3rd Quarter 2024
Financial Results & Corporate Update

November 4, 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: BioNTech's expected revenues and net profit/(loss) related to sales of BioNTech's COVID-19 vaccine, referred to as COMIRNATY where approved for use under full or conditional marketing authorization, in territories controlled by BioNTech's collaboration partners, 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; the impact of BioNTech's 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.

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3rd Quarter 2024 Highlights

Ugur Sahin, Founder & Chief Executive Officer

Q3 2024 Highlights

Execution in COVID-19 Franchise[1]

Successfully launched variant-adapted COVID-19 vaccines[1] for the 2024/2025 vaccination season in multiple regions

Progress in Oncology Pipeline

BNT327/PM8002[2]

- Presented clinical data for BNT327/PM8002[2] showcasing pan-tumor activity
- Dosed first patients in two global dose-optimization Phase 2 studies evaluating BNT327/PM8002[2] in SCLC and TNBC
- Dosed first patients in trial evaluating BioNTech's novel IO + ADC combination, BNT327[2] + BNT325[4]

mRNA Cancer Vaccine Candidates

- Announced positive topline Phase 2 results for mRNA cancer vaccine FixVac candidate BNT111[5] in cutaneous melanoma
- Presented clinical data for FixVac candidate BNT113
- Planned Phase 2 trial evaluating autogene cevumeran (BNT122/RO7198457)[3] in adjuvant MIUC

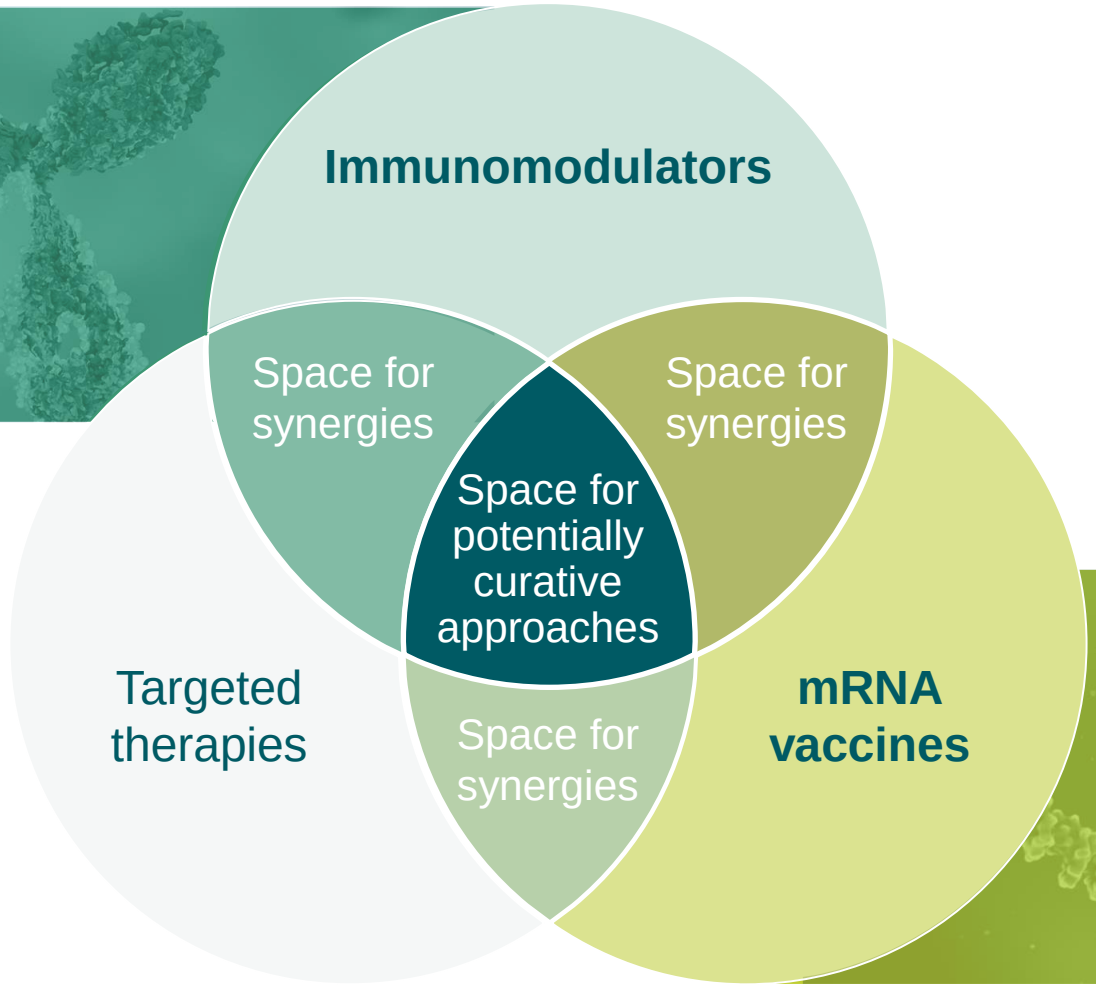
Corporate Update

Provided overview on BioNTech's strategy to scale and deploy AI capabilities across its pipeline at inaugural AI Day

Partnered with: 1. Pfizer; 2. Biotheus; 3. Genentech, a member of the Roche Group; 4. Duality Bio; 5. In collaboration with Regeneron.
A glossary of defined terms can be found at the end of the presentation.

