



Biolnvent

**UNLEASHING IMMUNITY
TO FIGHT CANCER**

January 2025

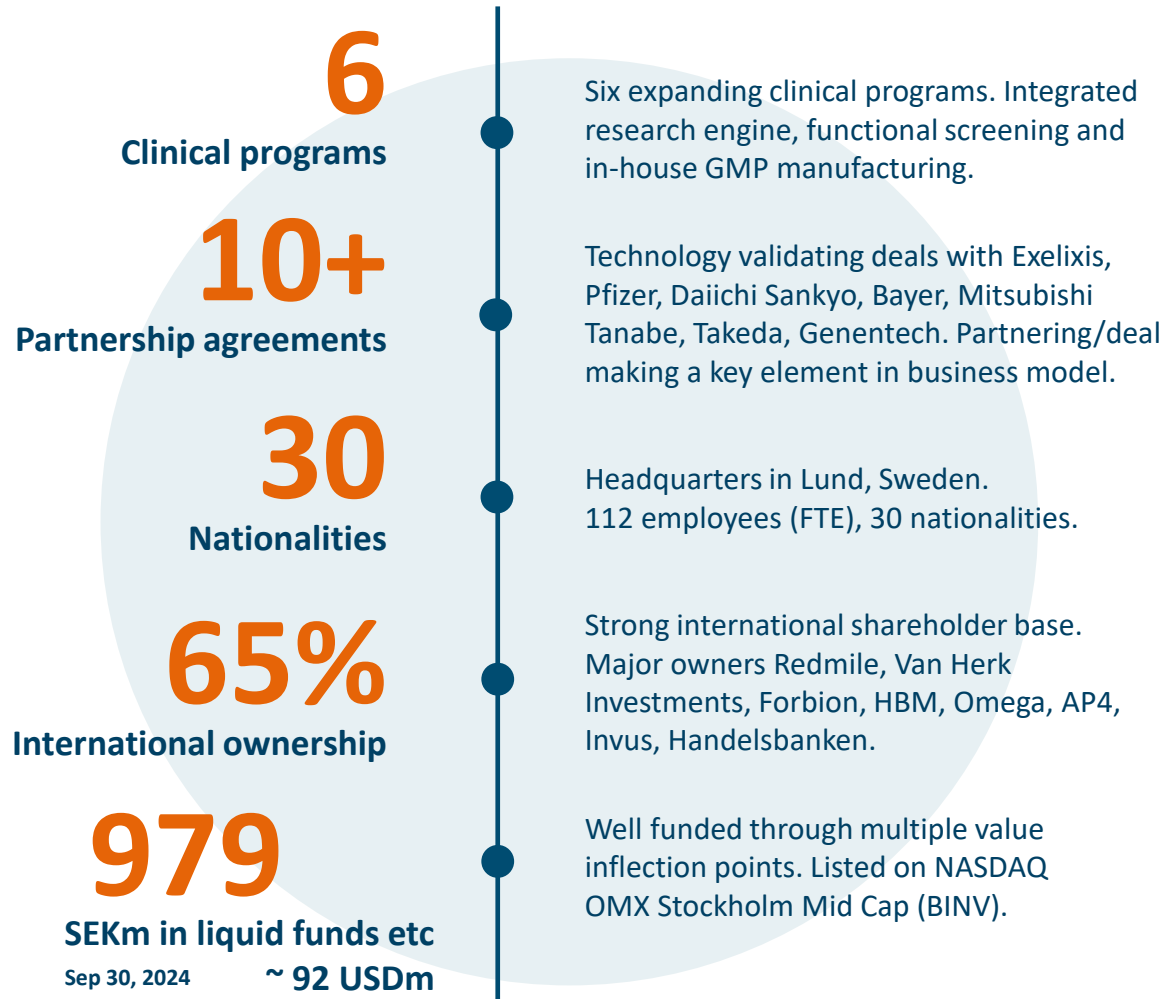
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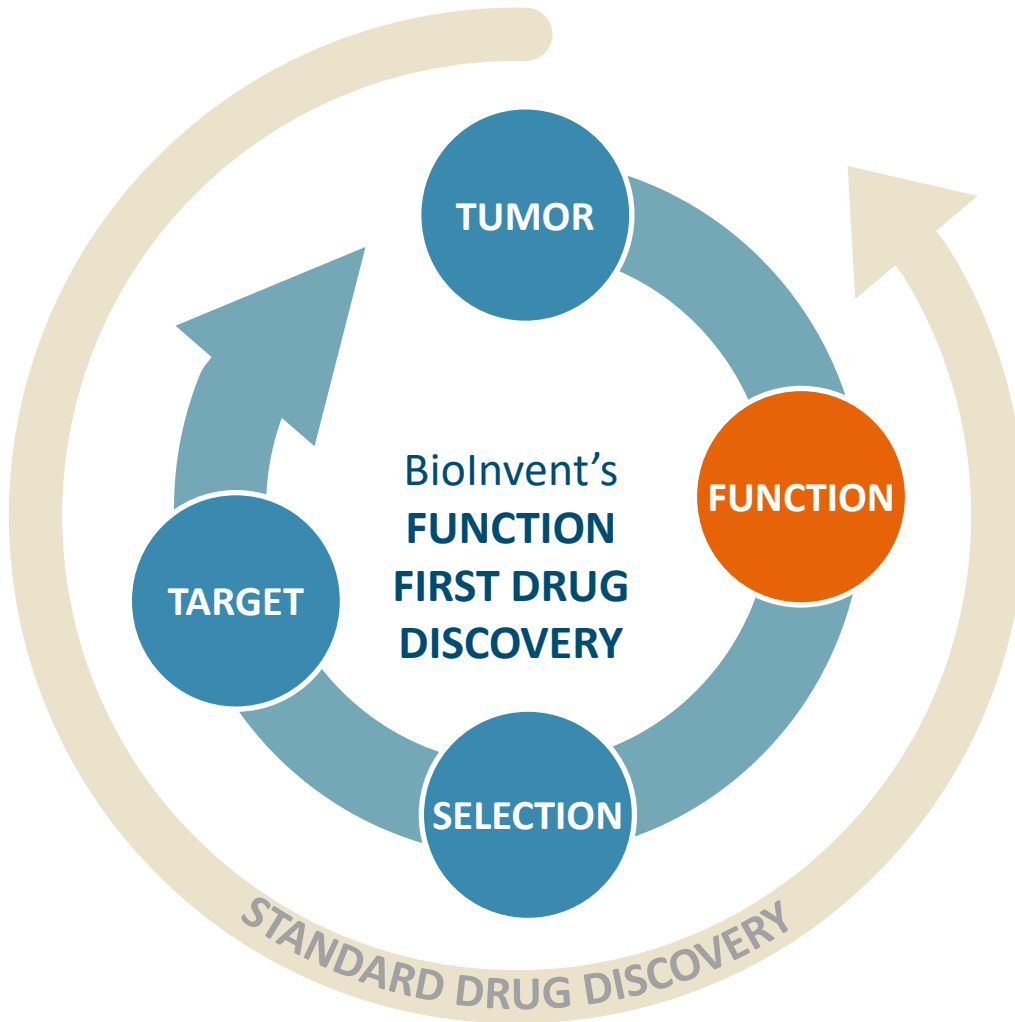
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Translating complex cancer biology into innovative antibody therapies

