THE NEXT-GENERATION IMMUNOTHERAPY OF CANCER

October 2026

BioInvent

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BioInvent
bringing antibodies to life

BioInvent is Developing the New Standard of Care for Recurring Ovarian Cancer

- $1.7 billion in estimated peak sales

We are a Swedish clinical-stage biotech developing first-in-class immune-modulating antibodies to treat cancer

4 Ongoing Clinical Programs

- Cancer immunotherapies with novel MoAs and excellent safety profiles
- Phase 2 trials ongoing with early evidence of efficacy
- History of successful partnerships to accelerate and expand our current efforts

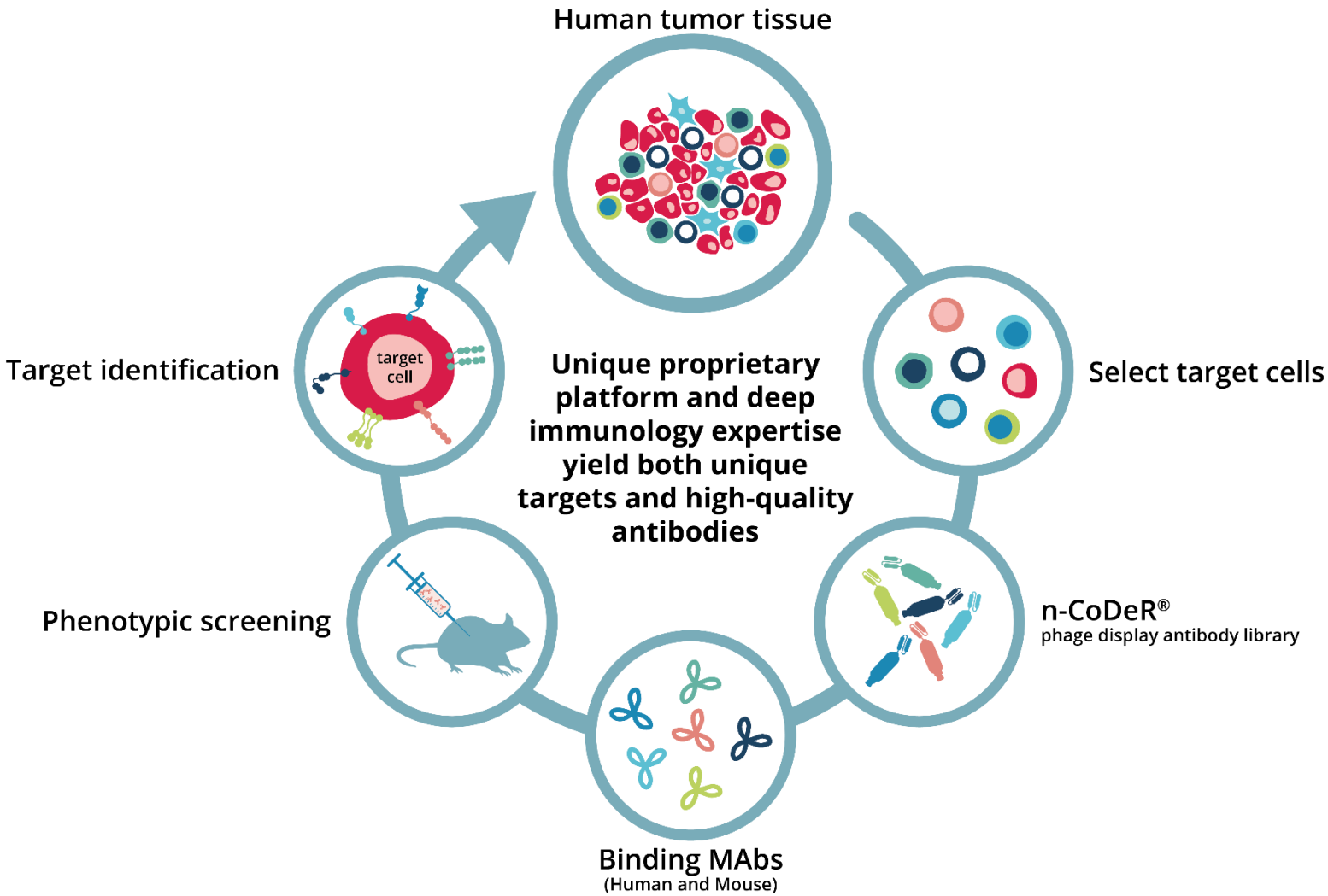
Core Capabilities Fuel Pipeline Expansion

- Unique and validated target discovery platform
- World class scientific team and development capabilities
- In-house GMP manufacturing suite

Solid Financial and Investor Base

- Listed on NASDAQ OMX Stockholm MidCap (BINV)
- Strong international shareholder base
- Operations funded to Q1 2027

Function F.I.R.S.T™ Enables Discovery of New Oncology Targets and Antibodies



BioInvent has First-in-class Clinical Assets Advancing Across Multiple Indications

	Compound/Indication	Phase 1	Phase 2a	Phase 2b	Milestone
TNFR2	**Ovarian cancer** Pembrolizumab[1]		*Ongoing*		→ **Further Phase 2a data at ESMO Oct 2026**
	Ovarian cancer Pembrolizumab[1] + Paclitaxel		*Planned*		→ **First Phase 2a data expected end 2027**
	CTCL Single agent		*Ongoing*	*Preparatory phase*	→ **Complete Phase 2a data dose optimization H1 2027**
BI-1808	**CTCL** Pembrolizumab[1]		*Ongoing*		→ **Conclude Phase 2a**
FcyRIIB	**NHL (FL, MCL, MZL)** Rituximab + Acalabrutinib[2]		*Ongoing*	*Preparatory phase*	→ **Potential start of pivotal triplet H1 2027**
	NSCLC 1L Pembrolizumab[1]		*Ongoing*	*Preparatory phase*	→ **Phase 2a data expected H2 2026**
BI-1206	**Uveal melanoma 1L** Pembrolizumab[1]		*Ongoing*		→ **Phase 2a data expected H2 2026**

1L: First line treatment
CTCL: Cutaneous T-cell Lymphoma, NHL: Non-Hodgkin's Lymphoma, FL: Follicular Lymphoma, MCL: Mantle Cell Lymphoma, MZL: Marginal Zone Lymphoma, NSCLC: Non-small cell lung cancer
Notes: 1) Supply agreement with Merck, 2) Supply agreement with AstraZeneca

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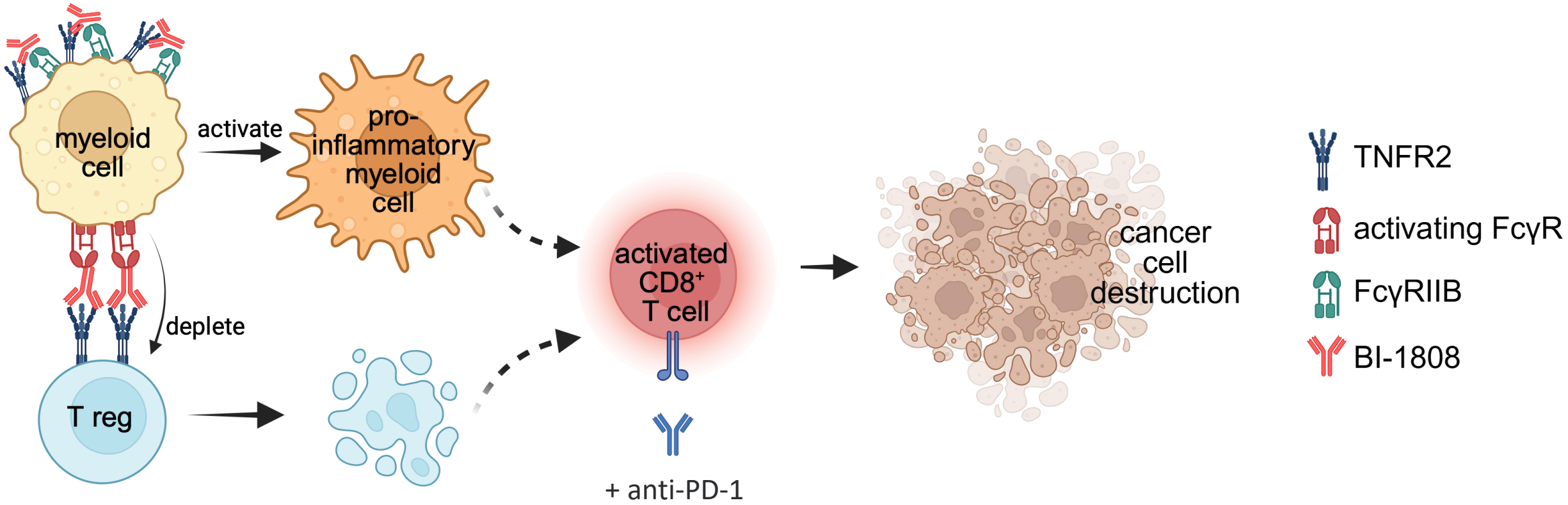
ANTI-TNFR2

BI-1808 in Ovarian Cancer

BI-1808 in T-cell Lymphoma

BI-1808's Differentiated Mechanism of Action

Depletes Tregs and activates macrophages to induce CD8+ T cell antitumor immunity



Mårtensson, et al (Cancer Research https://doi.org/10.1158/0008-5472.CAN-26-0274)

BI-1808 Clinical Trial Design Phase 1/2A (KEYNOTE-D20)

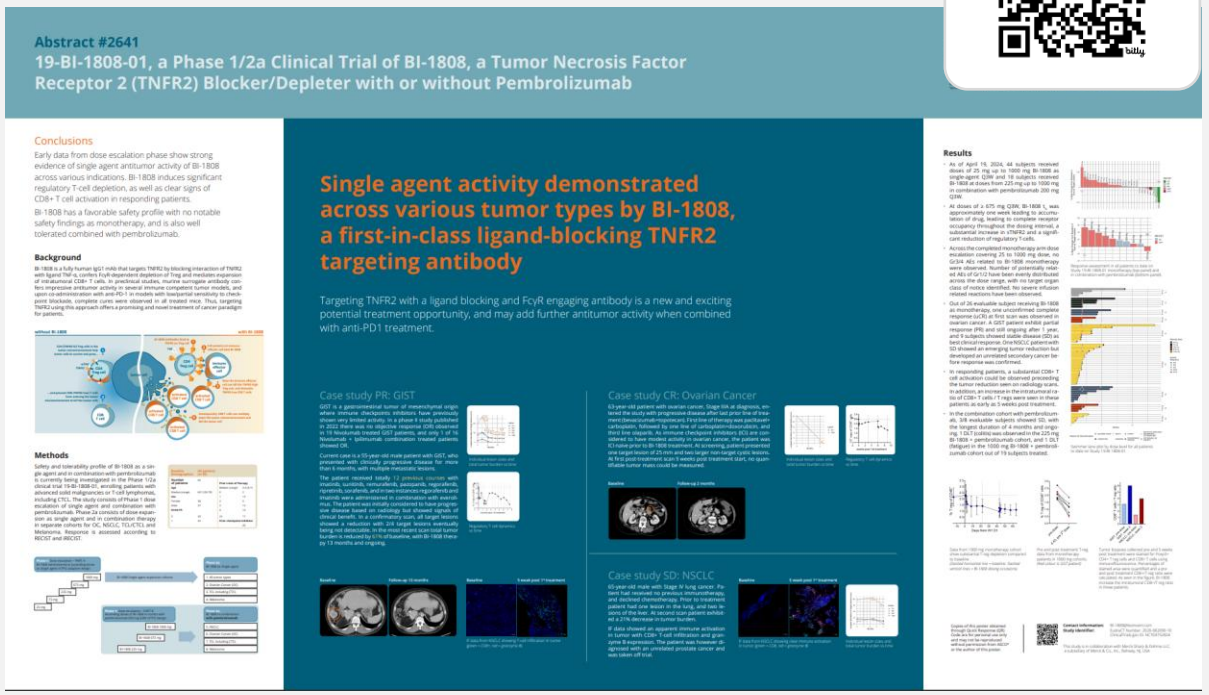
	Phase 1 All Cancer Types	Phase 2a Tissue-specific Cohorts	
	Dose Escalation mTPI2 design	**Signal Seeking** n=12 subjects per cohort	**Randomization** n=10/20 subjects per cohort *between 1000 mg and 250/500 mg BI-1808*
PART A BI-1808 single agent	1000 mg; 675 mg; 225 mg; 75 mg; 25 mg; **6 additional subjects**; Dose escalation BI-1808 as single agent – administered IV Q3W	**1.** All Tumor Types ✓; **2.** Ovarian Cancer (OC) ✓; **3.** T cell Lymphoma ✓; (**4.** Melanoma)	**CTCL** 1000 mg (n=10); **CTCL** 250 mg (n=10); Ongoing
PART B BI-1808 in combination with pembrolizumab MSD	1000 mg BI-1808 + pembro; 675 mg BI-1808 + pembro; 225 mg BI-1808 + pembro; Dose escalation BI-1808 in combination with pembrolizumab 200 mg Q3W	**5.** All tumor types ✓; **6.** Ovarian Cancer (OC) ✓; **7.** T cell Lymphoma ✓; (**8.** Melanoma)	**Indication of Interest** (n=20) 1000 mg BI-1808 + pembro; **Indication of Interest** (n=20) 500 mg BI-1808 + pembro; Now replaced by triplet (Part C)
PART C BI-1808 in combination with pembrolizumab + paclitaxel MSD	**Fast Track Designation** for Ovarian Cancer	BI-1808 in combination with pembrolizumab 200 mg Q3W + paclitaxel 80 mg/m2 weekly; **9.** TNBC	**Ovarian Cancer (OC)** (n=20) 1000 mg BI-1808 + pembro + paclitaxel; **Ovarian Cancer (OC)** (n=20) 500 mg BI-1808 + pembro + paclitaxel