Developing the Next Generation of Cancer Medicines: Leveraging Our Multi-Modal Technology Portfolio for Combination Approaches

BNT327/PM8002[1]



FixVacs
Autogene cevumeran (BNT122/RO7198457)[2]

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

2 COVID-19 & Oncology Pipeline Update

Özlem Türeci, Chief Medical Officer

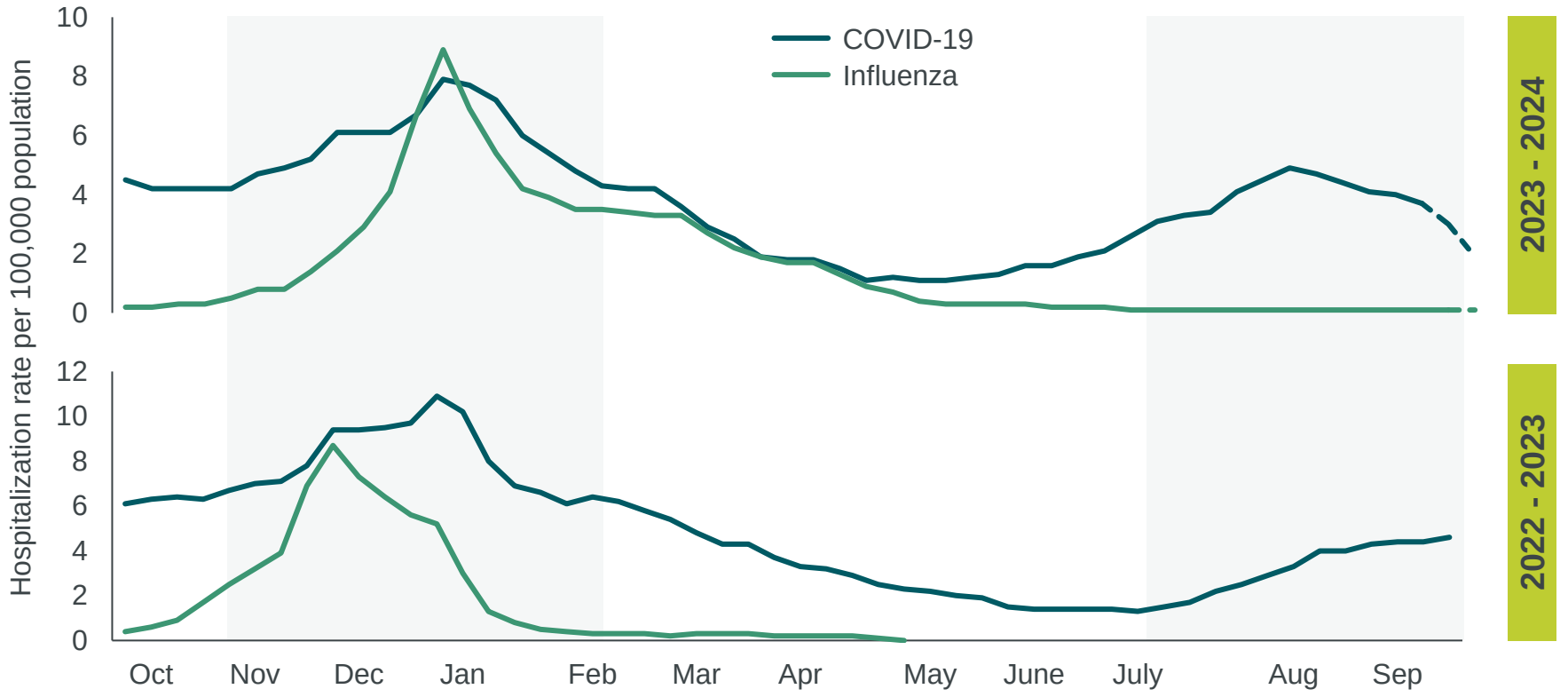
The Continuous Evolution of SARS-CoV-2 Has Led to Differing Regulatory Recommendations Globally

	 EC	 UK	 U.S.	 Canada	 Japan
JN.1-adapted	✓	✓			✓
KP.2-adapted	✓	✓	✓	✓	

mRNA vaccine technology enables us to rapidly meet regulators' specific recommendations in different regions and allows for timely availability of vaccines adapted to the most current SARS-CoV-2 variants

JN.1 is a SARS-CoV-2 variant. KP.2 is a sub-lineage of the JN.1 variant.

COVID-19 and Influenza Disease Burden Show Different Seasonality Patterns



Data on weekly new hospital admissions of patients from surveillance sites in the U.S. Respiratory Virus Hospitalization Surveillance Network.[1]

Susceptibility to infection remains a concern after the winter vaccination season.

Potential need for additional vaccination later in the season could contribute to improved vaccine coverage over time.

Data last updated: October 4, 2024

1. https://www.cdc.gov/respiratory-viruses/guidance/background.html?CDC_AAref_Val=https://www.cdc.gov/respiratory-viruses/background/index.html accessed 07 October 2024

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Oncology Pipeline with Three New Phase 2 Trials: BNT327/PM8002[5] and Autogene Cevumeran (BNT122/RO7198457)