BUILDING A PIPELINE: OUR STATE-OF-THE ART ANTIBODY TECHNOLOGY



Proprietary **F.I.R.S.T.™** platform is the engine discovering novel cancer treatments

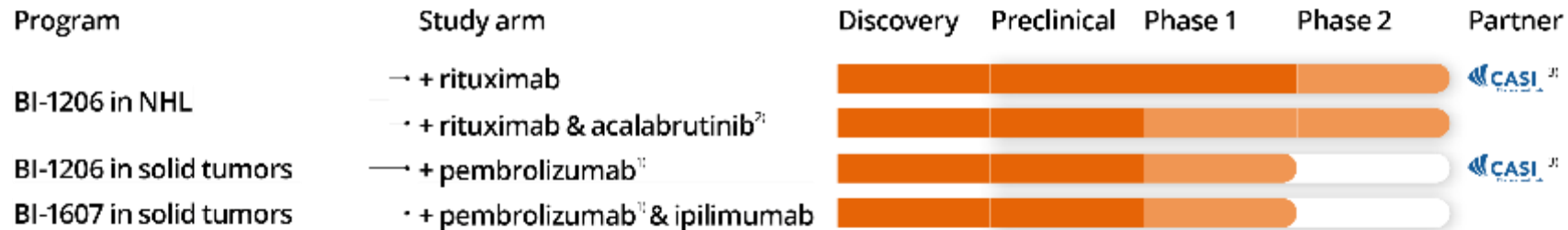
While others often focus on the targets and test function at the end, **we start from the function** (drug efficacy).

STRONG PROPRIETARY CLINICAL PIPELINE WITH MULTIPLE VALUE DRIVERS

TNFR2



FcyRIIB



CTLA-4



1) Supply agreement with MSD

2) Supply agreement with AZ

3) Licensed to CASI for China, Hong Kong, Macau and Taiwan

4) 50/50 co-development collaboration with Transgene

Completed Ongoing



ANTI-TNFR2

BI-1808

BI-1910

BIOINVENT LEADS THE WAY IN TNFR2 BIOLOGY

- A New And Exciting Potential Treatment Opportunity

Out of hundreds of antibodies
two highly potent candidates with
different MoAs were selected:

BI-1808 - a ligand-blocking FcγR-engaging mAb

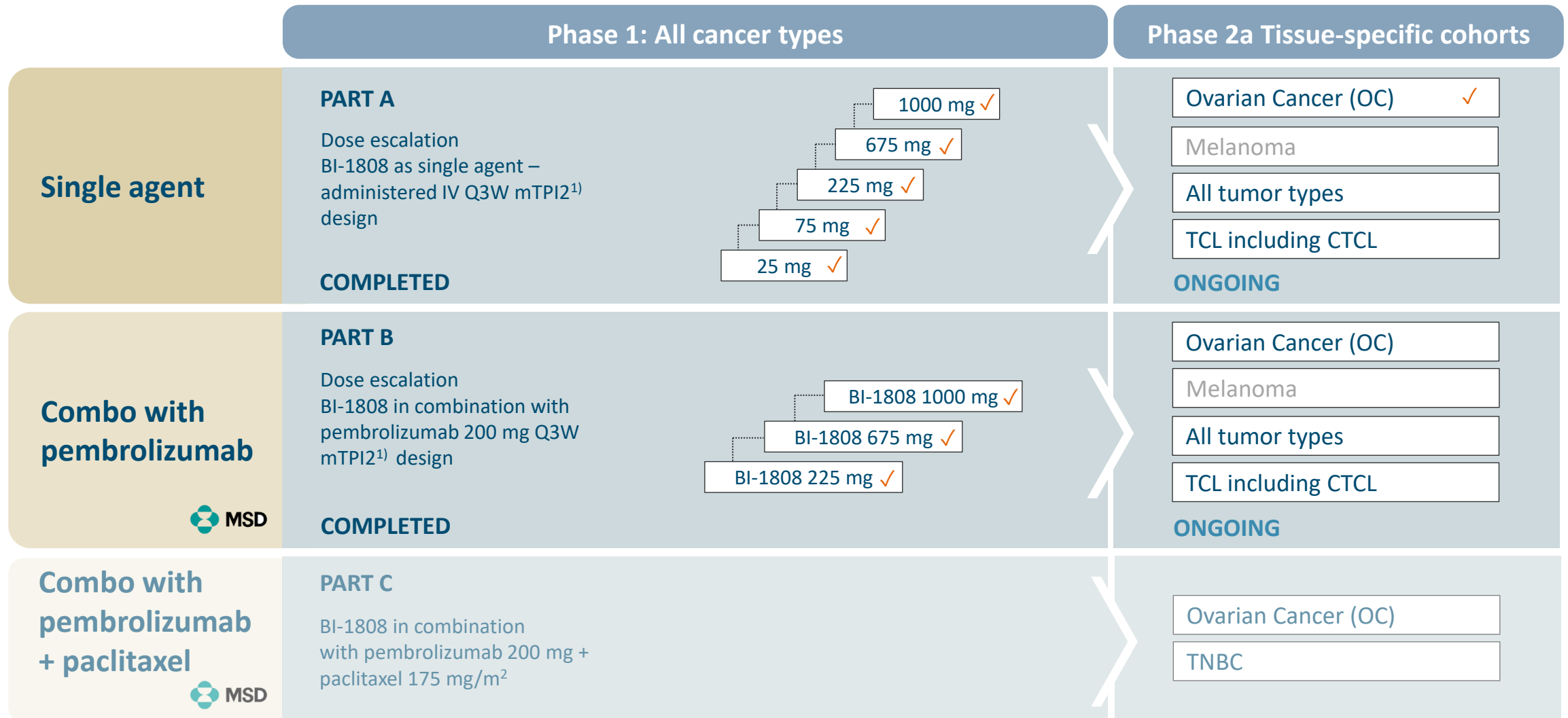
BI-1910 - an agonist mAb

Our focus is to pursue both MoA's to ensure patient benefit

Competitors are developing either agonists or antagonists

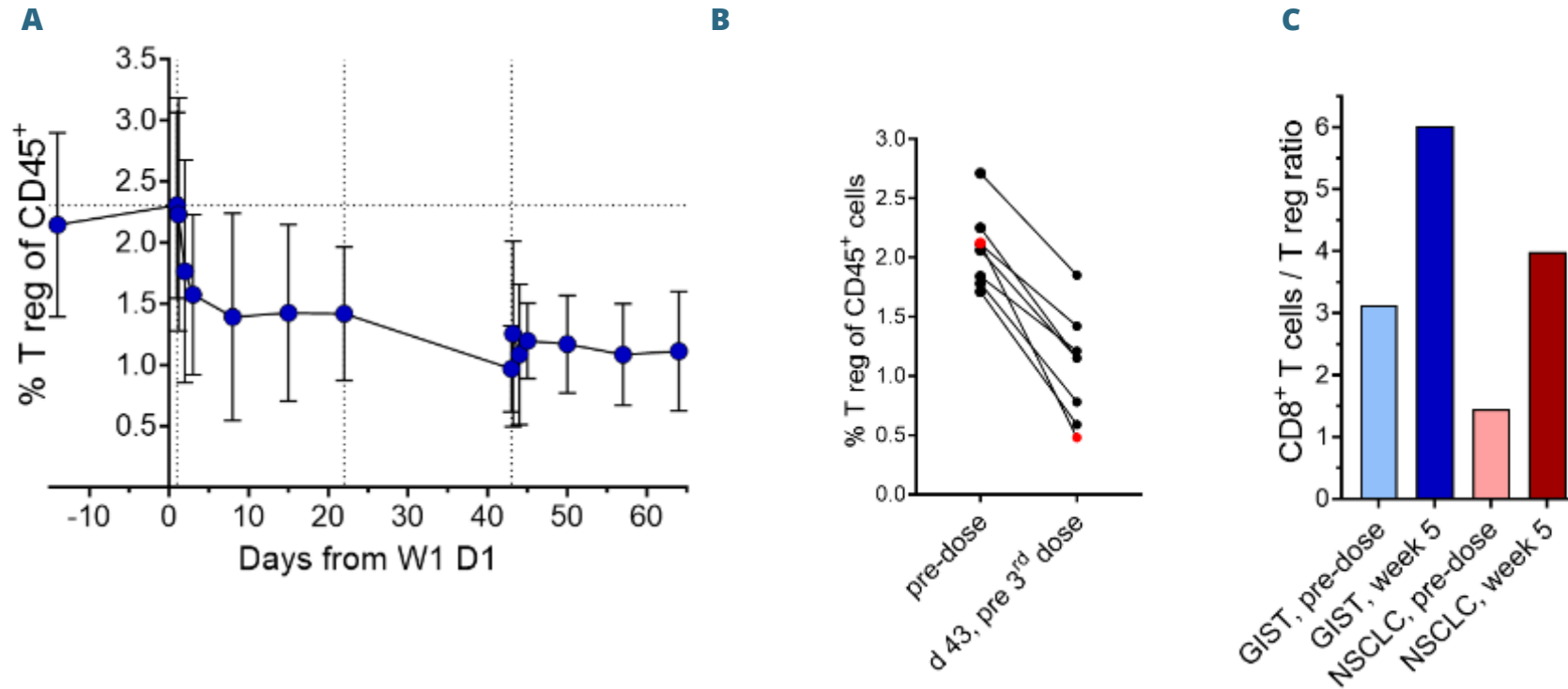
Drug Name	Company Name	Stage	Description
BI-1808	BioInvent	Phase 2	Human IgG1 Blocker/Depleter
BI-1910	BioInvent	Phase 1	Human antibody Agonist
LBL-019	Nanjing Leads Biolabs	Phase 1/2	Humanized IgG1 Blocker
SIM-0235	Simcere	Phase 1	Humanized IgG1 antibody Blocker/Depleter
HFB-200301	HiFiBiO	Phase 1	Humanized murine (IgG1) Agonist
NBL-020	NovaRock Biotherapeutics/ CSPC	Phase 1	Humanized IgG? Blocker
BIR-2101	BITT / BeiGene	IND-approved	Humanized IgG2 (variant) Antagonist
APX-601	Apexigen/Pyxis Oncology	IND ready	Humanized rabbit IgG1 Blocker/Antagonist
AN3025	Adlai Nortye/Biotime	IND-enabling	Humanized IgG1 (variant) Antagonist

BI-1808: KEYNOTE-D20 PHASE 1/2A CLINICAL STUDY DESIGN



BI-1808 SINGLE AGENT EFFICACY

Induces significant regulatory T-cell depletion and clear signs of CD8⁺ T-cell activation in responding patients



Tumor biopsies collected pre-, and 5 weeks post-treatment were stained for Foxp3⁺ CD4⁺ Treg cells and CD8⁺ T cells using immunofluorescence.

Percentages of stained area were quantified and a pre- and post-treatment CD8⁺/T reg ratio were calculated.

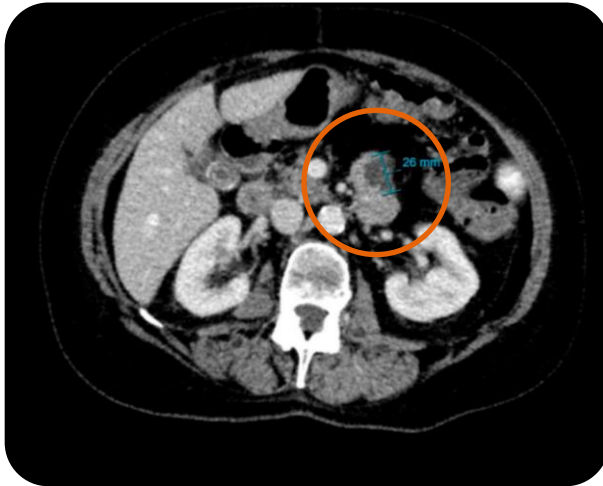
BI-1808 increases intratumoral CD8⁺/T reg ratio

Data from the 1000 mg monotherapy cohort.