BI-1808: Strong Single Agent Activity in Solid Tumors

- **Heavily pre-treated**, end-of the-line patients
- 1 complete response (**CR**) in ovarian cancer
- 1 partial response (**PR**) in GIST that continued through the full study treatment. Multiple biopsies with no tumor tissue detectable.
- 9 stable disease (**SD**) out of 26 evaluable patients
- Favorable Safety profile with **no grade 3-4 AEs** and no SAEs at highest dose

Link to poster

ASCO 2024 Poster Presentation



Abstract #2641
19-BI-1808-01, a Phase 1/2a Clinical Trial of BI-1808, a Tumor Necrosis Factor Receptor 2 (TNFR2) Blocker/Depleter with or without Pembrolizumab

Conclusions

Early data from dose escalation phase show strong evidence of single agent antitumor activity of BI-1808 across various indications. BI-1808 induces significant regulatory T-cell depletion, as well as clear signs of CD8+ T cell activation in responding patients.

BI-1808 has a favorable safety profile with no notable safety findings as monotherapy, and is also well tolerated combined with pembrolizumab.

Background

Methods

Single agent activity demonstrated across various tumor types by BI-1808, a first-in-class ligand-blocking TNFR2 targeting antibody

Targeting TNFR2 with a ligand blocking and FcγR engaging antibody is a new and exciting potential treatment opportunity, and may add further antitumor activity when combined with anti-PD1 treatment.

Case study PR: GIST

Case study CR: Ovarian Cancer

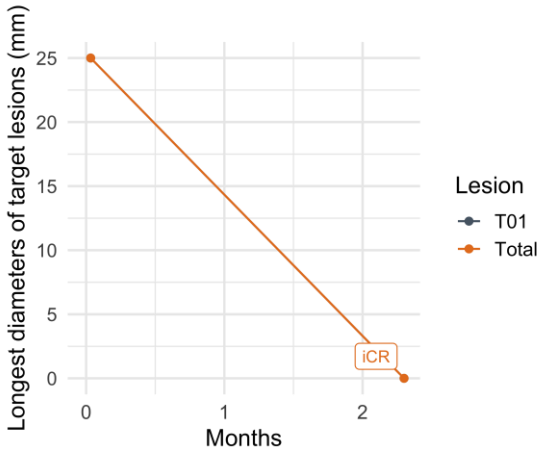
Case study SD: NSCLC

Results

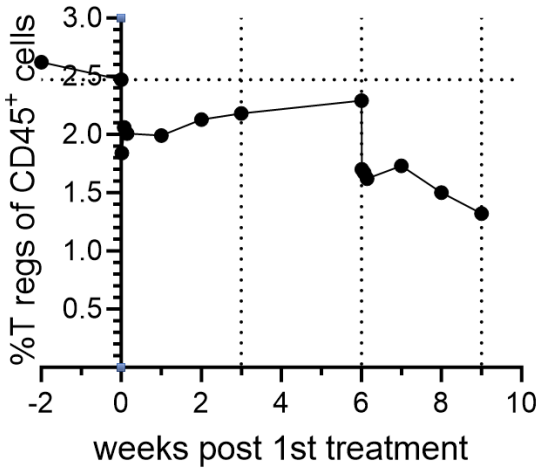
BI-1808 Single Agent Case Study: Complete Response in Ovarian Cancer

Baseline

2 months



Tumor assessment vs time on study



T reg levels vs time on study
Dashed lines indicate administration of BI-1808

63-year-old patient with ovarian cancer, Stage IIIA at diagnosis, entered the study with PD.

Four previous lines of treatment:

- Paclitaxel/carboplatin
- Carboplatin/doxorubicin
- Olaparib
- Bevacizumab/topotecan

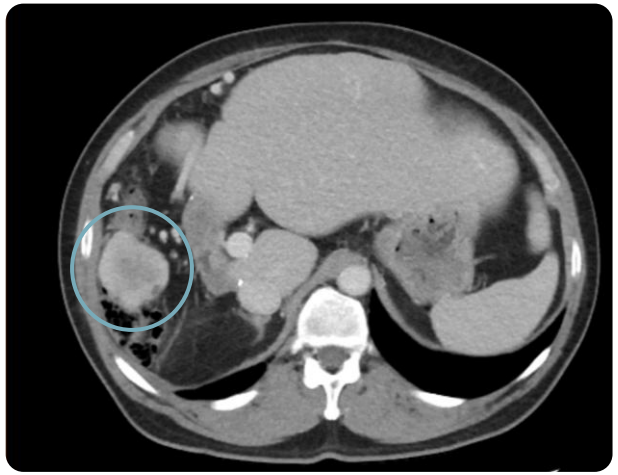
Patient had one target lesion of 25 mm and two larger non-target cystic lesions.

At first post-treatment scan, 9 weeks after the start of treatment, no quantifiable tumor mass could be measured.

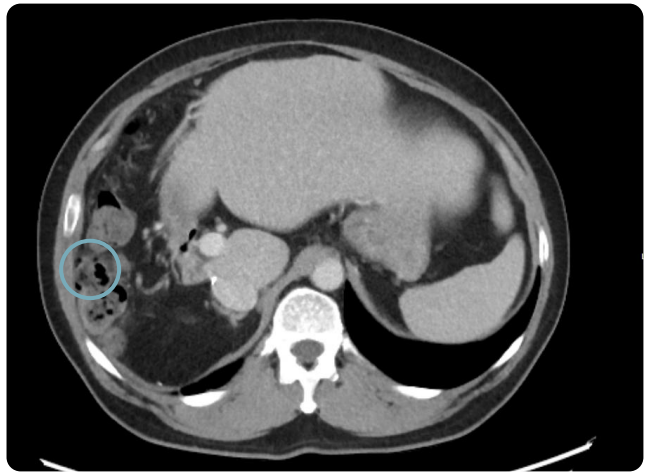
ASCO 2024 Poster #2641 BI-1808

BI-1808 Single Agent Case Study: Robust PR in a Patient with GIST*

Baseline

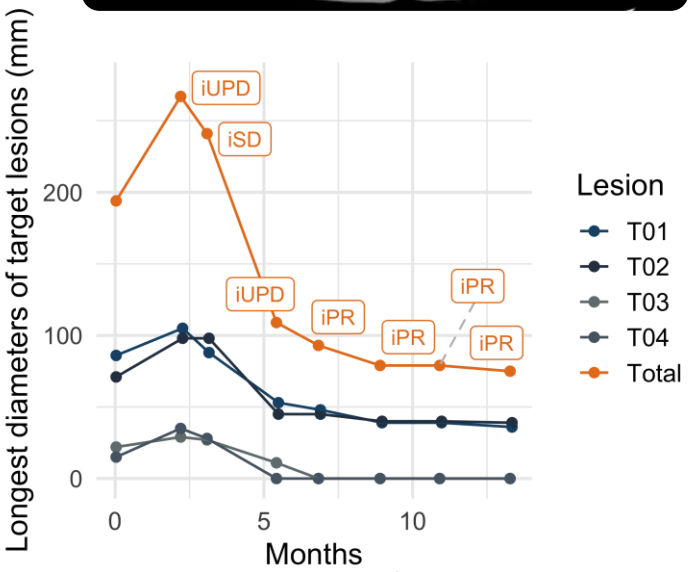


Follow-up 13 months

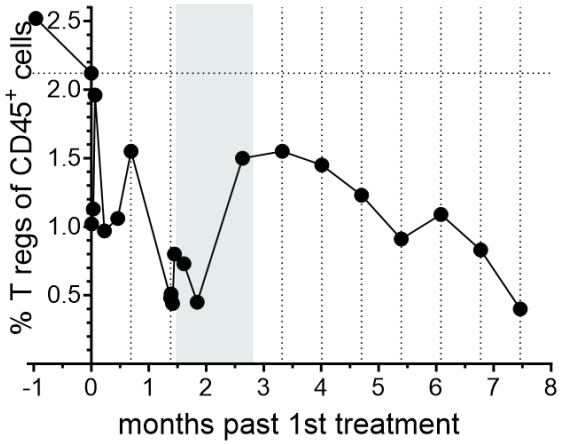


55-year-old male patient with GIST, who presented with clinical PD for more than six months with multiple metastatic lesions.

12 previous lines of therapy.

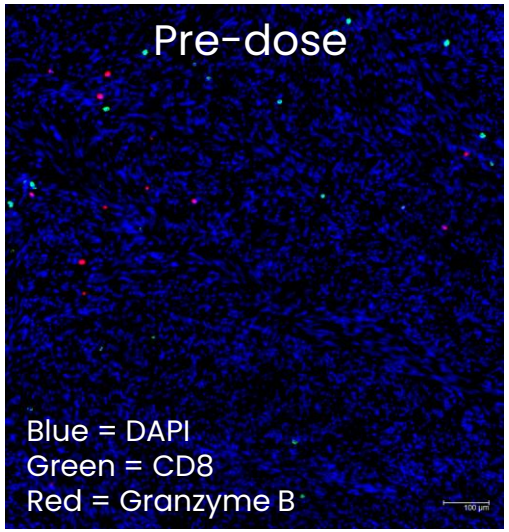


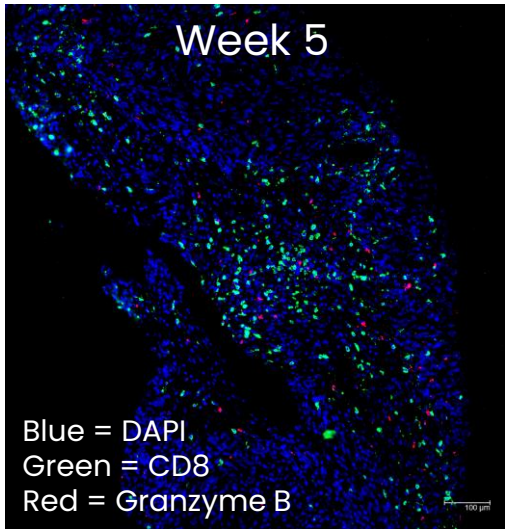
Tumor assessment vs time on study (months)



T reg levels vs time on study. Dashed lines indicate administration of BI-1808.