Phase 1	Phase 1/2	Phase 2	Phase 3
BNT116 Adv. NSCLC	**BNT142** (CD3xCLDN6) Multiple CLDN6-pos. adv. solid tumors	**BNT111**[7] aPD(L)1-R/R melanoma, + cemiplimab	**BNT316/ONC-392 (gotistobart)**[3] (CTLA-4) anti-PD-1/PD-L1 experienced NSCLC
Autogene cevumeran (BNT122/RO7198457)[1] Multiple solid tumors	**BNT311/GEN1046 (acasunlimab)**[2] **(**PD-L1x4-1BB) Multiple solid tumors	**BNT113** 1L rel./met. HPV16+ PDL-1+ head and neck cancer, + pembrolizumab	**BNT323/DB-1303**[4] **(trastuzumab pamirtecan)** (HER2) HR+/HER2-low met. breast cancer
BNT152 + BNT153 (IL-7, IL-2) Multiple solid tumors	**BNT312/GEN1042**[2] (CD40x4-1BB) Multiple solid tumors	**BNT116**[7] 1L adv. PD-L1 ≥ 50% NSCLC, + cemiplimab	
BNT211 (CLDN6) Multiple solid tumors	**BNT314/GEN1059**[2] **(**EpCAMx4-1BB) Multiple solid tumors	**Autogene cevumeran (BNT122/RO7198457)**[1] 1L adv. melanoma, + pembrolizumab	
BNT221 Refractory metastatic melanoma	**BNT316/ONC-392 (gotistobart)**[3] (CTLA-4) mCRPC, + radiotherapy	**Autogene cevumeran (BNT122/RO7198457)**[1] Adj. ctDNA+ stage II or III CRC	
BNT315/GEN1055[2] (OX40) Multiple solid tumors	**BNT316/ONC-392 (gotistobart)**[3] (CTLA-4) Multiple solid tumors	**Autogene cevumeran (BNT122/RO7198457)**[1] Adj. PDAC, + atezolizumab + mFOLFIRINOX	
BNT321 (sLea) Metastatic PDAC	**BNT321** (sLeA) adjuvant PDAC, +mFOLFIRINOX	**Autogene cevumeran (BNT122/RO7198457)**[1] **NEW** Adj. MIUC, + Nivolumab	
BNT322/GEN1056[2] Multiple solid tumors	**BNT323/DB-1303**[4] **(trastuzumab pamirtecan) (HER2)** Multiple solid tumors	**BNT311/GEN1046 (acasunlimab)**[2] (PD-L1x4-1BB) R/R met. NSCLC, +/- pembrolizumab	
BNT326/YL202[5] (HER3) Multiple solid tumors	**BNT324/DB-1311**[4] (B7H3) Multiple solid tumors	**BNT316/ONC-392 (gotistobart)**[3] (CTLA-4) PROC, + pembrolizumab	
	BNT325/DB-1305[4] (TROP-2) Multiple solid tumors	**BNT327/PM8002**[6] (PD-L1 x VEGF-A) **NEW** 1L/2L+ (ES-)SCLC, +chemotherapy	
	BNT327 / BNT325 combination[4,6] Multiple solid tumors	**BNT327/PM8002**[6] (PD-L1 x VEGF-A) **NEW** 1L/2L met. TNBC, +chemotherapy	

Legend

- mRNA
- Cell therapy
- Next generation IO
- ADCs
- Combination studies

Partnered with: 1. Genentech, member of Roche Group; 2. Genmab; 3. OncoC4; 4. DualityBio; 5. MediLink Therapeutics; 6. Biotheus; 7. In collaboration with Regeneron.

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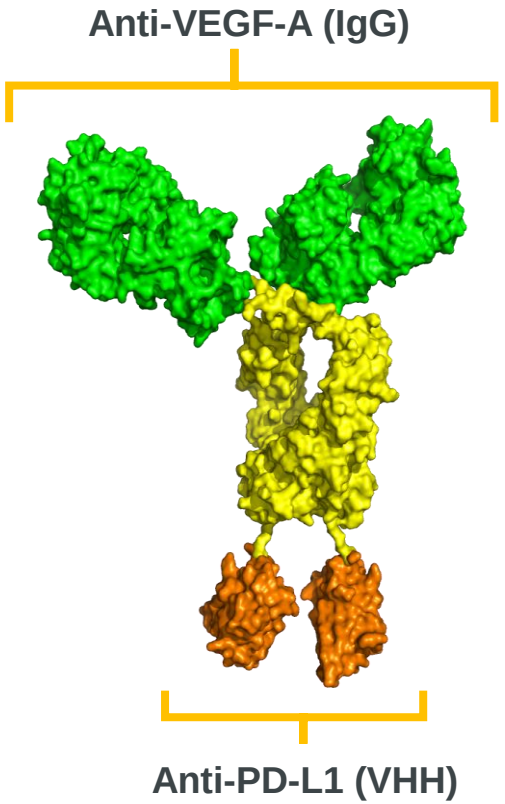
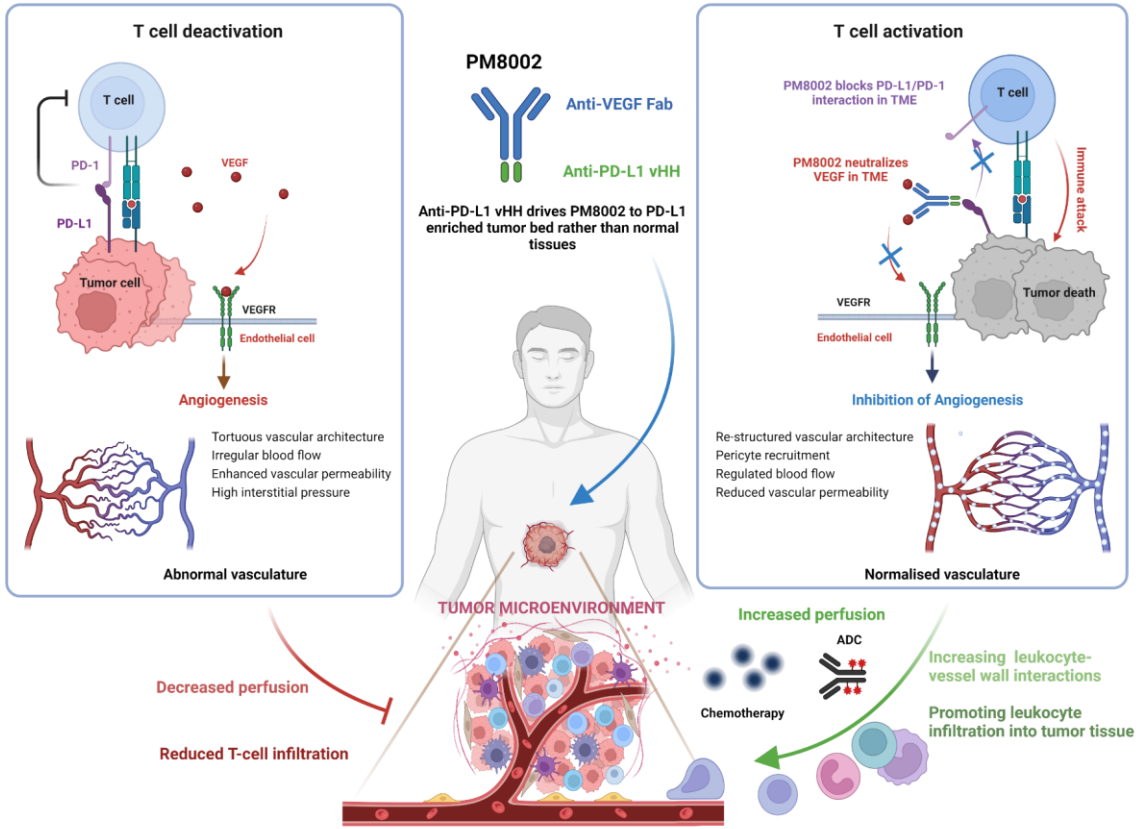
BNT327/PM8002[1] – A Next-Gen Investigational IO Agent that Combines Two Clinically Validated MoAs