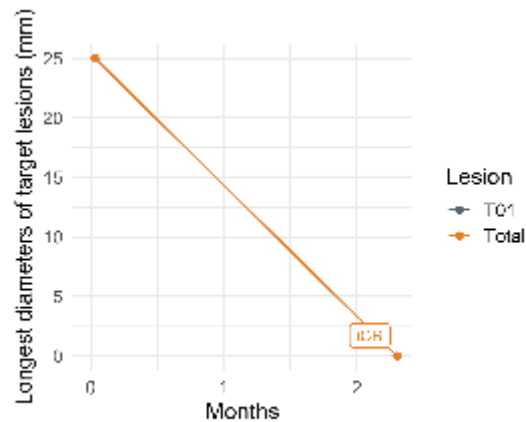
The data show substantial **T-reg depletion** compared to baseline. Panel B shows the individual patient drop in T-reg. Red dots indicate the drop in the GIST patient. (Dashed horizontal line = baseline. Dashed vertical lines = BI-1808 dosing occasions)

CASE STUDY: COMPLETE RESPONSE IN OVARIAN CANCER

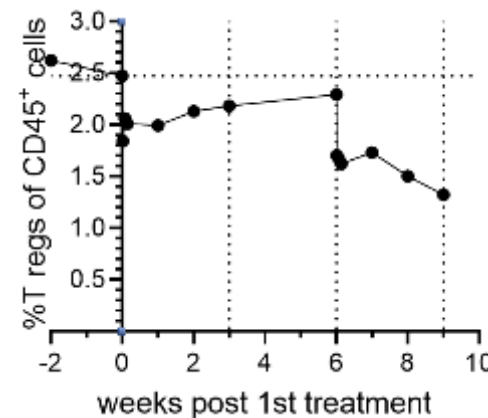
Baseline



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:

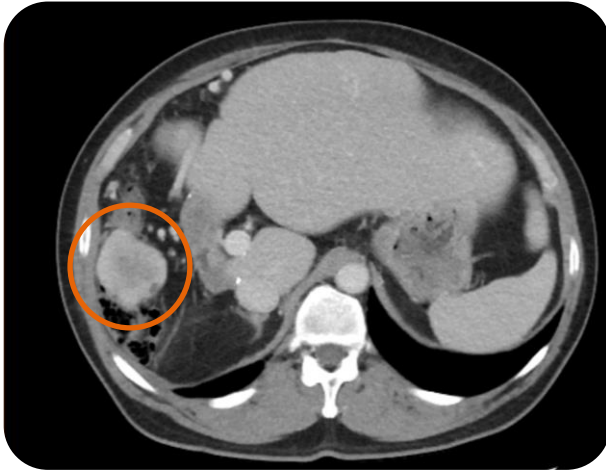
- Paclitaxel/carboplatin
- Carboplatin/doxorubicin
- Olaparib
- Bevacizumab/topotecan

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

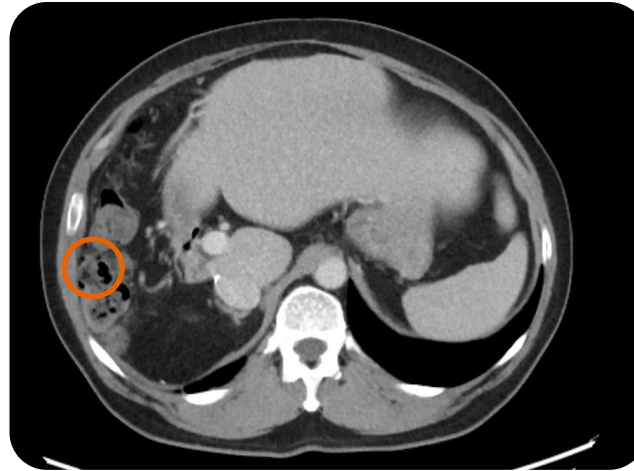
At first post-treatment scan, 9 weeks after the start of treatment, no quantifiable tumor mass could be measured.

CASE STUDY: ROBUST PR IN A PATIENT WITH GIST

Baseline

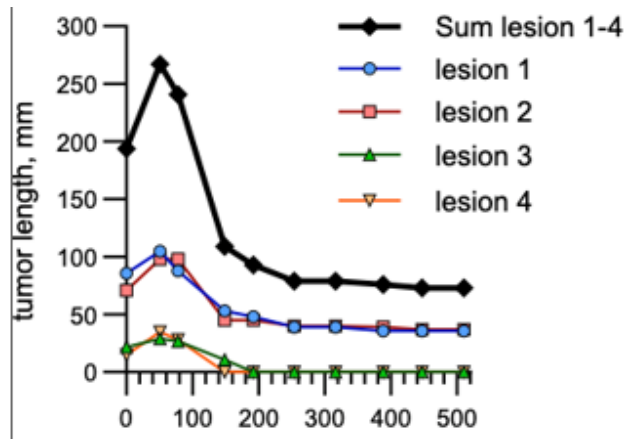


Follow-up 13 months

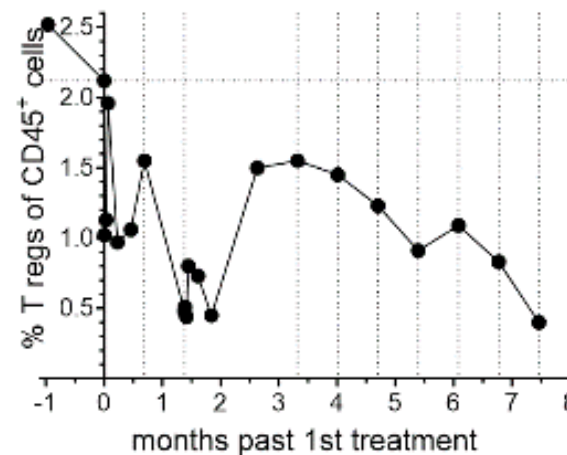


55-year-old male patient with GIST, who presented with clinical PD for more than 6 months with multiple metastatic lesions. **12 previous lines of therapy.**