Note treatment paused





BI-1808 shows evidence of CD8+ tumor infiltration which is associated with tumor regression

*GIST: Gastrointestinal Stromal Tumor
ASCO 2024 Poster #2641 BI-1808

BI-1808 in Ovarian Cancer

BI-1808 + Pembrolizumab Achieves 24% ORR in Heavily Pretreated Recurrent Ovarian Cancer Patients

No Chemotherapy Regimen

PATIENT PROFILE

26

Enrolled patients, 25 evaluable

Tumor Subtypes

- HGSA 17 (65%)
- ccOC 9 (35%)

Median age: 62 yrs (range 46–79)

TREATMENT HISTORY

5

median prior lines

Prior Treatment (1–10 prior lines)

100% platinum-based therapy

All patients received at least one platinum-containing regimen

Heavily pretreated, chemo-resistant population entering the study

TREATMENT RESPONSE

24%

overall response rate (ORR)

Best Response (n=25)

CR	1 (4%)
PR	5 (20%)
SD	8 (32%)
PD	11 (44%)

DCR 56% | mPFS 10.3 mo (maturing)

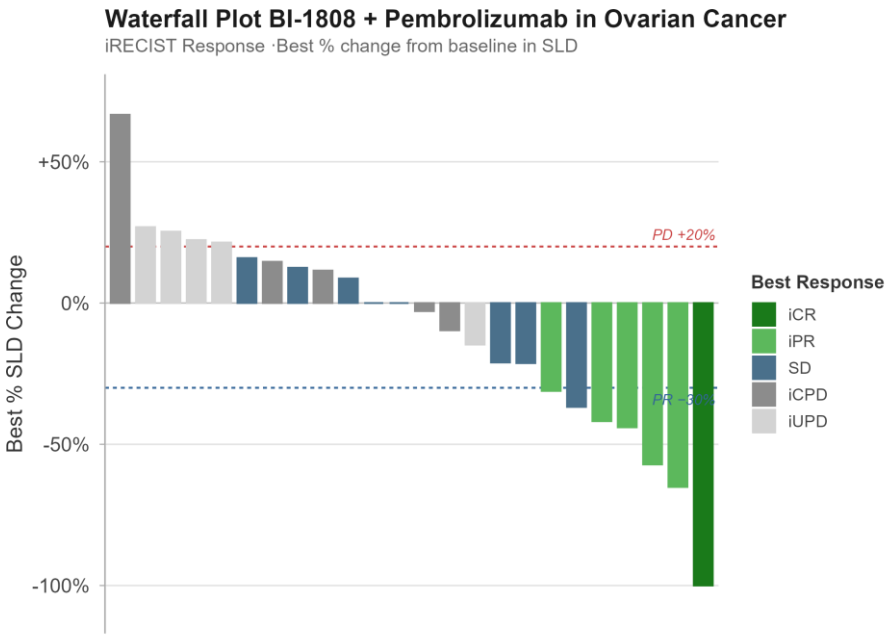
HGSA: High-Grade Serous Adenocarcinoma; ccOC: Clear Cell Ovarian Carcinoma; OC: Ovarian Cancer; ORR: Overall Response Rate; DCR: Disease Control Rate; mPFS: Median Progression-Free Survival; CR: Complete Response; PR: Partial Response; SD: Stable Disease; PD: Progressive Disease; UNK: Unknown stage. | BI-1808 + pembrolizumab, Ph2a single arm doublet, 8 EU & UK sites | Data cut-off: 20-April-2026

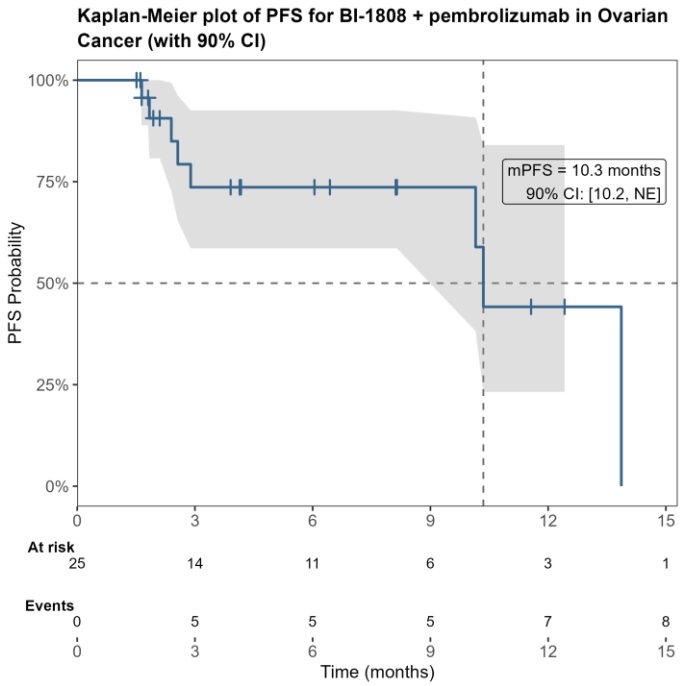
BI-1808 + Pembrolizumab: Promising Efficacy In Ovarian Cancer

Data presented at ASCO 2026

Phase / Design	Population	N	Dosing	Sites	Key Endpoints	Data Cut-off
Ph2a single arm (doublet)	OC (all subtypes)	25 of 40	BI-1808 1000 mg Q3W Pembro 200 mg Q3W	8 (OC) in EU & UK	Safety ORR exploratory	2026-04-20

- **24% ORR, 56% DCR** in 25 evaluable patients: 1 CR + 5 PR + 8 SD (several durable beyond 10 months and ongoing)
- **mPFS 10.3 months (90% CI: 10.2, NE)** 9/25 patients still on treatment at cut-off; PFS continues to mature
- Final readout expected H2 2026





ORR: Overall Response Rate
DCR: Disease Control Rate

Late Responses Signal Deeper, More Durable Activity: A Feature of BI-1808's Mechanism

ccOC (clear cell) — responses observed

HGSA (high-grade serous) — responses observed

Activity in both subtypes: high-grade serous (HGSA) and clear cell (ccOC)

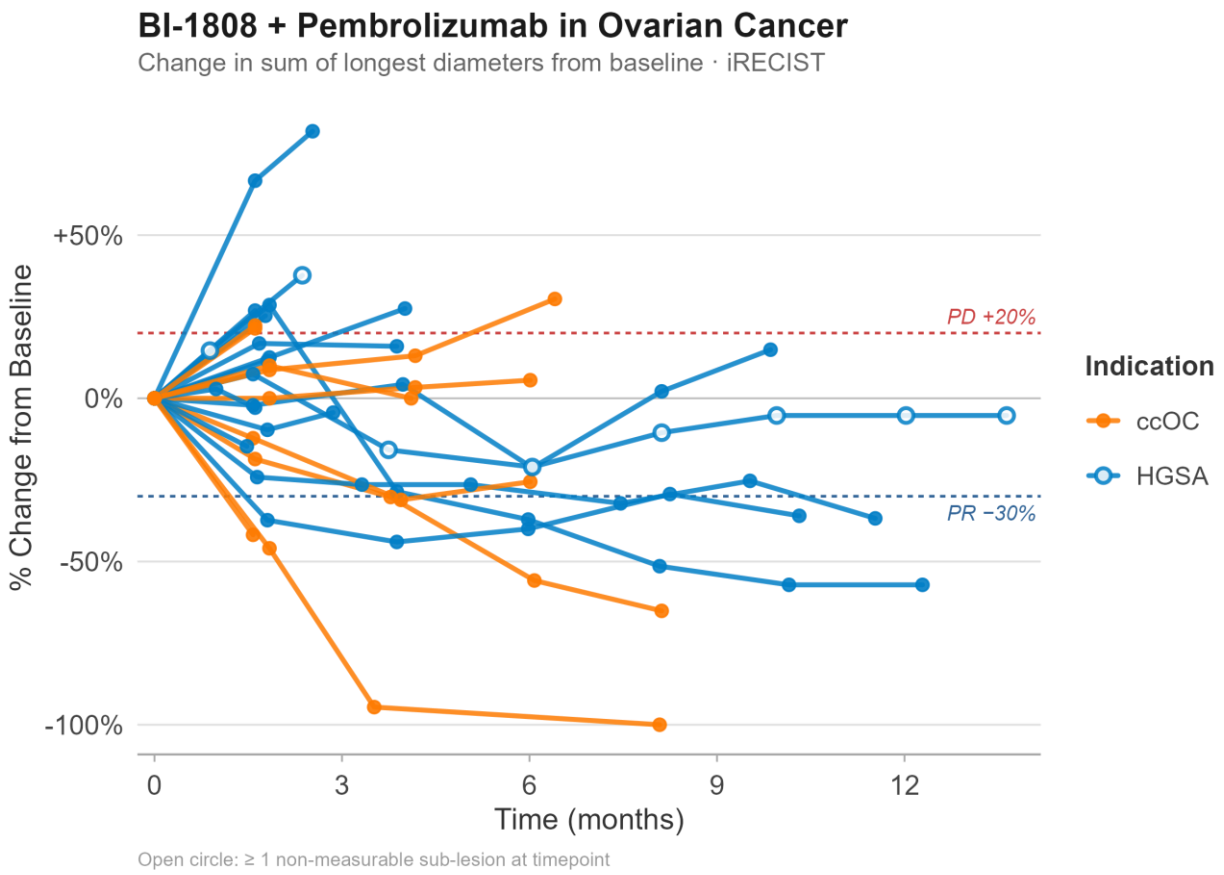
Late responses: a hidden positive feature

Some lesions increase in size initially before decreasing — consistent with pseudoprogression often seen with other immunotherapies.

- ✓ Consistent with BI-1808's mechanism: CD8+ T-cell expansion takes time
- ✓ Confirmed preclinically in vivo — not an artifact

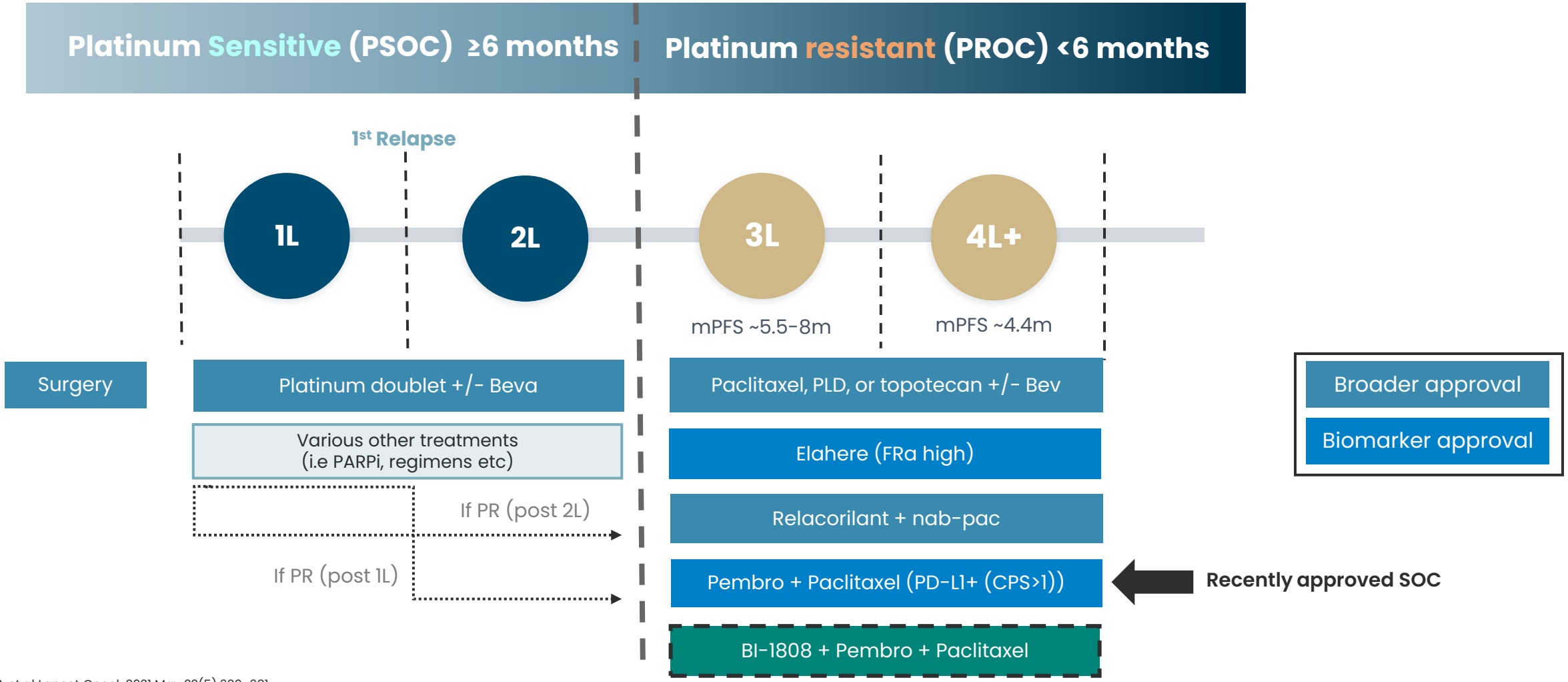
9 of 25 patients still on treatment

Responders may not yet be captured in the interim 24% ORR, suggesting the final readout could be stronger



SLD: Sum of Longest Diameters; PR: Partial Response (≥30% decrease); PD: Progressive Disease (≥20% increase); ccOC: Clear Cell Ovarian Carcinoma; HGSA: High-Grade Serous Adenocarcinoma; ORR: Overall Response Rate | Data cut-off: 20-April-2026

The Treatment Paradigm is Shaped by Platinum Sensitivity and Biomarker Status; With Few Recent Approvals in PROC*



1. Poveda A et al Lancet Oncol. 2021 May;22(5):620-631
2. Mirza MR et al N Engl J Med. 2016 Dec 1;375(22):2154-2164.
3. Aghajanian C J et al. Clin Oncol. 2012 Jun 10;30(17):2039-45.
4. Coleman RL et al. Lancet. 2017 Oct 28;390(10106):1949-1961
5. Hanker LC, et al. Ann Oncol. 2012;23(10):2605-12
6. González-Martín et al. Ann Oncol. 2023 Oct;34(10):833-848