Dual blockade of PD-L1 and VEGF-A has demonstrated clinical synergy

- Encouraging safety/activity profile with over 700 patients treated to date
- Monotherapy activity and synergy in combination therapy observed in early clinical studies
- Favorable safety profile vs. PD-L1 + VEGF inhibition or PD-1 alone



"Two-in-one" mechanism of action



1. Partnered with Biotheus.
The mechanism of action graphic was generated by Biorender.com.

BNT327/PM8002[1] Mono and Combo Have Been Investigated in More Than 700 Patients Across 10+ Indications

		Mono	Combo
Lung	1L NSCLC WT PD-L1+	✓	
	2L+ NSCLC EGFRm	✓	(+ Pemetrexed/Carboplatin) ✓
	2L SCLC		(+ Paclitaxel) ✓
	1L SCLC		(+ Etoposide/Platinum) ✓
Gynae-cology	PROC	✓	
	2L+ PSOC	✓	
	2L+ Cervical Cancer	✓	
	2L+ Endometrial Cancer	✓	
Breast	1L TNBC		(+ Nab-Paclitaxel) ✓
Gastro-intestinal	1L HCC		(+ FOLFOX4) ✓
	Advanced BTC	✓	
Geni-tourinary	nccRCC	✓	
	2L+ ccRCC	✓	
Others	1L MPM		(+ Pemetrexed / Platinum) ✓
	2L NEN	✓	(+ FOLFIRI) ✓

✓ Ongoing studies with BNT327/PM8002

1. Partnered with Biotheus.

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Extensive Clinical Data Collection Demonstrates Pan-Tumor Potential of BNT327/PM8002[1]

	TNBC[2]	SCLC[3]	NSCLC[4,5]			CC[6]	PROC[6]	ccRCC[7]	nccRCC[7]
	1L	2L Overall	1L[4]	2L[4]	2L/3L EGFRm [5]	2L+	1L+	2L	1L
BNT327 mono or combination	nab-paclitaxel	paclitaxel	mono	mono	carboplatin + pemetrexed	mono	mono	mono	mono
N	42	36	17	8	64	45	34	28	22
ORR*, %	73.8	61.1	47.1	12.5	57.8	42.2	20.6	25.0	36.4
DCR, %	95.2	86.1	100	62.5	95.3	93.3	67.7	82.1	90.9
mPFS, mos.	13.5	5.5	13.6	6.7	NR	8.3	5.5	10.9	15.1
mDOR, mos.	11.7	10.0	NR	3.7	NR	NR	9.6	19.6	NR
Congress	ESMO 2024	ESMO 2023	ASCO 2024	ASCO 2024	ESMO 2024	ASCO 2024	ASCO 2024	ESMO 2024	ESMO 2024

BNT327/PM8002[1] has shown encouraging clinical activity across broad range of indications

1. Partnered with Biotheus;
2. Wu J et al ESMO 2024 384MO; 3. Cheng Y et al ESMO 2023 1992P; 4. Wu C et al ASCO 2024 P8533; 5. Wu YL et al ESMO 2024 1255MO; 6. Wu L et al ASCO 2024 P5524 7. Sheng X. et al ESMO 2024 1692P.
* Confirmed ORR reported for the following cohorts: TNBC, 1L and 2L/3L EGFRm NSCLC and RCC. Unconfirmed ORR reported for the following cohorts: SCLC, 2L NSCLC, CC and PROC.

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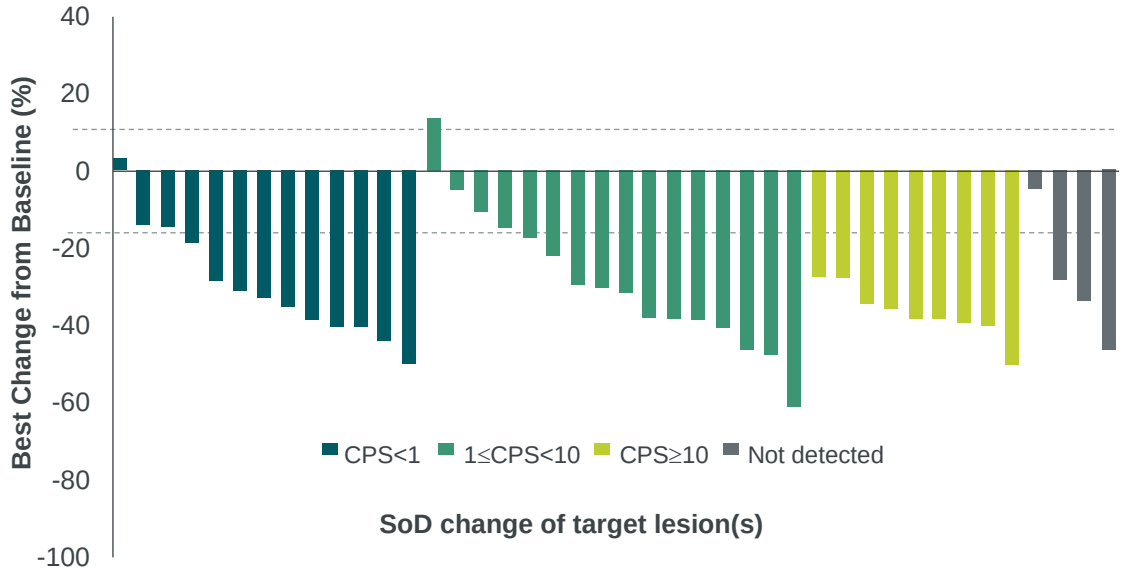
BNT327/PM8002[1] Shows Clinically Meaningful Efficacy in Metastatic Triple Negative Breast Cancer (mTNBC)

