: 6.41, 21.13

DFS rates in subgroups at 12 and 18 months[2]

	ctDNA- Stage II (n=197)	ctDNA- Stage III (n=543)	ctDNA+ (Stage II/III) (n=55)*
Events, n (%)	6 (3.1)	25 (4.6)	20 (36.4)
Median DFS (IQR), months	NR (NR, NR)	NR (24.6, NR)	10.55 (7.2, 14.4)
12-month DFS rate (95% CI), %	97.5 (94.7, 100)	91.5 (87.7, 95.5)	47.2 (31.9, 69.8)
18-month DFS rate (95% CI), %	87.1 (76.1, 99.6)	84.1 (77.4, 91.4)	23.6 (10.6, 52.3)

Due to a low number of patients with ctDNA+ Stage II disease (n=5), patients who were ctDNA+ post-surgery were pooled for the subgroup analysis of DFS

CI = confidence interval; ctDNA = circulating tumor DNA; DFS = disease-free survival; IQR = interquartile range; NR = not reached; HR = hazard ratio;
1. Data cut off: 15 March 2024. Patients who transferred to BNT122-01 (n=56) were excluded from these analysis. 2. Data cut off: 15 March 2024. Patients who transferred to BNT122-01 (n=56) were excluded from these analysis.

BNT000-001 Epidemiology Study DATA ASCO 2024: Key Takeaway Messages

Conclusion: This ongoing study adds to the existing evidence on the prognostic value of post-operative ctDNA positivity in patients with Stage II (high risk) or Stage III CRC

- Among 852 patients with known ctDNA status, 111 (13.0%) were ctDNA positive
- DFS rate at 12 months post-surgery was 47.2% for ctDNA positive patients and 93.2% for ctDNA negative patients

Outlook: These preliminary results support the use of ctDNA testing to identify patients with CRC undergoing surgery with curative intent who are at increased risk of recurrence

ctDNA = circulating tumor DNA; CRC = colorectal cancer; DFS = disease-free survival.

6 BNT211

Real-World Evidence of Overall Survival and Treatment Patterns of Patients with Testicular Germ Cell Tumors Receiving Palliative Chemotherapy in the United States

Darren R. Feldmann, Memorial Sloan Kettering Cancer Center, New York, NY, USA, 10065, et. al., ASCO 2024, Poster #5038

Real-World Evidence of Overall Survival and Treatment Patterns of Patients with R/R Testicular Germ Cell Tumors Receiving Palliative Chemotherapy in the U.S.

Retrospective study using Komodo Research Database (01/2016-03/2023), a claims database representing ~30% of U.S. population

Background information

Patients with R/R GCT have poor prognoses, with only palliative options remaining[1-3]

Real-world data, particularly around prior salvage strategies with high-dose (HDCT) or conventional-dose chemotherapy (CDCT), are needed to inform future treatment standards

Sample selection

Male patients with diagnoses of TC recorded at ≥2 visits ≥30 days apart who were ≥18 years of age as of the first observed TC diagnosis

n = 57,508

Patients with ≥1 TC-related chemotherapy regimen following the first observed TC diagnosis

n = 5,808 (10.1%)

Patients with ≥1 TC-related palliative regimen following the first observed TC diagnosis

n = 248 (4.3%)

Objective 1

Patients with ≥1 TC-related salvage chemotherapy regimen prior to the index date

n=97 (39.1%)

Objective 2

Patients with continuous health plan coverage from the TC diagnosis to the index date

n=51 (20.6%)

Study objectives:

Objective 1: **OS**, defined as the time from palliative chemotherapy initiation to death

Objective 2: Analysis of treatment patterns in a subgroup of patients with an eligible health plan

R/R = relapsed/refractory; TC = testicular cancer; GCT = germ cell tumor; OS = overall survival; CDCT = conventional-dose chemotherapy; HDCT = high-dose chemotherapy.

1. Kollmansberger C. et al. J Clin Oncol. 2004;22(1);108-14; doi: 10.1200/JCO.2004.06.068; 2. Bokemeyer C. et al. Ann Oncol. 2008;19(3);448-53; doi: 10.1093/annonc/mdm526; 3. Einhorn LH. Et al. J Clin Oncol. 2007;25(5);513-6; doi: 10.1200/JCO.2006.07.7271.