*PROC: Platinum-Resistant Ovarian Cancer

The Treatment Paradigm is Changing with Few Recent Approvals in PROC

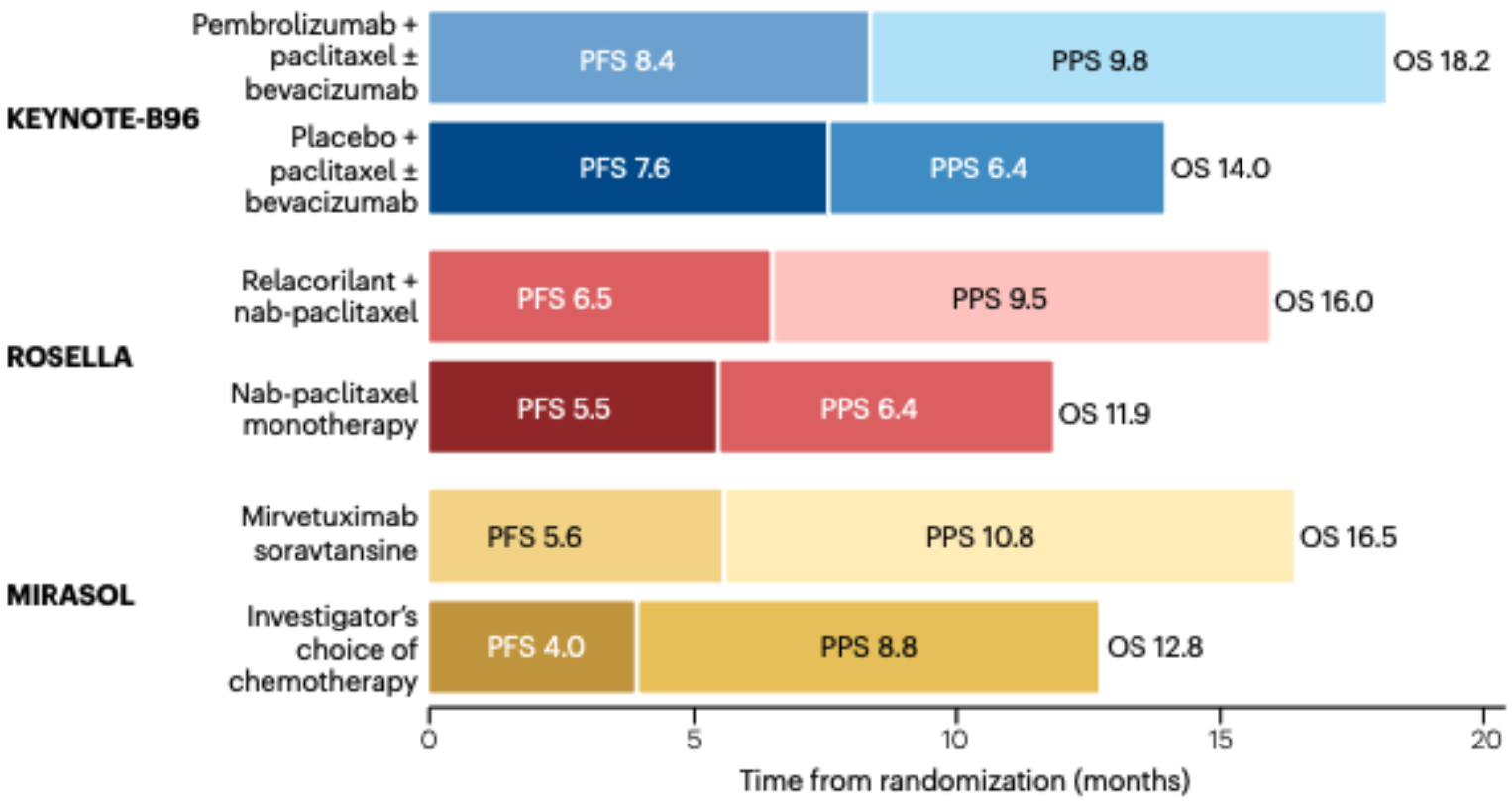


Fig. 1 | Outcomes across trials testing biologically driven therapies in ovarian cancer. Post-progression survival (PPS) was calculated as overall survival (OS) minus progression-free survival (PFS)[3–5]. Both PFS and PPS are descriptive arithmetic differences of medians. KEYNOTE-B96 values are from the analysis of the combined positive score ≥1 population[4]; ROSELLA data are from the updated final OS analysis[5]; and MIRASOL values are from the ESMO 2025 update[7].

nature reviews clinical oncology

Volume 23 | August 2026 | 566–568 | 566

Isabelle Ray-Coquard & Kathleen N. Moore

ADCs are not a competitive threat — and they may complement BI-1808

Four structural limitations of the ADC class

Significant toxicity

Boxed warnings across the class: ocular toxicity (MIRV, TV) and ILD (T-DXd, ~2% fatal). 91% any-grade and 46% grade ≥3 AEs across 22,000+ patients. Targeted delivery doesn't lower payload MTD.

Biomarker-restricted

MIRV requires FRα-high — only ~34–44% of HGSOC qualify. T-DXd requires HER2 IHC 3+ — ~5% of HGSOC. Assay variability and uneven tumor expression shrink the eligible pool further.

Near-universal resistance

Resistance develops in almost all patients. ~69% show cross-resistance to a second ADC that shares a target or payload class, limiting sequential ADC strategies.

Only two payload classes

The entire pipeline rests on microtubule and topoisomerase-1 inhibitors. Crowding around two payloads concentrates risk and drives pan-resistance.

BI-1808 is complementary, not competitive

Before an ADC

Biomarker-agnostic IO treats the full population and primes anti-tumor immunity; ADCs are reserved for biomarker-positive progressors.

Alongside an ADC

ADC-induced immunogenic cell death pairs with BI-1808's TME reprogramming — orthogonal mechanisms, no shared resistance.

After an ADC

Extends durability as ADC responses wane, and rescues biomarker-negative or ADC-resistant patients.

Orthogonal immune mechanism — *no cross-resistance with cytotoxic ADC payloads. BI-1808 can precede, accompany, or follow an ADC.*

Source: Moore et al., Antibody–drug conjugates in gynaecological cancers. Nat Rev Clin Oncol 2026. Supporting data: MIRASOL, DESTINY-PanTumor02, InnovaTV 301; class-wide AE meta-analysis (169 trials, >22,000 patients). MIRV, mirvetuximab soravtansine (Elahere); T-DXd, trastuzumab deruxtecan; TV, tisotumab vedotin.

BioInvent's BI-1808 as the Next Standard of Care in Ovarian Cancer

Estimated peak sales of BI-1808 in PROC of ~$1.7 billion (base-case) for current target product profile (TPP)

CURRENT

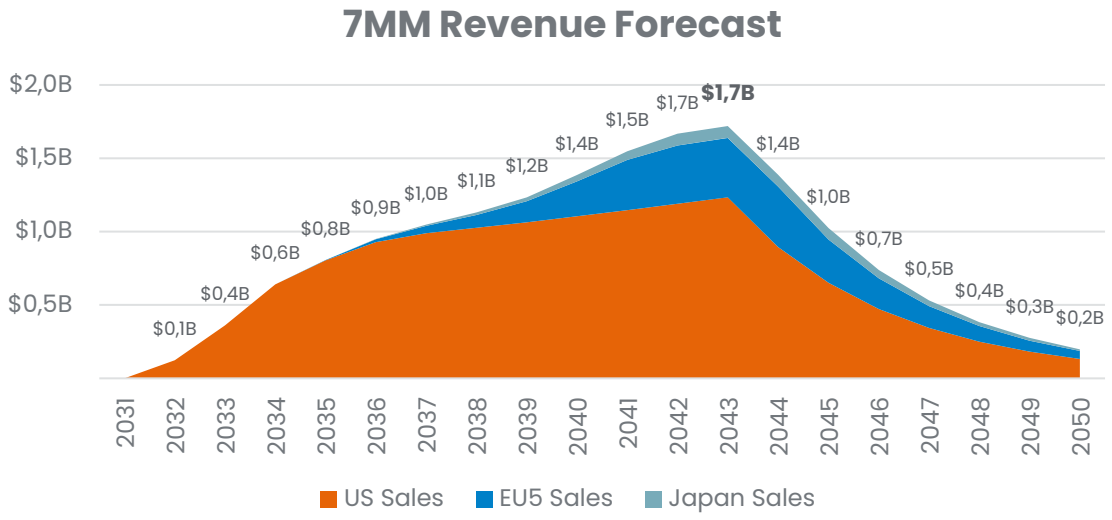
- Standard of care (**SoC**) in ovarian cancer the chemotherapy drug paclitaxel added to Keytruda, but **survival still poor**

NEXT

- BI-1808 on top of current SoC: preclinical results show **effect beyond current therapies**
- **In upside**, all-comer case: % increase in potential patients will yield similar % increase in peak sales

FORECAST

Region	Peak Sales	Peak Year
US Sales ($K)	$988,608	2037
EU5 Sales ($K)	$396,504	2042
Japan Sales ($K)	$82,250	2042
7MM Total Sales ($K)	**$1,719,786**	**2043**



SoC: a recognized benchmark of competence, quality, and broadly accepted practice. This is a very preliminary 7MM forecast, given the early stage of the program. Many assumptions are placeholders until more is known about the program, its' data and the market. Current assumptions have not been tested in market research.

Positioning BI-1808 in Recurring Ovarian Cancer

- **First-in-class BI-1808** depletes immunosuppressive Tregs and reprograms macrophages to expand and activate CD8+ effector T cells, converting the tumor microenvironment from “cold" to “hot."
- Pembrolizumab + paclitaxel achieved 53% ORR, and **18.2 months of OS**,[1] establishing a **new standard of care** in recurring ovarian cancer. It was approved by the FDA in February 2026.
- **BI-1808 + pembrolizumab** current on a **24% ORR and 56% DCR** in recurring OC patients, representing a **meaningful improvement** over the **8% ORR of pembrolizumab** monotherapy, in addition to a target-validating CR in an OC patient treated with BI-1808 monotherapy.
- While **ADCs** show relatively high ORR (44-57% ORR), PFS (and eventually OS) is **not better** than the lasting responses that can be achieved with immunotherapy, based on available data and experience with chemotherapeutic agents
- **Adding BI-1808 to pembrolizumab + paclitaxel** is a biomarker-agnostic treatment expected to **enhance efficacy** higher than the 53% KEYNOTE-B96 benchmark with a more **durable** activation of the immune response, establishing a new SOC in recurring Ovarian Cancer.
- This regimen will **not compete with ADCs** in development which can be administered prior or after treatment with this regimen

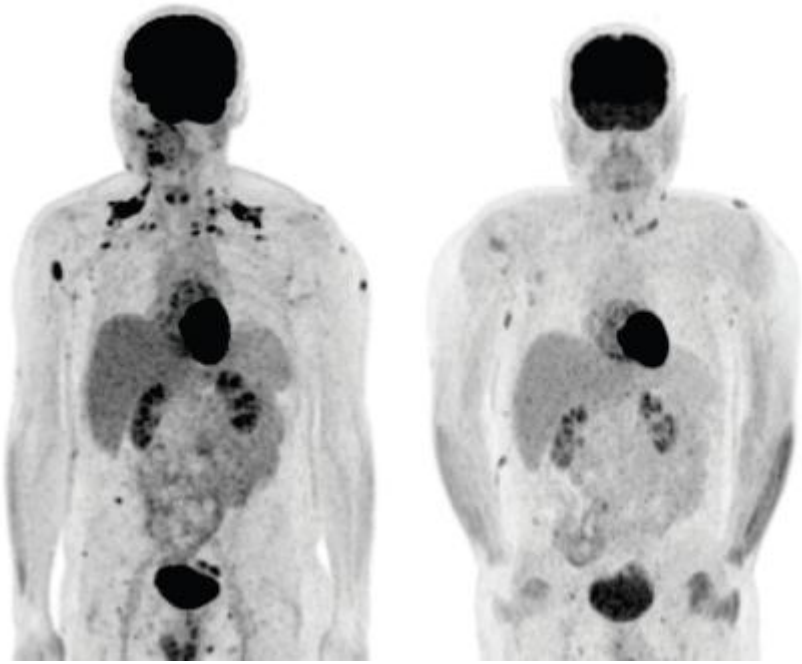
[1]KEYNOTE-B96, ESMO 2025
PFS: Progression-Free Survival, OS: Overall Survival

BI-1808 in CTCL

Impressive Responses Were Observed in Heavily Pre-treated Patients with PTCL or CTCL Treated with BI-1808 Monotherapy