Phase 1/2 (NCT05918133): clinical activity in combination with nab-paclitaxel by PD-L1 status in 1L TNBC

Yanchun Meng et al., ESMO 2024, Presentation #348MO

	ITT	PD-L1 CPS<1	PD-L1 1≤CPS<10	PD-L1 CPS≥10	Not detected
Population, N	42	13	16	9	4
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)	75.0 (19.4, 99.4)
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)	75.0 (19.4, 99.4)
mPFS, mos. (95% CI)	13.5 (9.4, --)	NR (5.7, --)	14.0 (7.2, --)	10.8 (5.5, 13.5)	14.0 (1.8, --)

For the ITT population, mTTR was 1.9 months. and mDoR 11.7 months; mOS was not reached



BNT327/PM8002[1] in combination with chemotherapy demonstrated meaningful efficacy, rapid tumor shrinkage and encouraging duration of response irrespective of PD-L1 status

1. Partnered with Biotheus.

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Global Clinical Development Strategy for BNT327/PM8002[1]

Explore potential of BNT327/PM8002[1] in three waves of focused development

1

Combine with SoC chemotherapy in potential Fast-to-Market indications

Ongoing

- Phase 2 dose opt in SCLC *NEW*
- Phase 2 dose opt in TNBC *NEW*

Outlook

- Phase 2/3 NSCLC planned for 2024
- Phase 3 SCLC planned for 2024
- Phase 3 TNBC planned for 2025

2

Explore novel combinations with ADCs in high unmet need indications

Ongoing

Phase 1/2 evaluating BNT327/PM8002[1] in combination with BNT325/DB1305[2] TROP-2 ADC in multiple solid tumors

Outlook

Additional combinations with ADCs planned to start in 2024 and in 2025

3

Expand chemo and novel combinations across indications

Partnered with: 1. Biotheus; 2. DualityBio

Positive FixVac Topline Data and Start of iNeST Phase 2 MIUC Trial Highlight Execution in Cancer Vaccine Portfolio

Select iNeST and FixVac trials based on BioNTech's mRNA-LPX technology platform

Individualized vaccine: iNeST[1]					FixVac		
	Adjuvant		1L	R/R	R/R	1L	Multiple settings
MIUC Phase 2	CRC Phase 2	PDAC Phase 2	Melanoma Phase 2	Solid Tumors Phase 1	Melanoma Phase 2	HPV16+ HNSCC Phase 2	NSCLC Phase 1 & 2
Autogene cevumeran (BNT122/RO7198457)					BNT111[2]	BNT113	BNT116[2]
+ Nivolumab	Monotherapy	+ Atezolizumab	+ Pembrolizumab	+ Atezolizumab	+ Cemiplimab	+ Pembrolizumab	Monotherapy, + Cemiplimab or CTx
Recruitment ongoing	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** expected to be published soon in peer-reviewed journal	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)	Enrollment completed Data of Ph 1 study presented at multiple conferences incl. ESMO-IO 2022 Data from safety run-in of Ph 1/2 trial and Ph1 IIT presented at **ESMO 2024**	Recruitment ongoing in Ph 2 in 1L NSCLC[2] Ph 1 trial ongoing Data presented at SITC 2023 and **AACR 2024** Data from Ph1 trial expected at **SITC.**
NEW					DATA	DATA	

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

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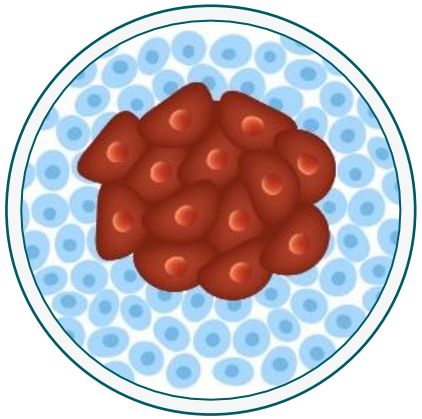
Evaluating Autogene Cevumeran in the Adjuvant Treatment Setting for Cancers of High Unmet Need

Rationale for adjuvant setting

Low tumor mass with residual cancer cells



Tumor resistance mechanisms not fully established

Healthier immune system allows for functional T-cell responses

Unmet medical need

Pancreatic Ductal Adenocarcinoma

69−75% relapse rate within 5 years after adjuvant therapy[1,2]

- Projected to become the 2nd leading cause of cancer-related death in the US by 2030[3]
- 5-year survival rates after resection are ~10%[4]
- Largely CPI resistant due to low mutation burden with few mutation-derived neoantigens and an immunosuppressive tumor microenvironment[5]

Phase 1 trial completed in adj. PDAC

Randomized Phase 2 trial ongoing

Colorectal Cancer

20-35% relapse rate within 4 years after adjuvant therapy[6]

- 5-year survival rates of locoregional disease are ~70%[7]
- ctDNA is a marker for minimal residual disease and thus can identify patients at high risk of disease recurrence[8,9,10]
- In ctDNA-positive, Stage 2 (high risk) and Stage 3 CRC post adjuvant chemotherapy, duration of disease-free survival is 10 months[11]

Randomized Phase 2 trial ongoing

1. Jones et al. JAMA Surgery 2019; **2**. Conroy et al. JAMA Oncology 2022; **3**. Rahib et al. JAMA Network Open 2021; **4**. Bengtsson et al., Sci Rep 2020; **5**. Kabacaoglu et al. Frontiers Immunol 2018; **6**. André et al., JCO 2015; **7**. NIH SEER cancer stat facts (Accessed July 31, 2024); **8**. Fan et al. PLoS One 2017; **9**. Loupakis et al. JCO Precis Oncol 2021; **10.** Kotani, D. et al Nat Med 2023**. 11**. Reinacher-Schick et al. ASCO 2024.