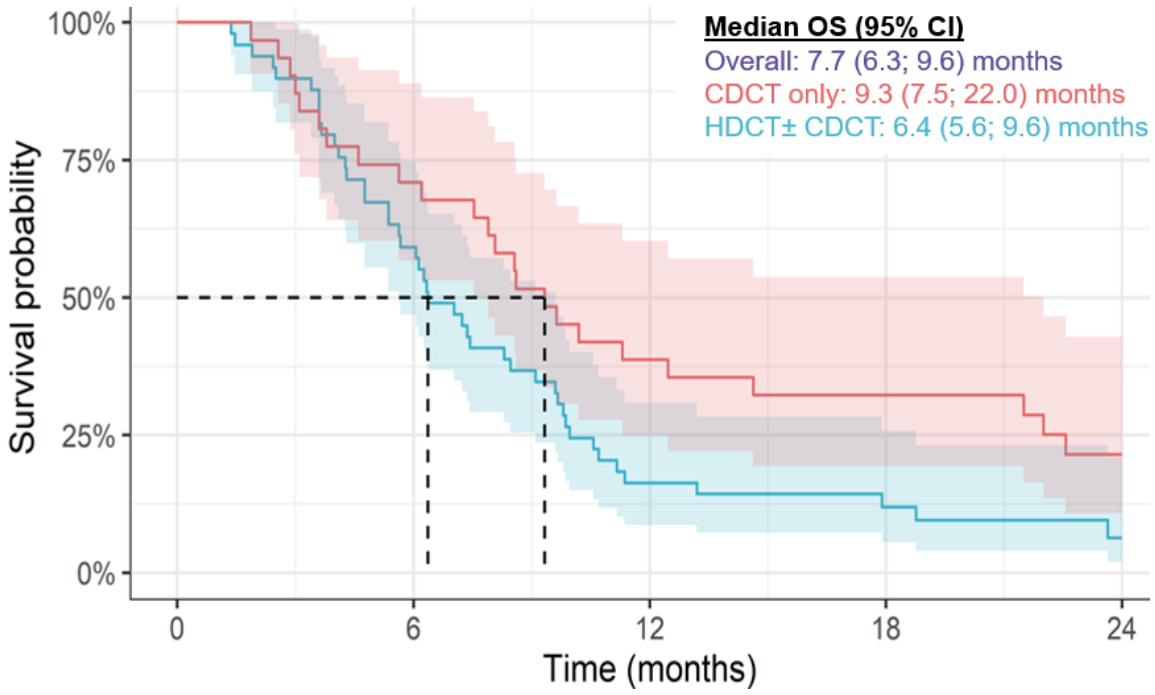
BIONTECH

mOS of 7.7 Months after Initiating Palliative Chemotherapy Comparable with Prior Clinical Trial Findings in this Population and Similar between Prior Salvage Strategies

Real-world evidence study: Results objective 1

Feldman, D. et al. presented at ASCO 2024. Abstract #5038.

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, % (95% CI)	100.0 (100.0; 100.0)	59.2 (46.9; 74.7)	16.3 (8.7; 30.8)	6.3 (1.9; 21.0)
Prior CDCT only				
Pts at risk, N	31	22	12	6
Cumulative deaths, N	0	9	19	24
Survival probability, % (95% CI)	100.0 (100.0; 100.0)	71.0 (56.7; 88.9)	38.7 (24.9; 60.3)	21.5 (10.8; 42.8)

OS was assessed among 80 pts 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).