Case Studies

PTCL Patient (stage IV, 6 prior lines of treatment)	**CTCL Patient** (stage IIb MF, 5 prior lines of treatment)



Baseline Week 9

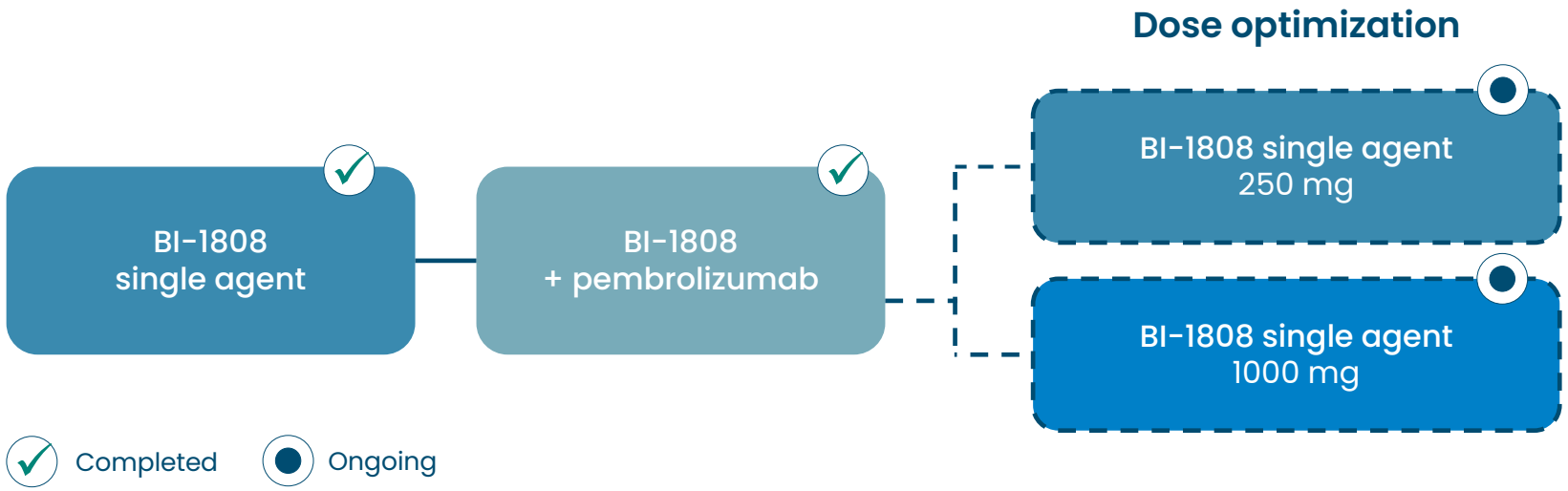
Baseline Week 21

BI-1808 Clinical Phase 1/2a Study Overview

Orphan Drug Designation for TCL

Fast Track Designation for CTCL

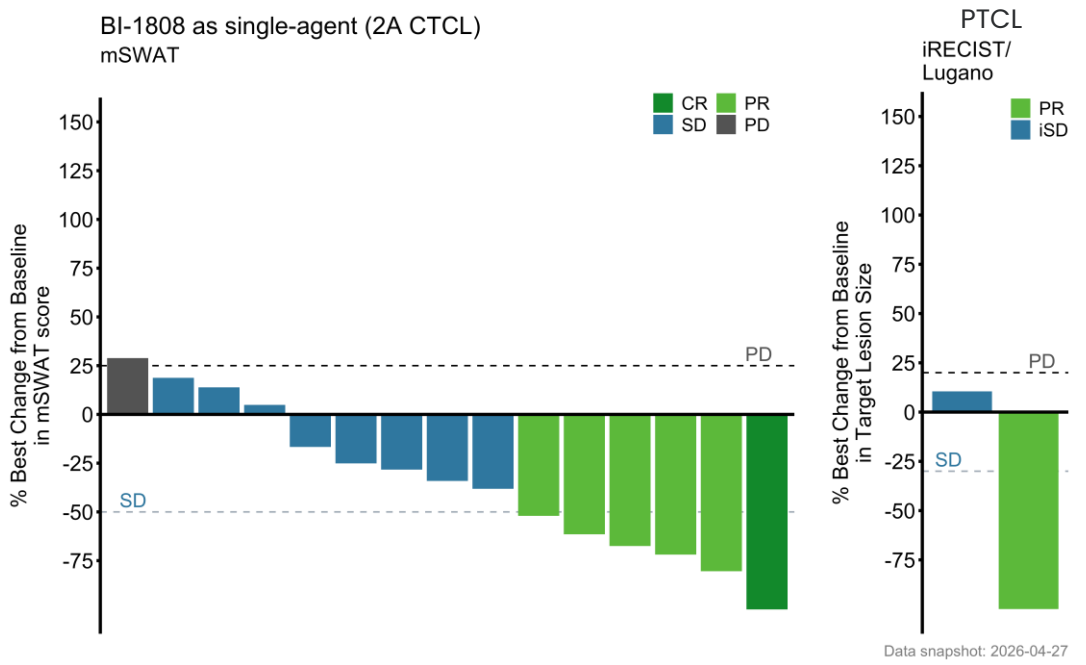
- Safety and preliminary efficacy currently investigated in CTCL patients (sub-cohort of the ongoing Phase 2a clinical trial)
- 20 patients enrolled for BI-1808 1000 mg as single agent every third week (Q3W)
- Followed by 10 patients treated with the combination of BI-1808 and pembrolizumab
- Currently enrolling 10 vs 10 patients evaluating BI-1808 at 250 mg vs 1000 mg Q3W as single agent



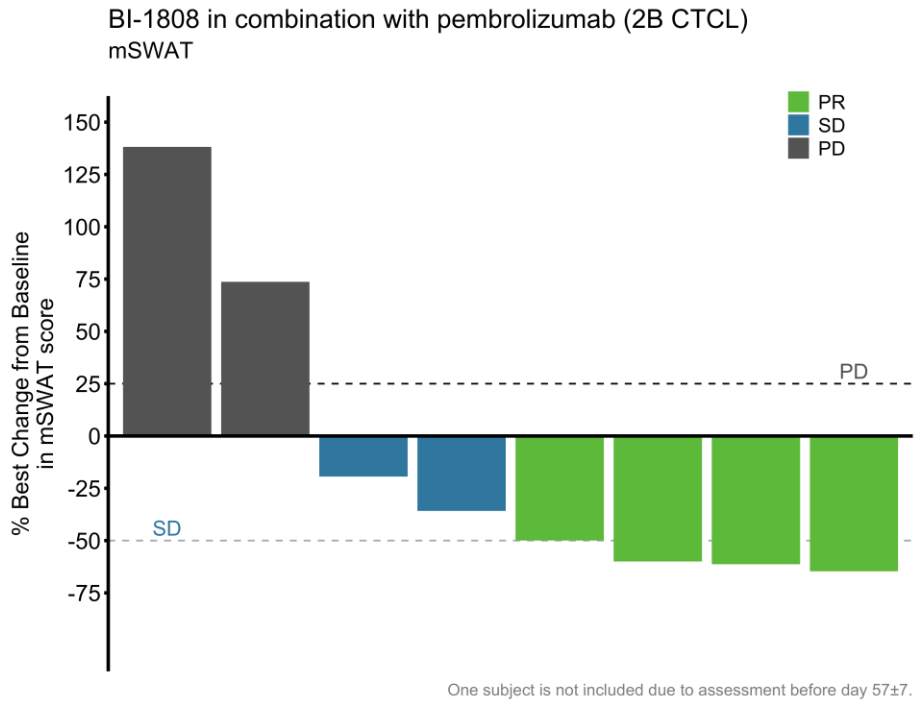
BI-1808 Shows Promising Efficacy in CTCL (and PTCL)

EHA 2026 poster Phase 2a monotherapy & combination data

Single Agent (2A CTCL) — mSWAT



+ Pembrolizumab (2B CTCL) — mSWAT



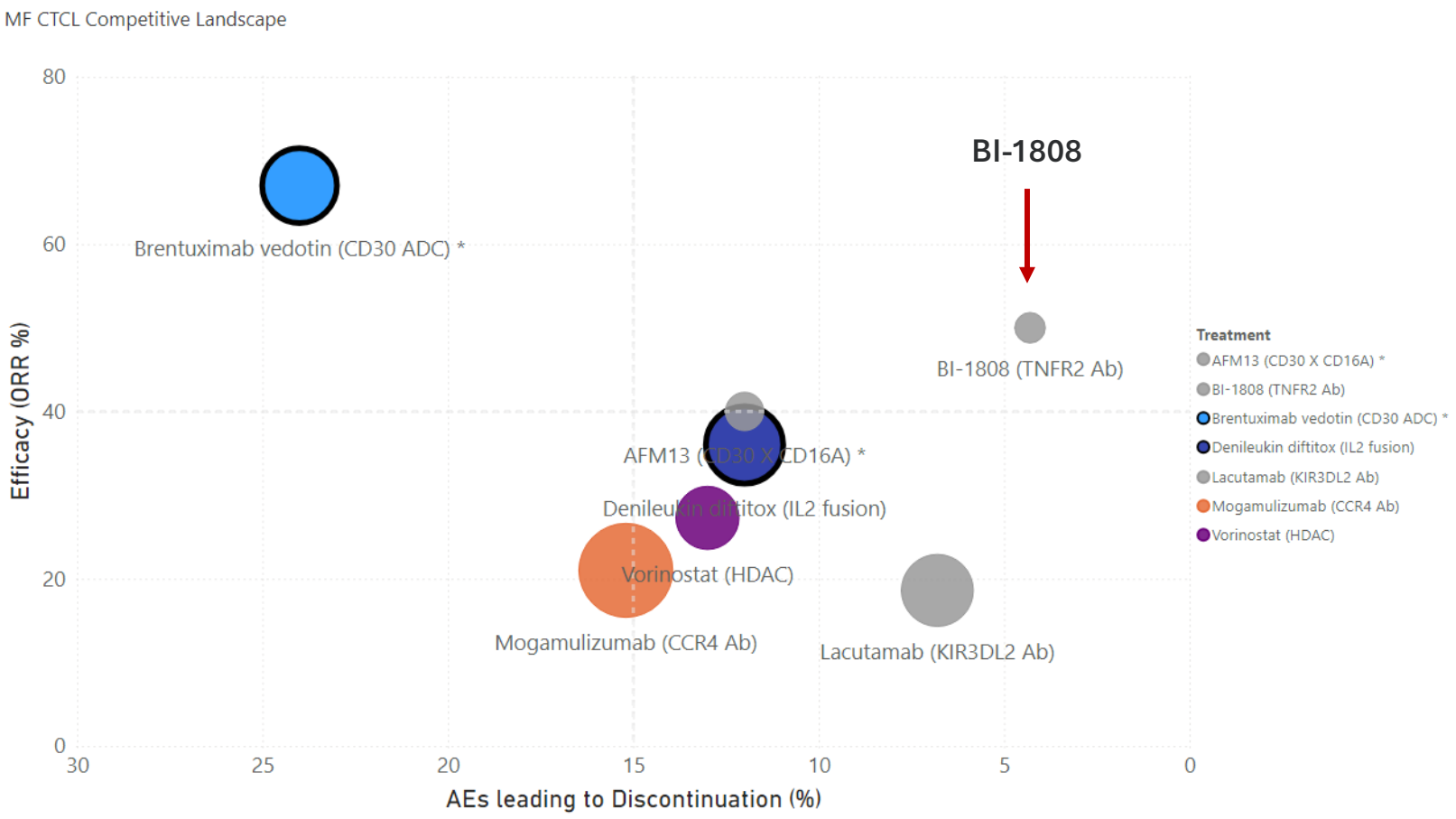
40%	93%	1 CR
ORR	**DCR**	**SS ongoing 2+ yrs**
5 PRs + 1 CR	15 evaluable pts	

50%	75%	4 PR
ORR	**DCR**	
4 PRs	8 evaluable pts	

CTCL: Cutaneous T-cell Lymphoma, PTCL: Peripheral T-cell Lymphoma | Data snapshot: 2026-04-27

BI-1808 is Differentiated Where it Matters Most: Mycosis Fungoides

MF represent the majority of CTCL patients (~70%), and where incumbents are weakest



- Higher efficacy in MF than all other treatments except for brentuximab (30% of patients, black box warning)
- No biomarker restriction
- Best-in-class tolerability with only 4% discontinuation

* Biomarker-selected subpopulation; Bubble size represents number of patients in reported dataset; Colored bubbles are approved treatments; Grey bubbles are unapproved treatments; Dark outline signifies black box warning

BI-1808 Potential Path to Approval – US

Potential Timelines for Ovarian Cancer*

- Breakthrough Designation
- Agreed Pivotal Design
- EOP Meeting
- Fast Track Designation ✓