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Phase 2 Trial Evaluating Autogene Cevumeran[1] in the Adjuvant Setting in MIUC

Unmet medical need

Standard of care

- Neoadjuvant chemotherapy, followed by cystectomy and, for eligible patients, this is followed by adjuvant treatment with an ICI.

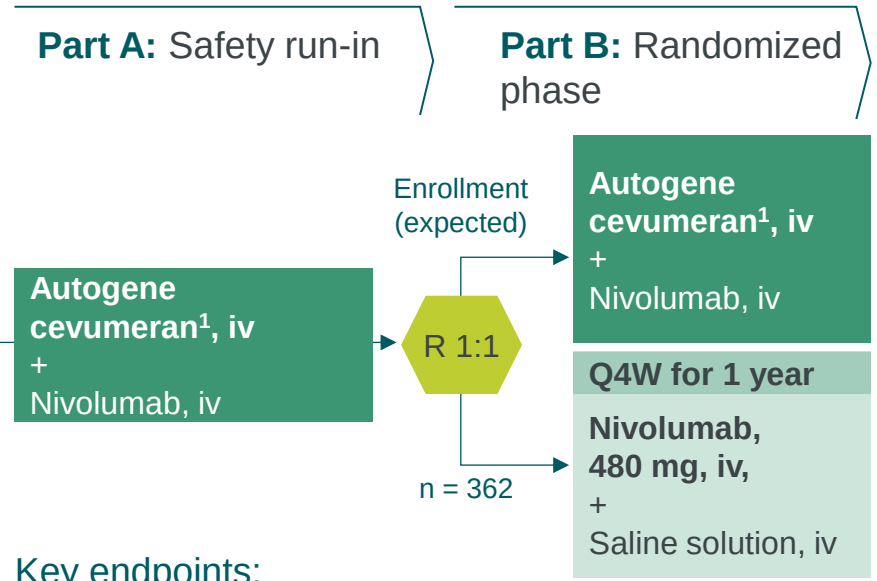
Medical need

- Adjuvant ICI significantly increases DFS 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]

Clinical trial design

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 (UICC/AJCC, 7th edition)
- ECOG status 0 or 1



Key endpoints:

Primary	DFS in PD-L1 ≥ 1 (INV)
Secondary	OS, Safety

Phase 2 randomized, double-blind, multi-site study to evaluate efficacy and safety of adjuvant autogene cevumeran[1] in combination with nivolumab vs nivolumab in MIUC (NCT06534983)

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

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3 Financial Update

Jens Holstein, Chief Financial Officer

Q3 and YTD 2024 Financial Results

(in millions €, except per share data)[1]	Three months ended September 30,		Nine months ended September 30,	
	2024	**2023**	**2024**	**2023**
Revenues	**1,244.8**	**895.3**	**1,561.1**	**2,340.0**
Cost of sales	(178.9)	(161.8)	(297.8)	(420.7)
Research and development expenses	(550.3)	(497.9)	(1,642.4)	(1,205.3)
Sales and marketing expenses	(18.1)	(14.4)	(46.6)	(44.7)
General and administrative expenses[2]	(132.4)	(139.1)	(420.3)	(370.7)
Other operating result[2]	(354.6)	(9.0)	(616.9)	(134.4)
Operating profit / (loss)	**10.5**	**73.1**	**(1,462.9)**	**164.2**
Finance result	148.2	154.3	484.0	358.7
Income taxes	39.4	(66.8)	54.1	(50.5)
Net profit / (loss)	**198.1**	**160.6**	**(924.8)**	**472.4**
Earnings / (Loss) per share				
Basic earnings / (loss) per share	0.82	0.67	(3.83)	1.96
Diluted earnings / (loss) per share	0.81	0.66	(3.83)	1.94

Balance Sheet as of September 30, 2024	
Cash and cash equivalents plus security investments[3]	€17.8bn

1. Numbers have been rounded; numbers presented may not add up precisely to the totals and may have been adjusted in the table. Presentation of the consolidated statements of profit or loss has been condensed.
2. Adjustments to prior-year figures due to change in functional allocation of general and administrative expenses and other operating expenses.
3. 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.

More information can be found in BioNTech's Report on Form 6-K for the period ended September 30, 2024, filed today with the United States Securities and Exchange Commission and available at https://www.sec.gov/.

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2024 Financial Year Guidance[1]
Revenues Expected to be at Low End of Range and Reduced SG&A Expenses and Capex Guidance[1]

		Guidance March 2024	Guidance November 2024	Commentary
FY 2024 revenues	Total revenues	**€2,500 – 3,100 m**	**€2,500 – €3,100 m**	***Expected to be at low end***
Planned FY 2024 expenses and capex	R&D expenses[2]	**€2,400 – 2,600 m**	**€2,400 – €2,600 m**	***No change***
	SG&A expenses	**€700 – 800 m**	**€600 – €700 m**	***€100 m reduction[3]***
	Capital expenditures for operating activities	**€400 – 500 m**	**€300 – €400 m**	***€100 m reduction[3]***

Revenue guidance considerations:

Top-line sensitivity mainly dependent on the following factors

- Vaccination rates and price levels in markets where significant COVID-19 vaccine sales are expected
- Inventory write-downs and other charges, which are estimated to be ~10% of Company revenues
- Anticipated revenues related to service businesses, including InstaDeep, JPT Peptide Technologies, IMFS and from the German pandemic preparedness agreement

1. Guidance excludes external risks that are not yet known and/or quantifiable. It does not include potential payments resulting from the outcomes of ongoing and/or future legal disputes or related activity, such as judgements or settlements, or other extraordinary items, all of which may have a material effect on the Company's results of operations and/or cash flows. The Company continues to expect to report a loss for the 2024 financial year.
2. Guidance reflects the expected impact of collaborations and potential M&A transactions, in each case to the extent disclosed, and which are subject to change based on future developments. Guidance does not otherwise reflect M&A, collaboration or licensing transactions that the Company may enter into in the future.
3. For simplicity, midpoint in guidance ranges is applied when comparing the guidance provided in March 2024 with the guidance provided in November 2024.
IMFS = BioNTech's Innovative Manufacturing Services GmbH
More information can be found in BioNTech's Report on Form 6-K for the period ended September 30, 2024, filed today with the United States Securities and Exchange Commission and available at https://www.sec.gov/.