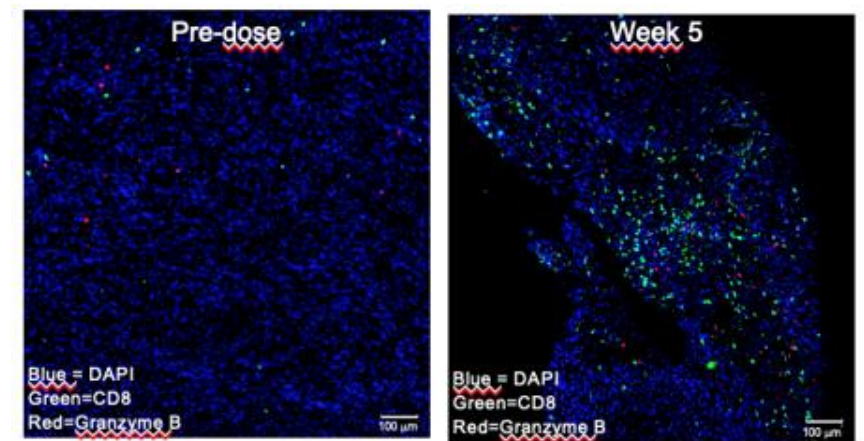
The partial response continues to improve after more than 80 weeks (Dec 2024).



Tumor assessment vs time on study (days)



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



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

BI-1808 **SINGLE AGENT** AND IN COMBINATION WITH **PEMBROLIZUMAB**

Strong BI-1808 single agent activity in CTCL

(September 2024)

- **3 partial responses (PR)** currently ongoing and deepening
- **1 patient with stable disease (SD)**
- 4 evaluable CTCL patients
- All of these patients had **previously deteriorated** after standard treatment

Clinical Phase 1/2a study ongoing

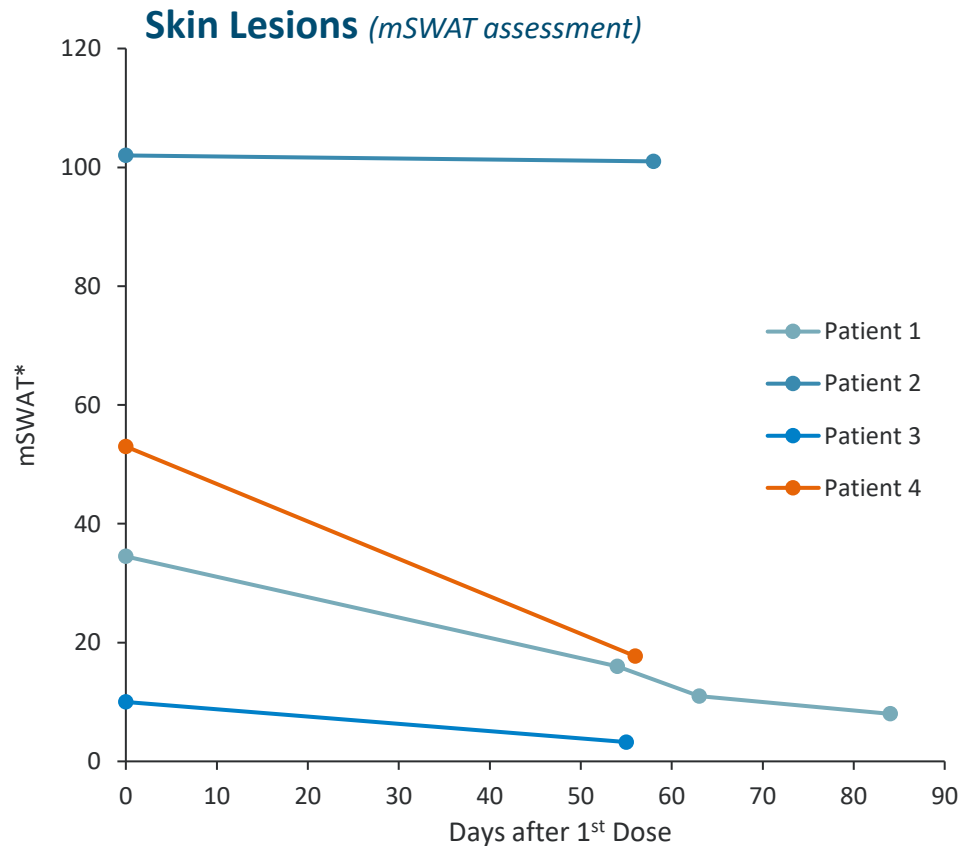
- Earlier disclosed **single agent data (ASCO 2024)** showed 1 complete response (CR) in ovarian cancer, 1 PR in GIST that continues to improve after more than 80 weeks (cut-off Dec 2024). Furthermore, 9 patients showed SD (26 evaluable patients).
- Promising signs of efficacy and favorable safety profile in Phase 1 dose escalation with **BI-1808 in combination with KEYTRUDA®** also presented at ASCO 2024. Phase 2a dose expansion study with pembrolizumab ongoing.

WHAT'S NEXT?

- **Additional single agent Ph 2a data mid-2025E**
- **First Ph 2a pembrolizumab combination data H2 2025E**

OUTSTANDING EARLY RESPONSES IN EXHAUSTIVELY PRE-TREATED CTCL PATIENTS

- 4 patients are evaluable post treatment
- 3 exhibited partial response (50-99% decrease from baseline), with 1 patient showing stable disease



Prior Treatment in responding CTCL patients

Diagnose	Regimen	Prior treatment	Best prior response	BI-1808 response
MYCOSIS FUNGOIDES	Regimen 1	BEXAROTENE	Not Evaluable (NE)	PR
	Regimen 2	METHOTREXATE VALCHLOR GEL	Partial Response (PR)	
	Regimen 3	DURVALUMAB	Partial Response (PR)	
MYCOSIS FUNGOIDES	Regimen 1	METHOTREXATE	Stable Disease (SD)	PR
	Regimen 2	TTI-621	Complete Response (CR)	
	Regimen 3	BNZ-131-1-40	Stable Disease (SD)	
	Regimen 4	LENALIDOMIDE /DURVALUMAB	Partial Response (PR)	
	Regimen 5	METHOTREXAT / IMIQUIMOD CREAM	Not Evaluable (NE)	
	Regimen 6	MOGAMULIZUMAB	Stable Disease (SD)	
SEZARY SYNDROME (IV)	Regimen 1	MOGAMULIZUMAB	Stable Disease (SD)	PR
	Regimen 2	PEGASYS 180 MCG/ML SUBCUTANEOUS SOLUTION (PEGINTERFERON ALFA-2A)	Stable Disease (SD)	
	Regimen 3	ROMIDEPSIN	Unknown	