Phase 2, Part A monotherapy (n=20) ✓

Phase 2, Part B
Combo with Pembro (n= 40)
ongoing

Randomized study in combo with pembro and paclitaxel vs SoC (n = 20 vs 20)

Pivotal study

2025	2026	2027-

Potential Timelines for CTCL*

- Orphan Drug Designation ✓
- Fast Track Designation ✓
- Breakthrough Designation
- Agreed Phase 2 Design
- EOP1 Meeting
- EOP2
- BLA Submission
- **Approval** ★

Phase 2, Part A monotherapy (n=20) ✓

Phase 2, Part B ✓
Combo with Pembro (n= 10)

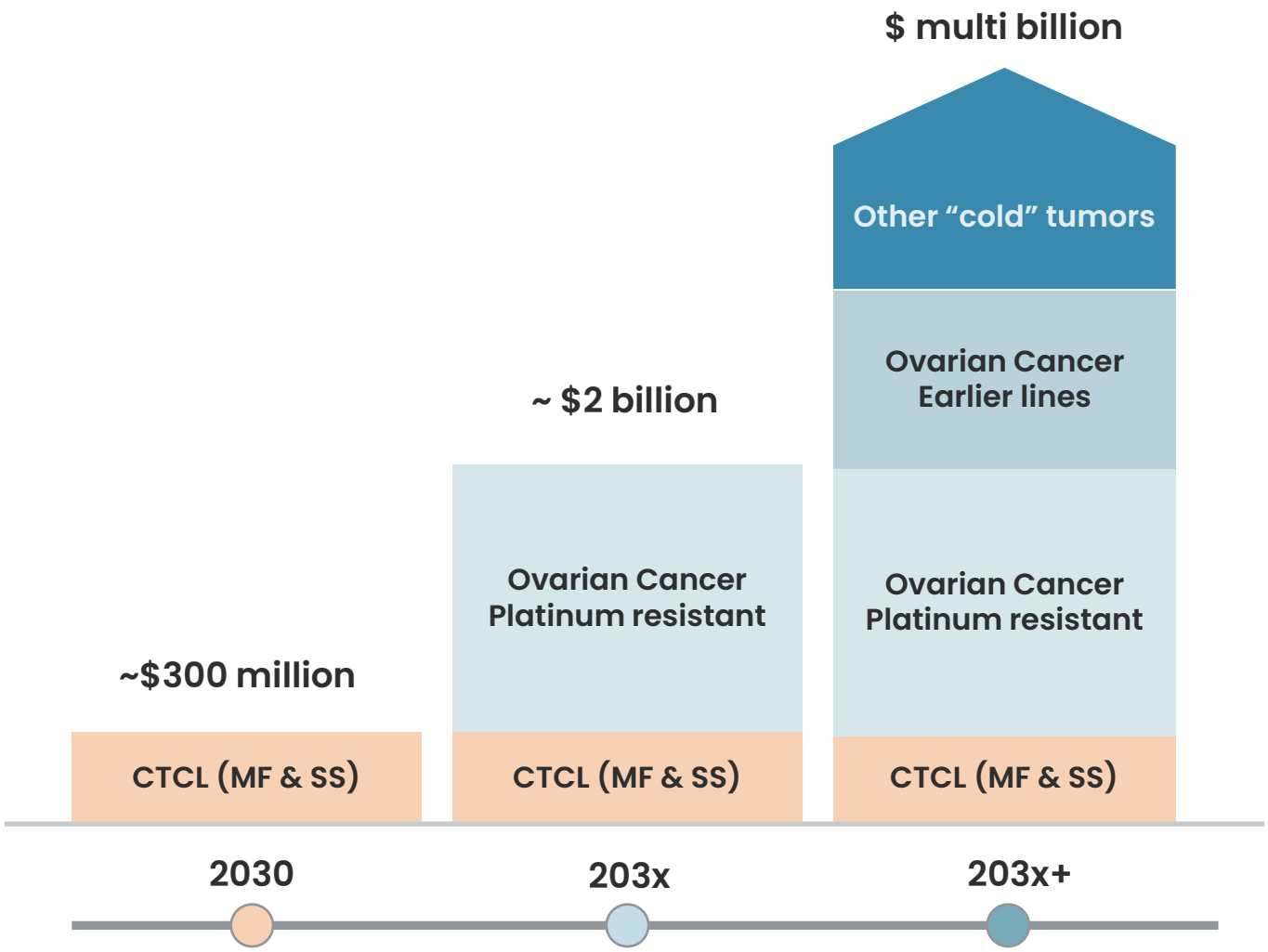
Dose Optimization** monotherapy (n = 10+10) *ongoing*

Pivotal Phase 2 monotherapy

Confirmatory study Phase 3

* Depending on partnering discussions and acceptance of development plan by FDA
** Clinical study protocol approved in the US

A Pragmatic Development Strategy With Billion-Dollar Potential



- Pursue **Fast to market** indication in CTCL (plan for BTD and accelerated approval)
- **Develop triplet regimen** with BI-1808 +pembrolizumab+paclitaxel in PROC
- Future development options include:
  - Earlier lines of ovarian cancer in combination with pembro + paclitaxel
  - Other myeloid-driven tumors (e.g., MSS Colorectal cancer, TNBC or Small cell lung cancer)
  - Other "cold" tumors

FPA: Platinum Resistant Ovarian Cancer (PROC) forecast
Eversana: CTCL forecast
Major Markets, i.e US, France, Germany, Italy, Spain, UK, Japan

MF: Mycosis Fungoides
SS: Sézary Syndrome
PROC: Platinum-Resistant Ovarian Cancer

ANTI-FcγRIIB

BI-1206 in Solid Tumors

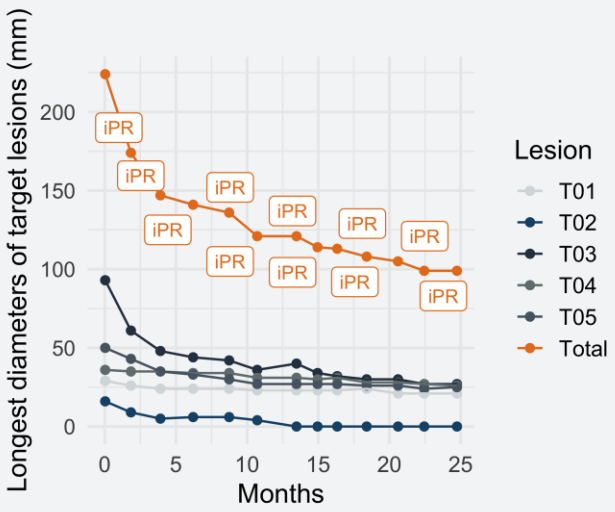
BI-1206 in Non-Hodgkin's Lymphoma (NHL)

BI-1206 in Solid Tumors:
Non-Small Cell Lung Cancer
Uveal Melanoma

Co-administration of BI-1206 with Pembrolizumab - Promising Responses in Uveal Melanoma Who Previously Failed anti-PD-1

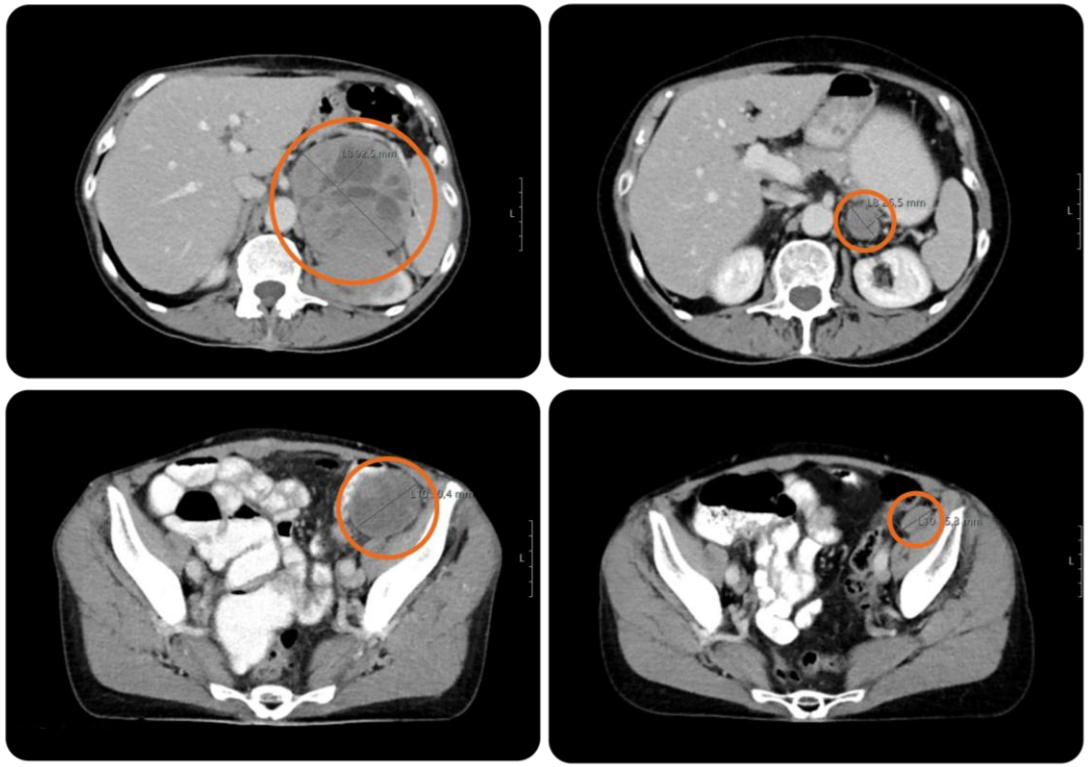
Case study: PR

69 YO female with uveal melanoma.
No response to prior immunotherapy or chemotherapy. Multiples lines of ICIs and Chemo. Progressing when entering study. Showed early partial response at first scan on BI-1206 + pembrolizumab, continued PR deepening during whole study duration (2 years) with tumor burden reduced by 56% at end of trial.



Baseline

End of treatment 2 years

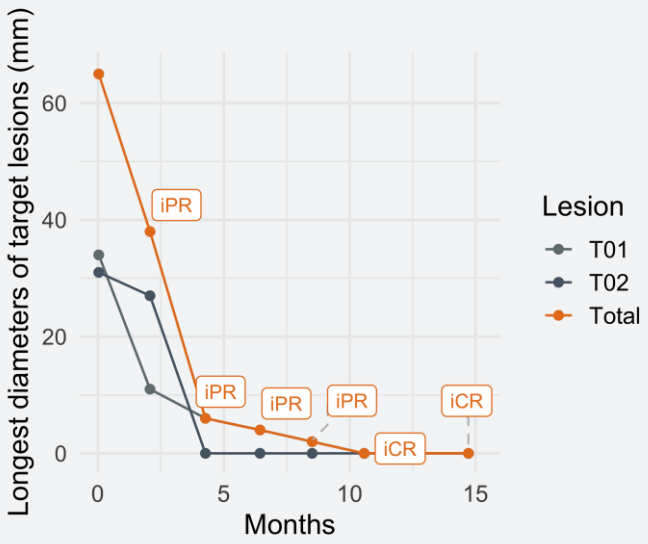


ASCO 2024 Abstract #2593 BI-1206

Co-administration of BI-1206 with Pembrolizumab Promising Responses Observed in Melanoma, who Previously Failed Anti-PD-1 Therapy

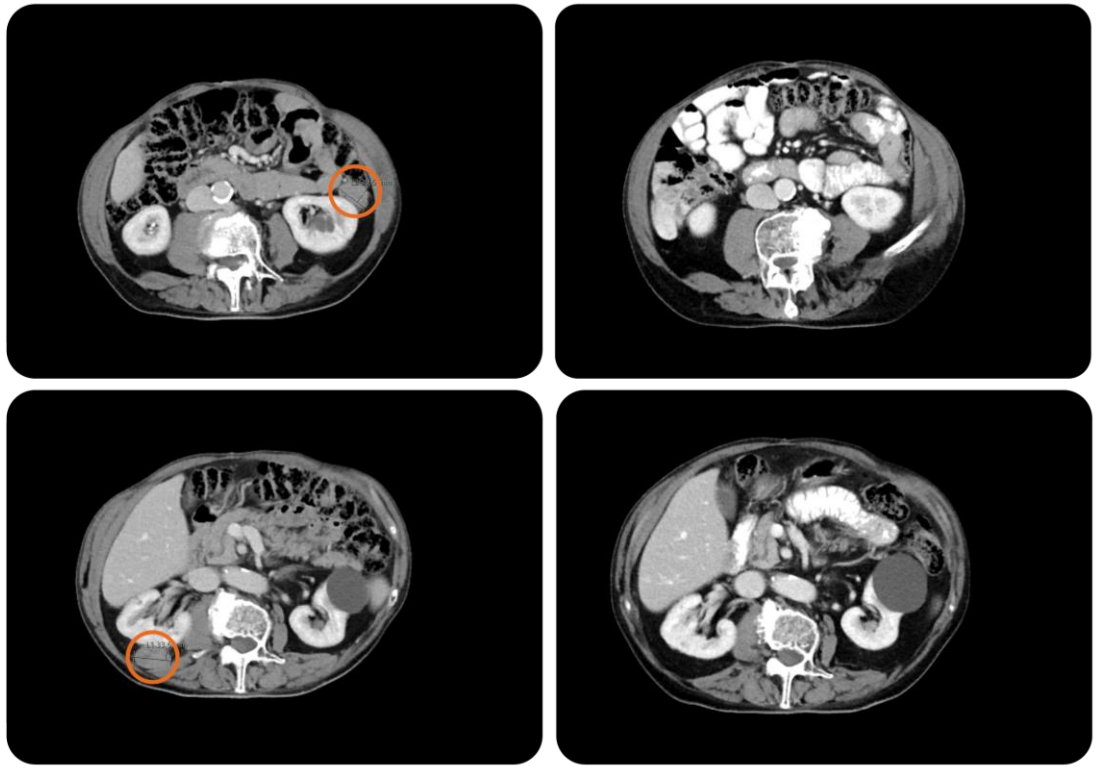
Case study: CR

77 YO male melanoma patient, stage IV.
Deep Partial Response at first scan at 2 months, evolving to CR at 10 months, still ongoing at 16 months. Three lines of previous ICI therapy, with PR as best prior response to ipilimumab + nivolumab.