4 Strategic Outlook

Ryan Richardson, Chief Strategy Officer

Launch Progress in Q3 Reiterates Strength of COVID-19 Franchise[1]

	 EC	 UK	 U.S.	 Canada	 Japan
JN.1-adapted	✓	✓			✓
KP.2-adapted	✓	✓	✓	✓	

Dose switching from JN.1- to KP.2-adapted vaccines underway or expected in countries with both approved

Vaccination rates are higher in the U.S. versus the comparable period in 2023[2]

Shift to commercial markets in UK, Japan, Switzerland, Australia, South Korea, Singapore and Brazil

1. Partnered with Pfizer; 2. CDC Weekly Vaccination Dashboard.
JN.1 is a SARS-CoV-2 variant. KP.2 is a sub-lineage of the JN.1 variant.

COVID-19 Vaccine Market Presents a Long-term Business Opportunity

Global Market Leadership

Anticipate maintenance of high market share in U.S., EU and Japan

Lean Fixed Cost Base Business

Low OpEx leveraging partners' global commercial infrastructure and sharing R&D expenses

Potential for Cashflow Generation

Expected continuous demand for COVID-19 vaccines globally with evolving epidemiology of virus

Clinical Data Updates & Planned Regulatory Submissions in 2025 on Track Based on Strong Execution in 2H 2024

2H 2024

COMIRNATY[1]
Updated variant-adapted vaccine roll-out

COVID-19 / Flu Combination vaccine[1]
Phase 3 topline data

BNT327/PM8002[2]
NSCLC, TNBC, RCC
Phase 2 data

BNT211
CLDN6+ tumors
Phase 1 data

BNT327/PM8002[2]
TNBC
Phase 2 data

2025+

COMIRNATY[1]
Updated variant-adapted vaccine roll-out

BNT323/DB-1303[3]
2L+ HER2 EC
Regulatory submission

BNT327/PM8002[2]
1L ES-SCLC and 2L SCLC
Phase 2 data

BNT327/PM8002[2]
1L and 2L TNBC
Phase 2 data

BNT323/DB-1303[3]
2L+ HER2 EC
Phase 2 data

Autogene cevumeran (BNT122/RO7198457)[4]
ctDNA adj. CRC
Phase 2 topline data

BNT111[5]
2L+ melanoma
Phase 2 data

Data update
Regulatory event

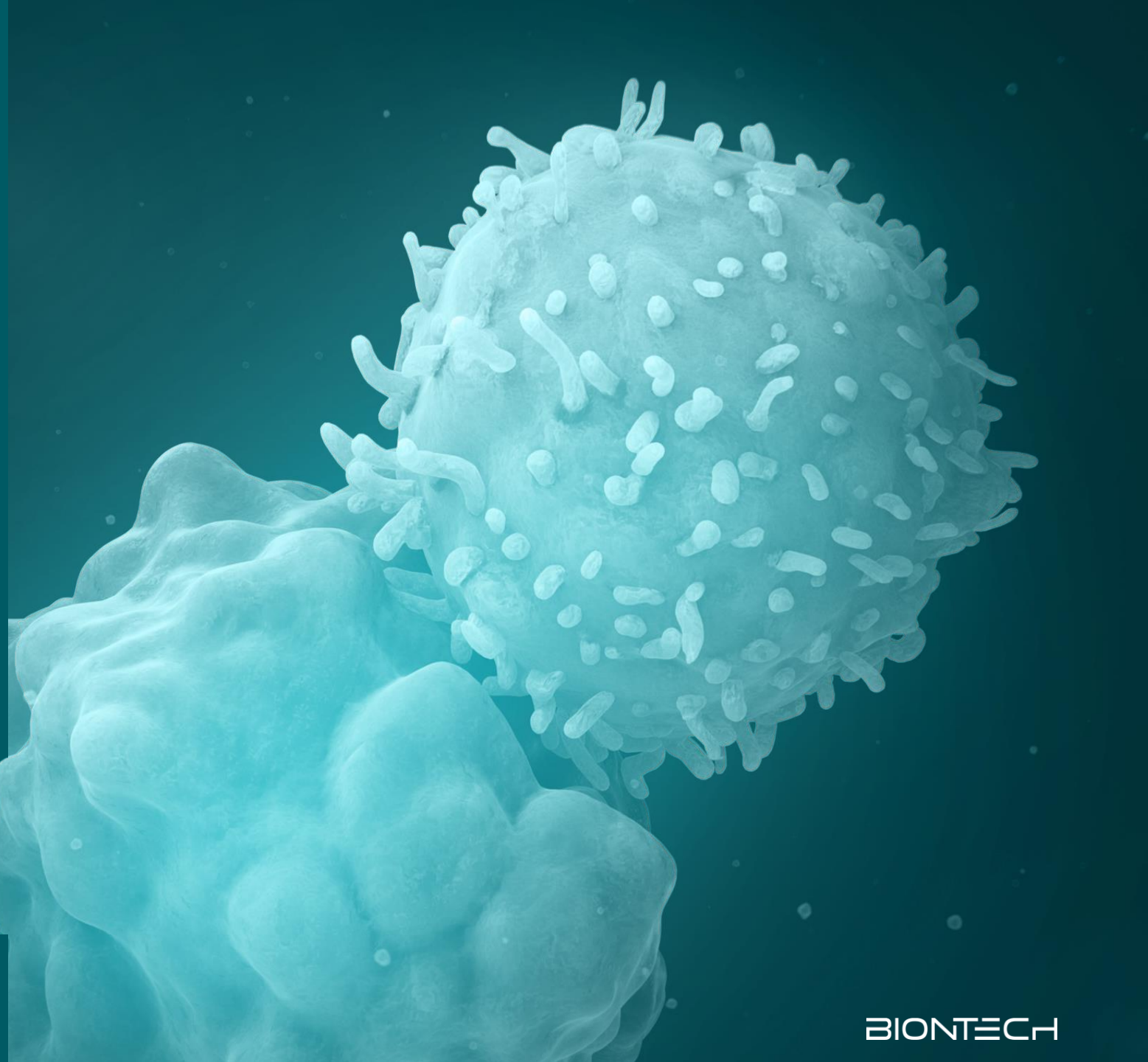
Catalyst-rich period for mid- to late-stage pipeline consisting of more than 10 Phase 2 and Phase 3 trials covering several tumor types with high unmet medical need