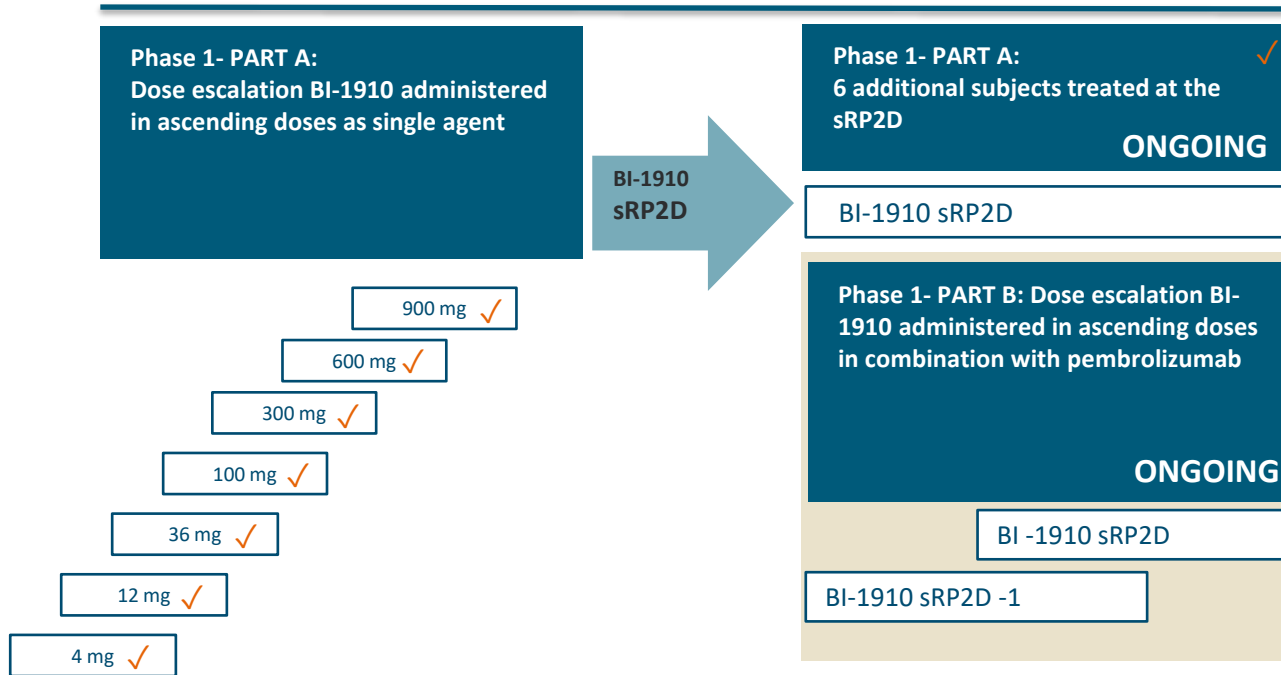
*mSWAT (Modified Severity-Weighted Assessment Tool), a disease score

BI-1808 POSITIONING IN THE MARKET LANDSCAPE

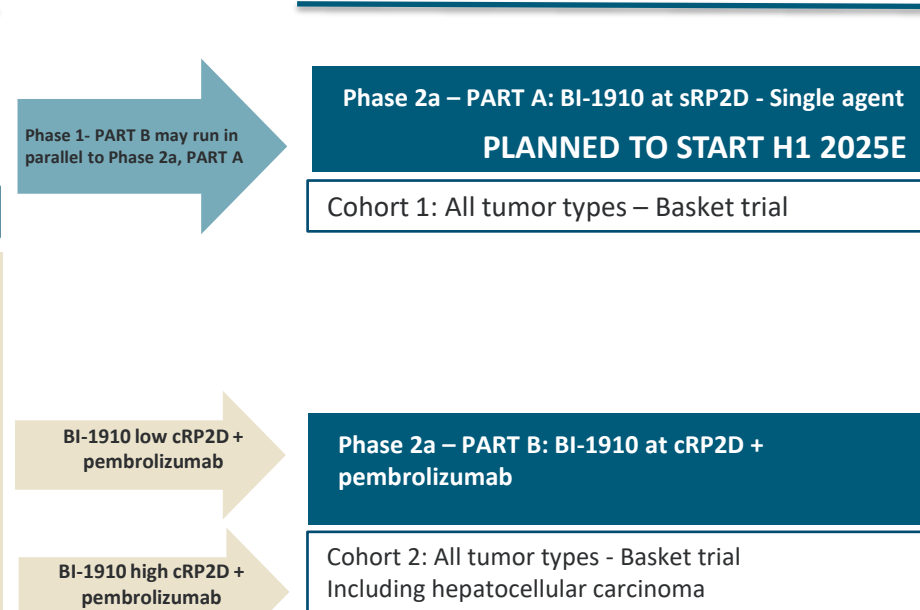
- BI-1808 can be **developed as frontline** for the treatment for **Mycosis Fungoides** and **Sézary Syndrome (CTCL)**:
 - Exceptional Safety and Tolerability profile for the treatment of a chronic devastating disease
 - All available therapies are deficient from the safety and efficacy standpoint
 - ORR $\geq 40\%$ will comfortably place BI-1808 as the treatment of choice in the **front line**
 - Potential market opportunity as first line monotherapy
 - High market potential in a short timeframe
- In addition, the **largest commercial** potential of BI-1808 is for the treatment of **solid tumors**:
 - Demonstrated single agent activity and induction of antitumor immunity in several patients across different types of malignancies (OC, NSCLC, GIST, TCL)
 - Demonstrated synergistic activity with anti-PD1 in preclinical models
 - Exceptional safety profile makes it ideal for a cocktail component with anti-PD1/L1 in several tumor types

BI-1910 STUDY DESIGN

All Solid Tumors Phase 1



Tissue-specific cohorts Phase 2a



RP2D=recommended phase 2 dose; cRP2D=combination RP2D; sRP2D= single agent RP2D

BI-1910: SINGLE AGENT AND IN COMBINATION WITH PEMBROLIZUMAB

Promising Phase 1 data for BI-1910 as single agent

(January 2025):

Clinical Phase 1/2a study ongoing

- BI-1910 single agent **Phase 1** Part A **dose escalation completed** and reached a biologically active dose level
- **Stable disease** (6/12 evaluable patients) as **best clinical response** with no notable adverse events even at the highest doses tested
- Favorable pharmacokinetic data and a **robust target engagement**, showing evidence of induction of T-cell proliferation
- As clinical response and biomarker data mature from the Phase 1 patients, **Phase 2a with BI-1910 as single agent planned to start in H1 2025** in several tumor types including HCC (hepatocellular cancer) patients
- First patients have been enrolled in the **Phase 1 Part B study of BI-1910 in combination with pembrolizumab***.