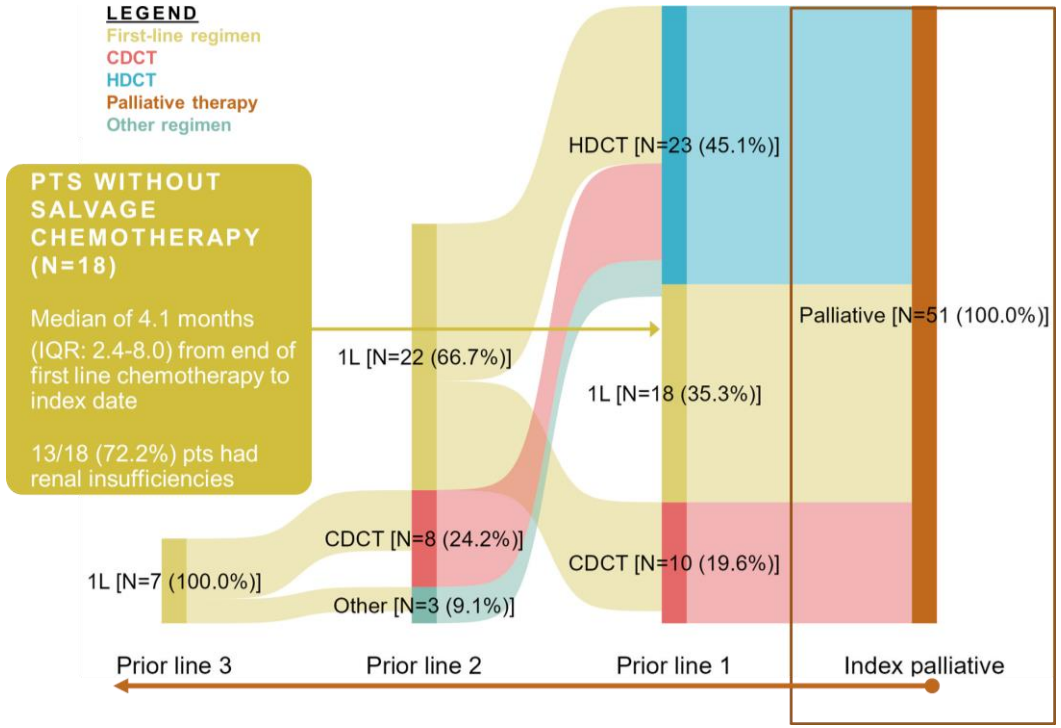
CDCT = conventional-dose chemotherapy; CI = confidence interval; HDCT = high-dose chemotherapy; GCT = germ cell tumor; mOS = median overall survival; R/R = relapsed/refractory; Pts = patients.

Heterogeneous Treatment Journey of Patients Without a Salvage Regimen Prior to Palliative Chemotherapy, Many with Evidence of Renal Insufficiencies

Real-world evidence study: Results objective 2

Feldman, D. et al. presented at ASCO 2024. Abstract #5038.

Prior treatment patterns among patients with R/R testicular GCT receiving palliative chemotherapy with complete health plan coverage (N=51)



Treatment characteristics among patients with R/R testicular GCT receiving palliative chemotherapy with complete health plan coverage	Patients with complete health plan coverage N=51
Time from first observed TC diagnosis to initiation of TC-related chemotherapy (months), median [IQR]	0.9 [0.5 - 2.1]
Time from first observed TC diagnosis to index date (months)	12.5 [9.0 - 16.8]
Time from start of previous TC-related chemotherapy to index date (months)	4.8 [2.9 - 6.2]
Duration of index palliative therapy (months)	2.1 [1.2 - 3.4]
TC-related chemotherapy regimens prior to the index palliative therapy, n (%)	
≥1 first-line regimen*	47 (92.2%)
BEP	28 (59.6%)
EP	11 (23.4%)
VIP	4 (8.5%)
Other combination of first-line regimens/agents	5 (10.6%)
≥1 salvage chemotherapy	33 (64.7%)
HDCT ± CDCT	23 (69.7%)
CDCT only	10 (30.3%)
No salvage chemotherapy	18 (35.3%)
≥1 unclassified chemotherapy	3 (5.9%)

* Non-mutually exclusive; patients may have had two first-line regimens (e.g., BEP -> EP)

BEP = bleomycin-cisplatin-etoposide; CDCT = conventional-dose chemotherapy; EP = cisplatin-etoposide; HDCT = high-dose chemotherapy; IQR = interquartile range; TC = testicular cancer; VIP = cisplatin-etoposide-ifosfamide; ; R/R = relapsed/refractory; PTS = patients; !L = first line; GCT = germ cell tumor.

Real-World Evidence ASCO 2024 Data: Key Takeaway Messages

Conclusion: Real-world data captured treatment patterns, palliative chemotherapy use, and outcomes for patients with R/R testicular GCT receiving palliative chemotherapy

These patients had:

Objective 1: **Median overall survival of 7.7 months** after initiating palliative chemotherapy, comparable with prior clinical trial findings in this population; results were similar between prior salvage strategies (CDCT only: 9.3 months; HDCT ± CDCT: 6.4 months)

Objective 2: **Heterogeneous treatment journey,** with 1/3 of patients not receiving a salvage CDCT/HDCT regimen prior to palliative chemotherapy, many of whom had evidence of renal insufficiencies

Outlook: This study highlights the unmet needs of this understudied population and establishes benchmarks for outcomes that may be used for future research and trial design
This analysis will inform the design of BioNTech's planned pivotal trial with the Company's CAR-T cell therapy candidate BNT211 in patients with germ cell tumors, expected to start in 2024

R/R = relapsed/refractory; GCT = germ cell tumor; CDCT = conventional-dose chemotherapy; HDCT = high-dose chemotherapy; CAR-T = chimeric antigen receptor-t-cell.

Thank you