Partnered with: 1. Pfizer; 2. Biotheus; 3. DualityBio; 4. Genentech, member of Roche Group. 5. In collaboration with Regeneron.

Save the date

Innovation Series

November 14, 2024



Thank you

Appendix

Program Updates Expected in 2024 and Beyond

	Program	Indication	Trial Phase	Anticipated Timing
Oncology	BNT111[1]	R/R Melanoma	Phase 2	2025
	BNT116	Advanced NSCLC	Phase 1/2	2024
	Autogene cevumeran (BNT122/RO7198457)[2]	Adjuvant ctDNA+ stage II (high risk)/III CRC	Phase 2	2025+
	BNT312/GEN1042[3]	Multiple solid tumors	Phase 1/2	2025
	BNT316/ONC-392 (gotistobart)[4]	R/R Melanoma	Phase 1/2	2025
	BNT323/DB-1303[5]	Multiple solid tumors	Phase 1/2	2025
	BNT323/DB-1303[5]	HR+ HER2-low met. BC	Phase 3	2026
	BNT324/DB-1311[5]	Multiple solid tumors	Phase 1/2	2024
	BNT325/DB-1305[5]	Multiple solid tumors	Phase 1/2	2025
	BNT327/PM8002[6]	TNBC	Phase 2	2024
	BNT327/PM8002[6]	ES-SCLC, SCLC and met. TNBC	Phase 2	2025+

In collaboration with: 1. Regeneron. Partnered with 2. Genentech, member of Roche Group 3. Genmab; 4. OncoC4; 5. DualityBio; 6. Biotheus.

Abbreviations

n L	*nth* line	EpCAM	Epithelial cell adhesion molecule	NSCLC	Non-small cell lung cancer
AACR	American Association for Cancer Research	ESMO	European Society for Medical Oncology	NR	Not reported
ADC	Antibody-drug conjugate	GI	Gastrointestinal	(c)ORR	(Confirmed) objective response rate
adj.	Adjuvant	HCC	Hepatocellular carcinoma	OS	(median) Overall survival
adv.	Advanced	HER2 (or 3)	Human epidermal growth factor receptor 2 (or 3)	PDAC	Pancreatic ductal adenocarcinoma
AI	Artificial intelligence	HNSCC	Head and neck squamous cell carcinoma	PD-(L)1	Programmed cell death protein (ligand) 1
ASCO	American Society of Clinical Oncology	HPV	Human papilloma virus	PFS	Progression-free survival
BC	Breast cancer	HR	Hormone receptor	PROC	Platinum-resistant ovarian cancer
BTC	Biliary tract cancer	HSV	Herpes simplex virus	PSOC	Platinum-sensitive ovarian cancer
CC	Cervical cancer	ICI	Immune checkpoint inhibitor	QxW	Every x week
CD	Cluster of differentiation	IL-x	Interleukin x	R	Randomized
CI	Confidence interval	IgG	Immunoglobulin G	(ncc/cc)RCC	(non-clear cell/clear cell) Renal cell carcinoma
CLDN6	Claudin 6	IIT	Investigator initiated trial	R&D	Research and development
CPI	Checkpoint inhibitor	iNeST	Individualized Neoantigen-Specific Therapy	R/R	Relapsed/refractory
CPS	Combined positive score	INV	Investigator	(ES)SCLC	(Extensive stage) small cell lung cancer
CRC	Colorectal cancer	IO	Immuno-oncology	SG&A	Selling, general and administrative
(m)CRPC	(Metastatic) castration resistant prostate cancer	ITT	Intention to treat	SITC	Society of Immunotherapy of Cancer
CT	Computer tomography	iv	Intravenously	SoC	Standard of care
ctDNA	Circulating tumor DNA	LPX	Lipoplex	SoD	Sum of diameters
CTLA-4	Cytotoxic T-lymphocyte-associated protein 4	m	Median	TNBC	Triple-negative breast cancer
CTx	Chemotherapy	met	Metastatic	TNM	Classification systemof malignant tumors
DCR	Disease control rate	MIUC	Muscle-invasive urothelial carcinoma	TROP-2	Trophoblast cell-surface antigen 2
DFS	Disease-free survival	M0	Metastasis 0	TTR	Time to response
DOR	(median) Duration of response	MoA	Mechanism of Action	UK	United Kingdom
EC	Endometrial cancer	mo(s).	Month(s)	U.S.	United States
EC	European Community	MPM	Malignant pleural mesothelioma	VEGF(R)	Vascular edothelial growth factor (receptor)
ECOG (PS)	Eastern Cooperative Oncology Group (performance status)	MRI	Magnetic resonance imaging	VHH	Heavy chain variable
		mRNA	Messenger ribonucleic acid	WT	Wild type
EGFRm	Epidermal growth factor receptor (mutated)	NEN	Neuroendocrine neoplasm		