ANTI-Fc γ RIIB

BI-1206 + rituximab + acalabrutinib

BI-1206 + pembrolizumab

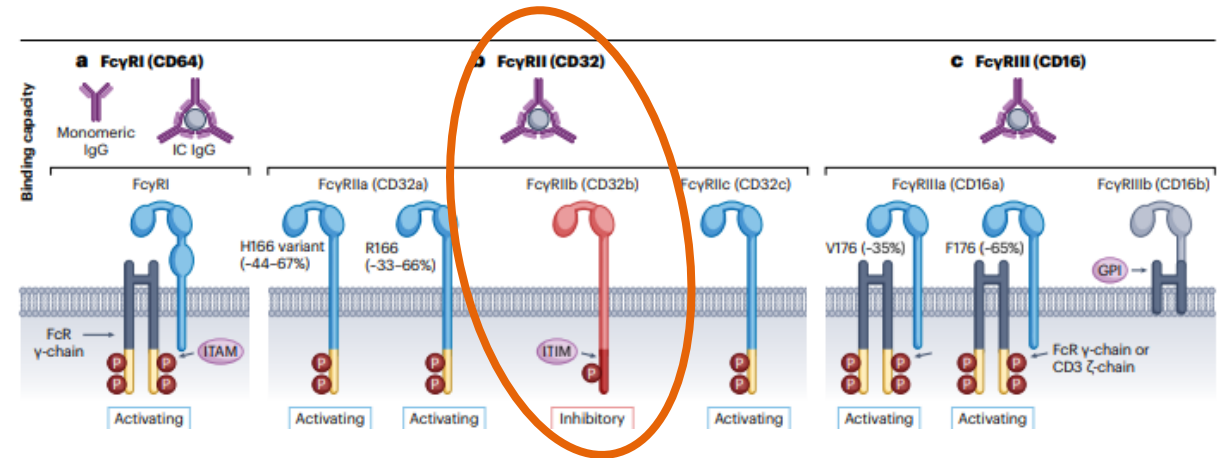
BI-1607

LEVERAGING OUR FcγRIIB TARGET EXPERTISE WITH A MULTI-PRONGED APPROACH

We have developed two antibodies with different mechanisms of action to tackle different needs

BI-1206 is an Fc-competent IgG1 antibody that enhances anti-CD20 and anti-PD-1 therapies. In **two separate programs**.

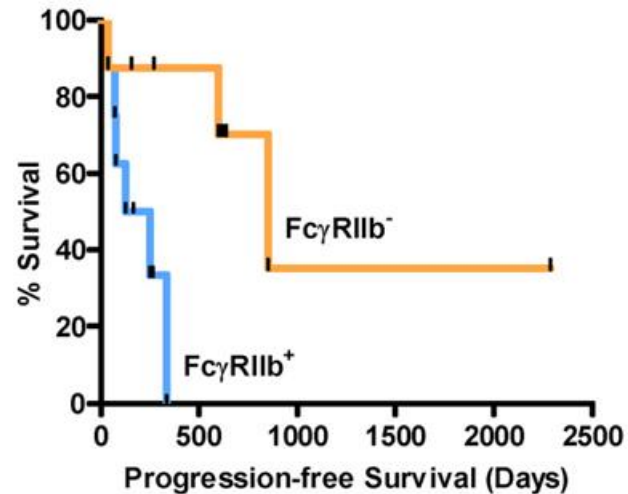
BI-1607 has a different MoA compared to BI-1206 having been engineered for reduced Fc-binding to FcγR.



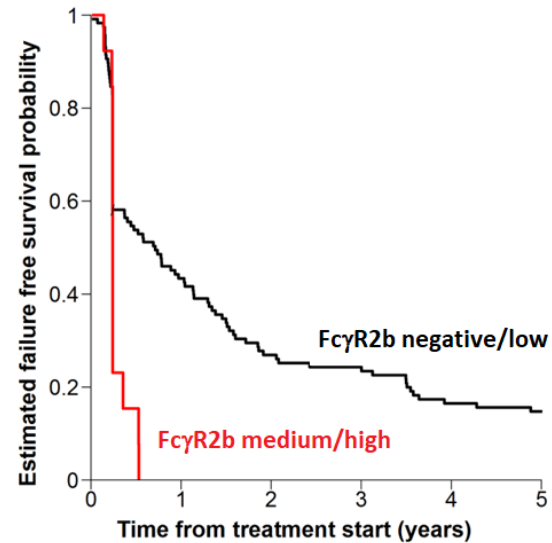
Galvez-Cancino, F., Simpson, A.P., Costoya, C. et al. Fcγ receptors and immunomodulatory antibodies in cancer. *Nat Rev Cancer* **24**, 51–71 (2024). <https://doi.org/10.1038/s41568-023-00637-8>