Baseline

Scan at 16 months



ASCO 2024 Abstract #2593 BI-1206

Phase 2a study Ongoing: BI-1206 + KEYTRUDA in Treatment-Naïve Patients

- To evaluate safety and efficacy of BI-1206 in combination with pembrolizumab
- Advanced or metastatic NSCLC and uveal melanoma
- Patients will be enrolled at sites in Georgia, Germany, Poland, Romania, Spain, Sweden and the US

BI-1206 combo with pembrolizumab

MSD

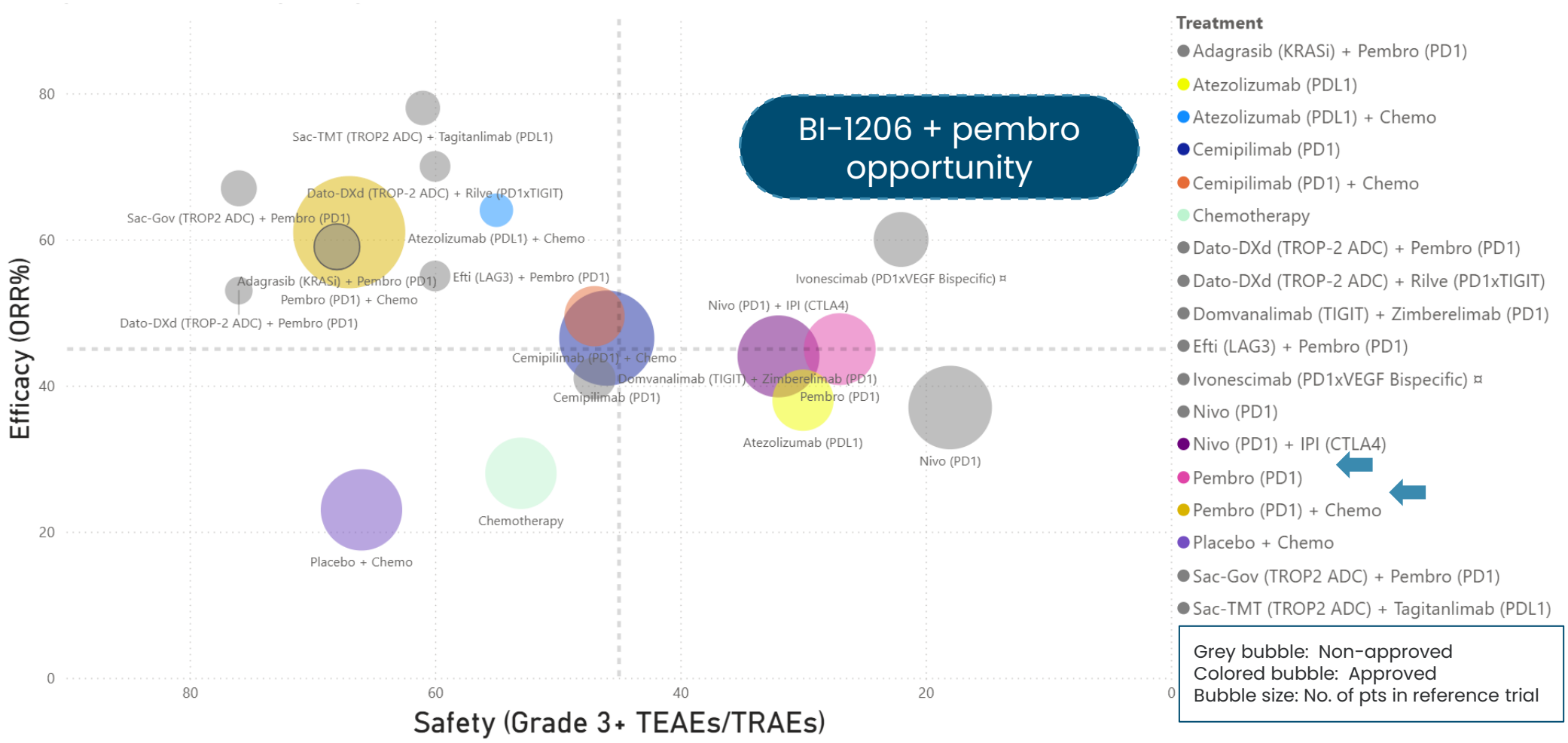
Phase 1 All cancer types	Phase 2 Tissue-specific Cohorts	
Dose escalation	Signal seeking	Dose optimization
mTPI-2* design	BI-1206 twice + pembrolizumab	Randomization
COMPLETED	ONGOING	
300 mg twice dosing 300 mg 225 mg 150 mg	NSCLC (30 pts) Uveal Melanoma (12 pts)	BI-1206 twice + pembro BI-1206 once + pembro Pembrolizumab

Selection of RP2D

WHAT'S NEXT? First Phase 2a data in front-line NSCLC and uveal melanoma H2 2026E

* modified Toxicity Probability Interval 2

Competitive Landscape in PD-L1 High NSCLC



Key - Size of bubble : No. of pts.; Colored Bubbles : Approved treatments in US or EU; Grey Bubbles : Unapproved treatments; ¤ : China-run trial

Main toxicities : ICI : Pneumonitis, colitis, hepatitis, severe skin reactions. ICI + Chemo : Increased risk/severity of irAEs, Pneumonitis, sepsis. ICI+ TKI : Markedly increased ILD/pneumonitis

Positioning of BI-1206 in Non-Small Cell Lung Cancer

- BI-1206 blocks FcγRIIB (CD32b), a receptor on myeloid cells that actively removes anti-PD-1 antibodies off T-cells, internalizing and degrading them. By **blocking FcγRIIB, BI-1206 prevents the removal of pembrolizumab** from the T-cell surface, extending receptor occupancy and potential therapeutic activity. This would work in **any pembro combination** treatment.

- Despite high PD-L1 expression (TPS >50%), approximately **40–50% of patients do not respond to pembrolizumab monotherapy**. BI-1206 may also capture part of this specific segment by overcoming FcγRIIB-mediated resistance.

- This doublet offers a **strategy that avoids the severe toxicity** of platinum-based chemotherapy. It positions itself as a **superior "all-immunotherapy" option** for patients who cannot tolerate or wish to avoid chemo-associated side effects.

- Early clinical data (Phase 1/2a) demonstrated **proof-of-concept with durable responses** (including Complete Responses) in **heavily pre-treated**, anti-PD-1 refractory patients—suggesting the mechanism translates from the lab to the clinic.

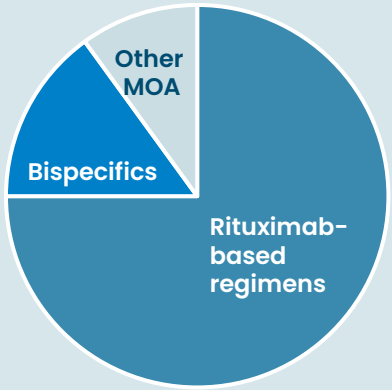
- Moving to the 1st-line setting targets patients with healthier immune systems, **maximizing the potential synergy**. Success here opens access to the largest and most lucrative segment of the NSCLC market.

- **Phase 2 in 1st line NSCLC and uveal melanoma** in combination with pembrolizumab is **ongoing** (first data readout H2 2026).

BI-1206 in NHL

Paired with Entrenched Rituximab, BI-1206 can Compete in a Highly Competitive FL Market

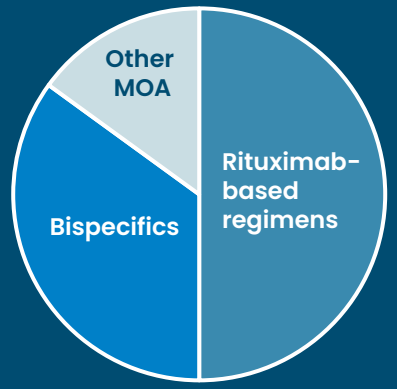
Now



Follicular Lymphoma (FL) Market Shifts

- Increasing bispecific options
- Expansion of other MOAs (BTKi, CAR-T)
- Switch to rituximab biosimilars

2030



Opportunities for BI-1206

- Capturing 2nd line after 1st line bispecific (CD19XCD3)
- First anti-CD20 after bispecific will increase response rates of the triplet
- Safe and convenient, community hospital-friendly backbone (no CRS, neurotoxicity, neutropenia, infections, or hospital logistics associated with bispecifics/CAR-Ts)
- Combines with biosimilar rituximab, which remains the drug of choice for a majority of hematologists

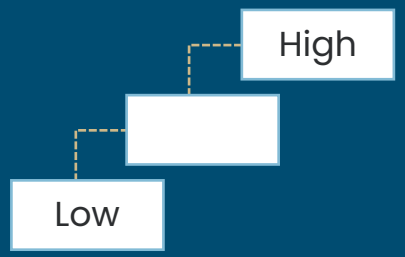
Eversana market research
CRS: Cytokine Release Syndrome

BI-1206 Clinical Study Overview

- Phase 1: BI-1206 enhances the activity of rituximab *(next slide)*
- Phase 2a: Adding acalabrutinib to the combination results in impressive efficacy (and Safety!)

Phase 1
BI-1206 + rituximab (Doublet)

Dose Escalation Adaptive



Selection of Phase 2a SC Dose

COMPLETED

Phase 2a
BI-1206 + rituximab + acalabrutinib (Triplet)

Signal Seeking

Safety Run-in

150 mg (n = 6) → 225 mg (n = 6)

Dose expansion

Signal Seeking Dose (225 mg) (n = up to 15)

COMPLETED

COMPLETED ENROLMENT

Triplet Combination Results in High Response Rates Across NHL Subtype

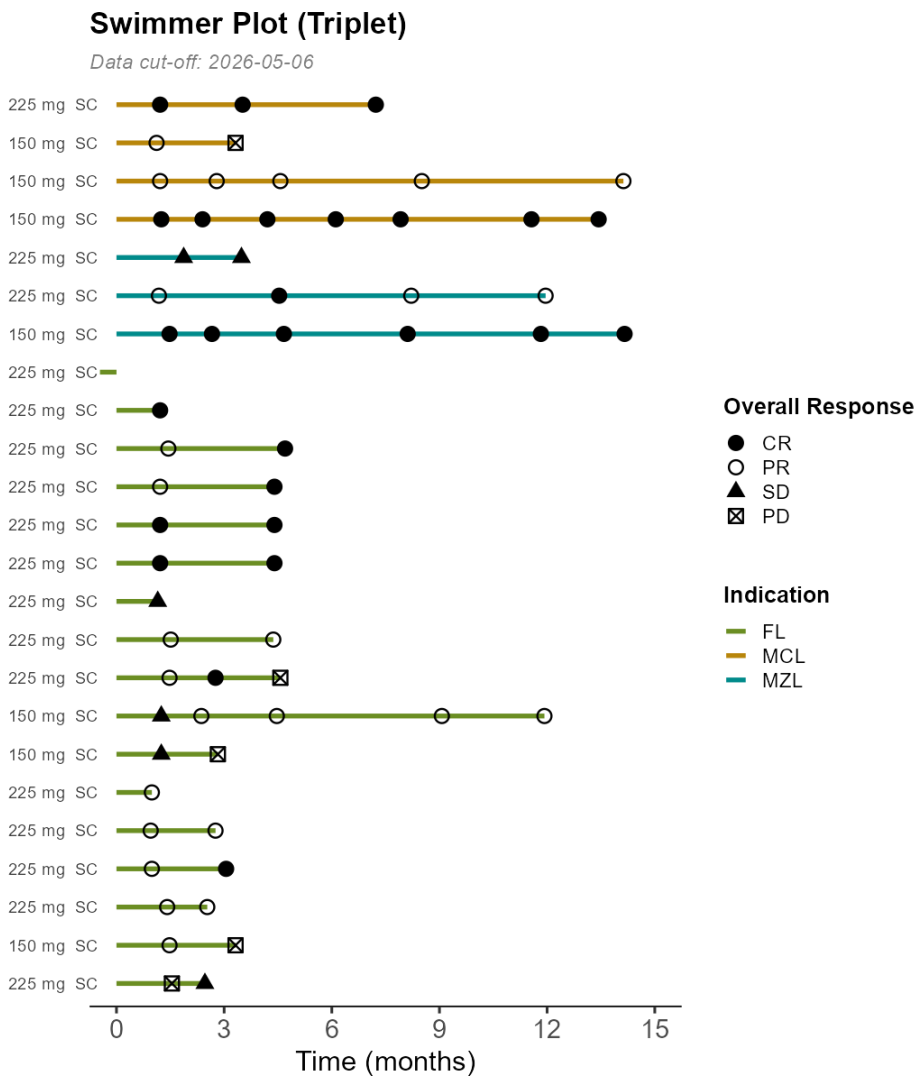
83% ORR (n=23)	**48%** CRR	**100%** DCR	**81%** ORR in **FL** (n=16)	**44%** CRR in **FL**	**No CRS · No ICANS** No increased infection rate

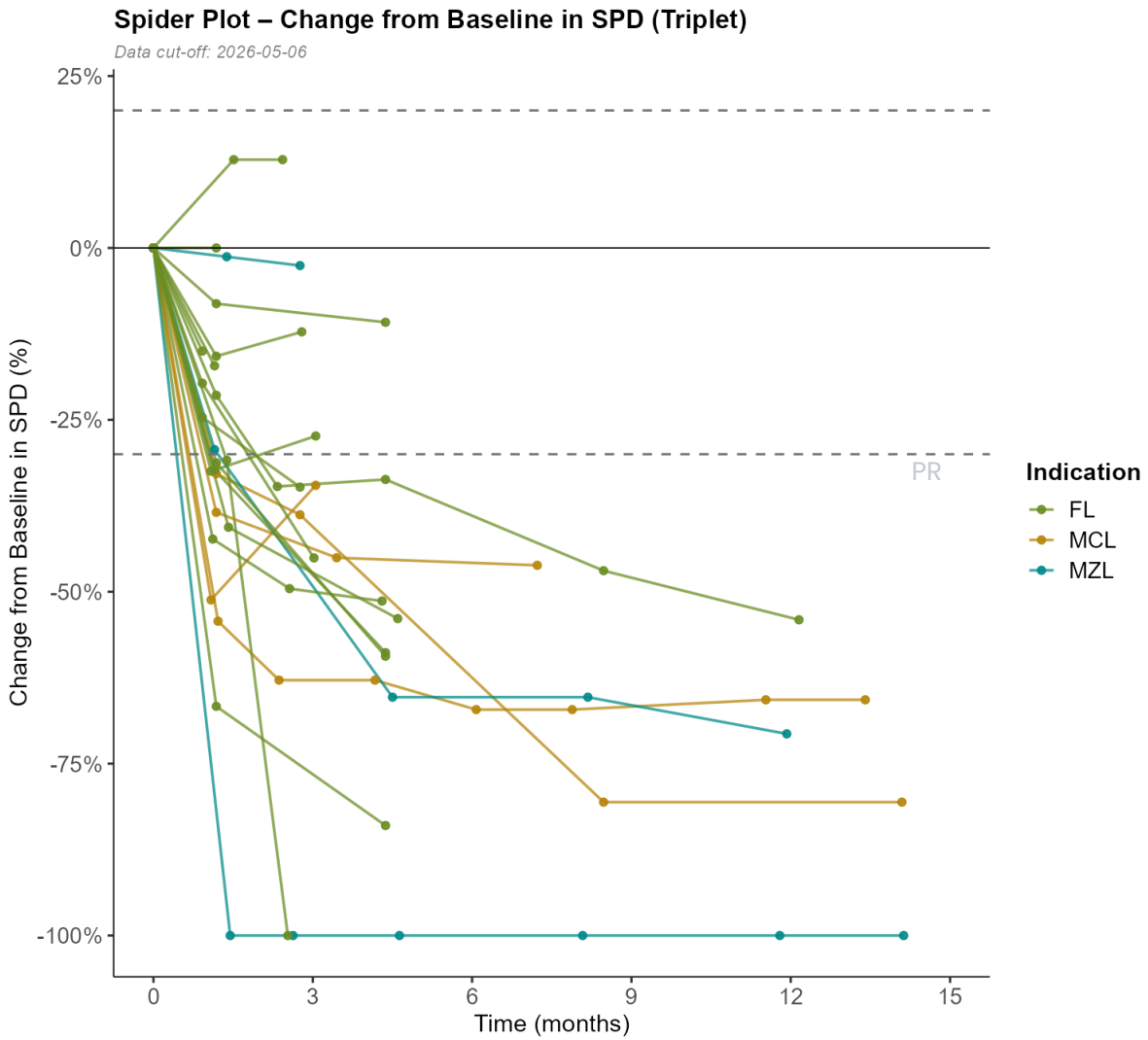
- **ORR of 83%, CRR of 48% and DCR of 100%** (n=23)
- Best Response in 23 evaluable patients:
  - 11 complete responses (CR)
  - 8 partial responses (PR)
  - 4 Patients with stable disease (SD)
- In the **follicular lymphoma (FL) subset (n=16), ORR was 81% and CRR 44%**
- The treatment has been **well-tolerated with no safety or tolerability concerns**
  - No CRS
  - No ICANS
  - No increased rate of infections

Waterfall plot of **BI-1206 + rituximab + acalabrutinib** triplet across NHL subtype. Response assessed through FDG-PET according to Lugano criteria (changes in metabolic parameters).

Data cut-off 2026-05-06

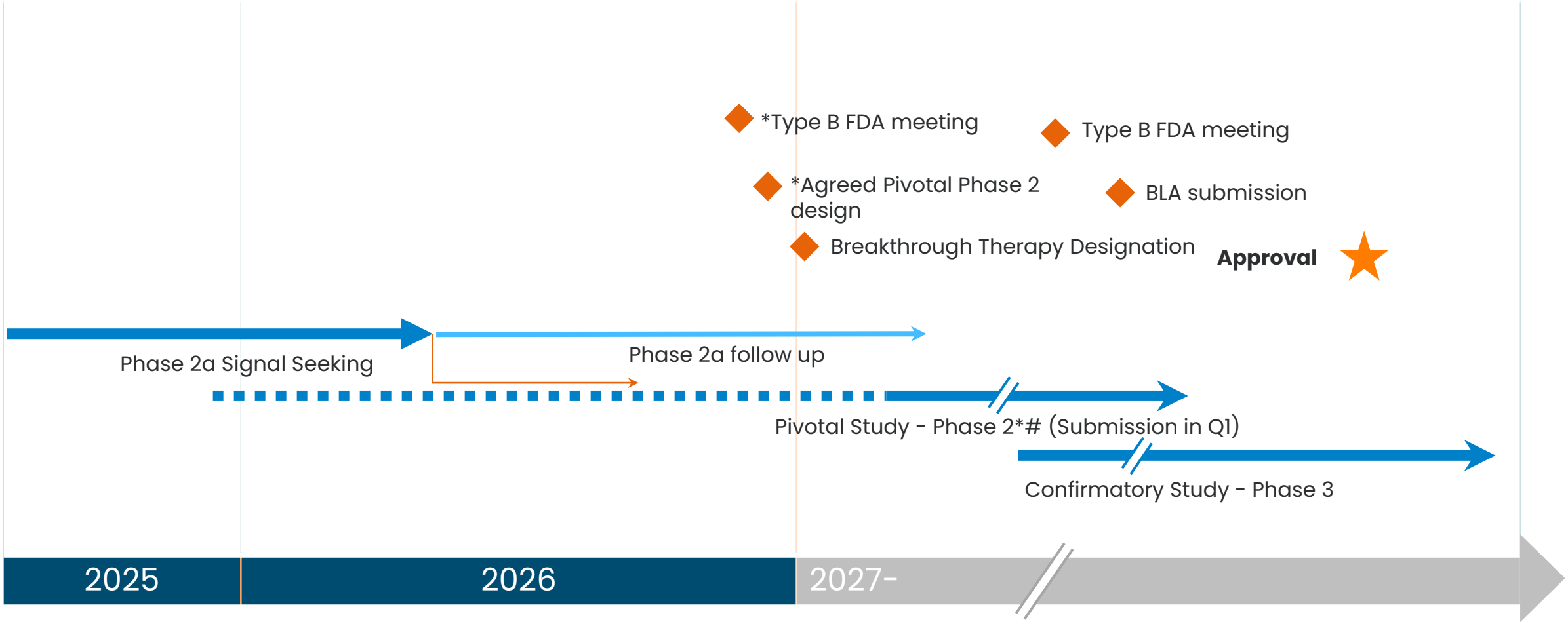
BI-1206 + Rituximab + Calquence* Triplet: Best Response (FL, MZL, MCL)





* Acalabrutinib, supplied by AstraZeneca. Data cut-off 2026-05-06

BI-1206 in NHL: Combination with Rituximab + Acalabrutinib - Potential Timelines



*Depending on partnering discussions
Depending on acceptance of development plan by FDA

BI-1206 Positioning in Follicular Lymphoma

- In FL, repeated exposure to **Rituximab leads to resistance** via FcγRIIB-mediated internalization; **BI-1206 blocks** this escape route, potentially "resensitizing" the tumor to CD20 therapy even in heavily pre-treated patients.
- While BTK inhibitors (e.g., zanubrutinib) are approved in FL, their monotherapy activity is modest; this triplet aims to exceed the efficacy of the zanubrutinib + obinutuzumab standard (69% ORR) by **adding a distinct mechanism of action without adding chemotherapy**.
- Designed as **an effective alternative to bispecific antibodies** (mosunetuzumab, epcoritamab) but with no risk of CRS or ICANS, allowing for **easy administration** in community oncology practices without complex monitoring.
- Positions the **therapy for "early progressors“** or frail elderly patients who need deep responses but cannot tolerate the toxicity of chemotherapy or the logistics of CAR-T.
- Combines intracellular B-cell receptor blockade (**acalabrutinib**) with optimized extracellular immune clearance (**BI-1206 + rituximab**) to attack the indolent lymphoma clone from two independent angles.
- With the subcutaneous (SC) formulation of BI-1206, this creates a **patient-friendly, injection-based regimen that avoids the burden of long infusions.**

BTK: Bruton’s Tyrosine Kinase, ICANS: Immune Effector Cell-Associated Neurotoxicity Syndrome

Key Expected Milestones 2026-2027

	2026	2027
TNFR2 BI-1808	Ovarian cancer: Additional Phase 2a data with Keytruda ✓; Additional Phase 2a data with Keytruda	First Phase 2a data triplet + Keytruda +Paclitaxel
	CTCL: First Phase 2a data with Keytruda + additional monotherapy data ✓	Complete Phase 2a data dose optimization, monotherapy; Potential start of pivotal study

	2026	2027
FcyRIIB BI-1206	NHL (FL, MCL, MZL): Additional Phase 2a data with rituximab + Calquence ✓	Potential start of pivotal triplet
	NSCLC 1L, Uveal melanoma 1L: First read-out Phase 2a data with Keytruda	Potential start Phase 2b + Keytruda

1L: First line treatment
CTCL: Cutaneous T-cell Lymphoma, NHL: Non-Hodgkin's Lymphoma, FL: Follicular Lymphoma, MCL: Mantle Cell Lymphoma, MZL: Marginal Zone Lymphoma, NSCLC: Non-small cell lung cancer

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Appendix

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Chief Financial Officer
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Andres McAllister, M.D., Ph.D.
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Kristoffer Rudenholm Hansson
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AGC Biologics (Your friendly CDMO expert) · Dako · Servier Symphogen

Sylvie Ryckebusch, Ph.D.
Chief Business Officer
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Merck · Domain Therapeutics · Index Ventures · McKinsey & Company

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