FcγRIIB EXPRESSION CORRELATES INVERSELY WITH SURVIVAL

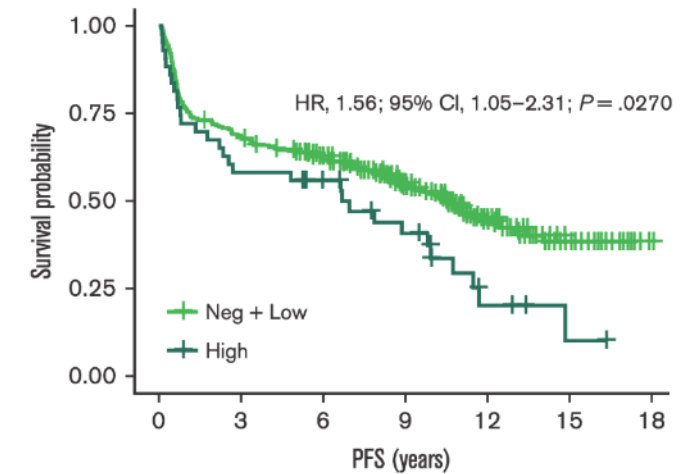
Mantle Cell Lymphoma



Follicular Lymphoma



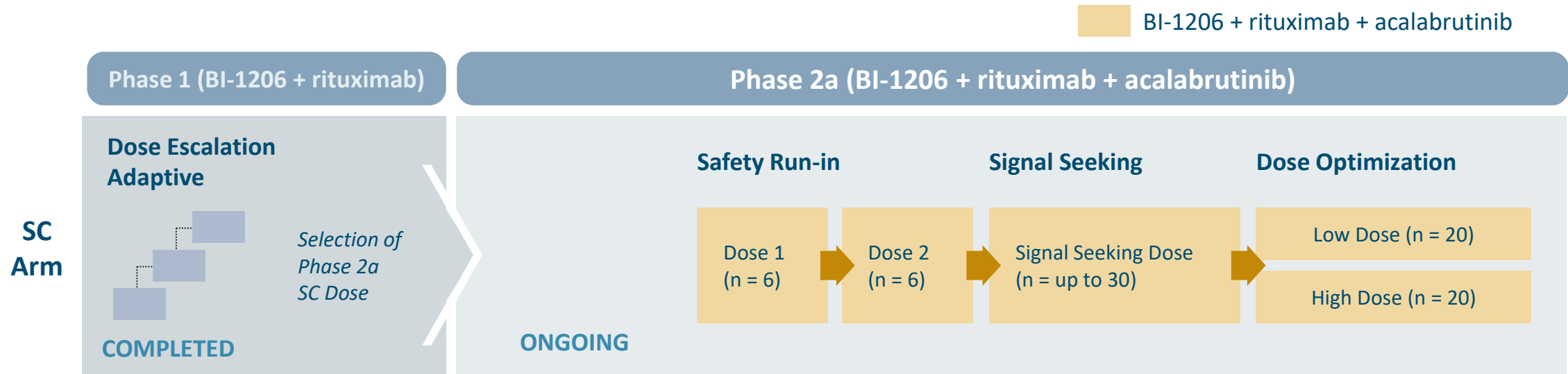
Diffuse Large B-Cell Lymphoma



High FcγRIIB expression is associated with shorter survival in patients receiving rituximab therapy

BI-1206 IN NHL: COMBINATION WITH RITUXIMAB AND ACALABRUTINIB

- Approximately **30 patients** expected to be enrolled in Spain, Germany, the US, and Brazil



WHAT'S NEXT?

Additional Phase 2a triplet data mid-2025E

BI-1206 IN NHL: COMBINATION WITH RITUXIMAB AND ACALABRUTINIB

Promising initial efficacy Phase 2a data from BI-1206 SC triple combination arm

(January 2025)

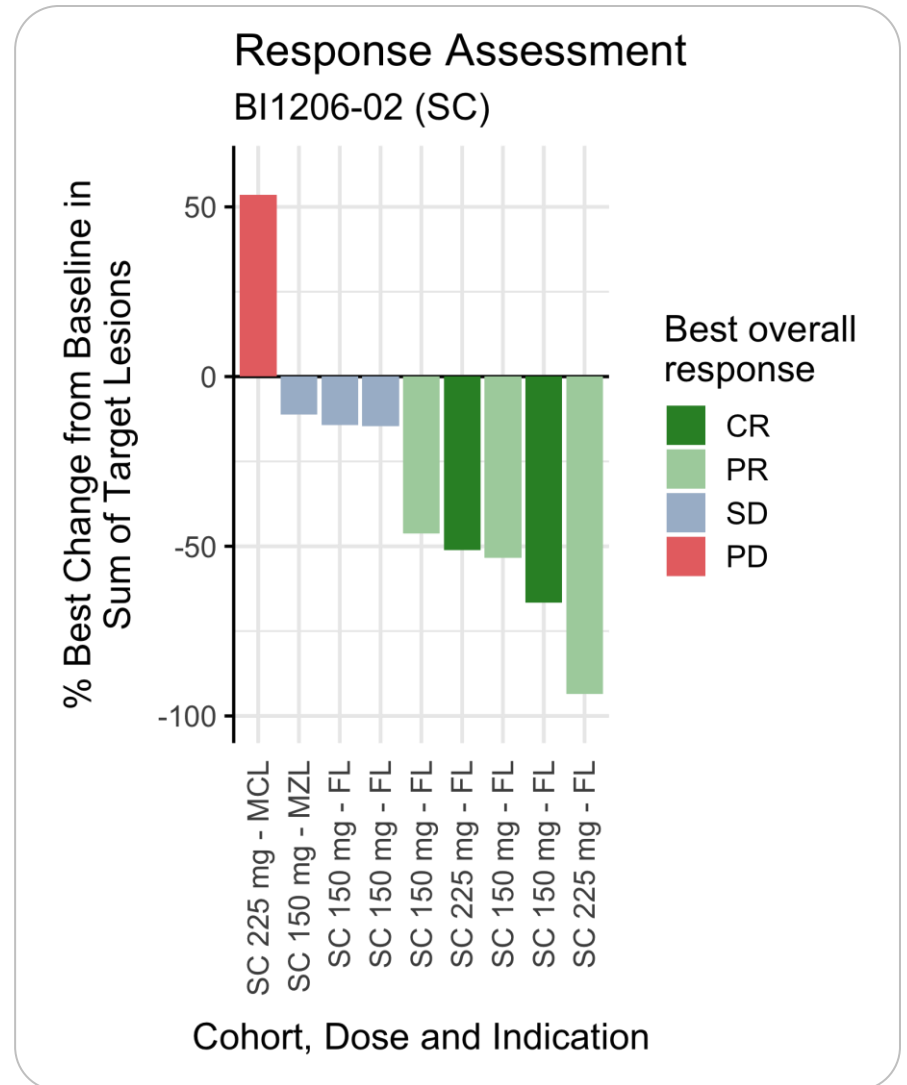
- The **first two patients** enrolled in the **Phase 2a study triplet** arm combining BI-1206 with rituximab and Calquence® responded to treatment
 - One complete response (**CR**) and one partial response (**PR**)
 - The treatment has been well-tolerated with no safety or tolerability concerns
- Phase 1/2a clinical study in patients with NHL who have **progressed or are refractory to rituximab**
- The **conveniency and safety profile** of this **triplet** should be **very competitive** in the treatment landscape of NHL

BI-1206 IN NHL: DATA FROM PHASE 1 SC DOSE ESCALATION WITH RITUXIMAB

Impressive clinical efficacy data BI-1206 SC and rituximab (*doublet*)

(cut-off October 31, 2024)

- 2 complete responses (CR)
- 3 partial responses (PR)
- 3 stable disease SD
- Out of 9 evaluable patients

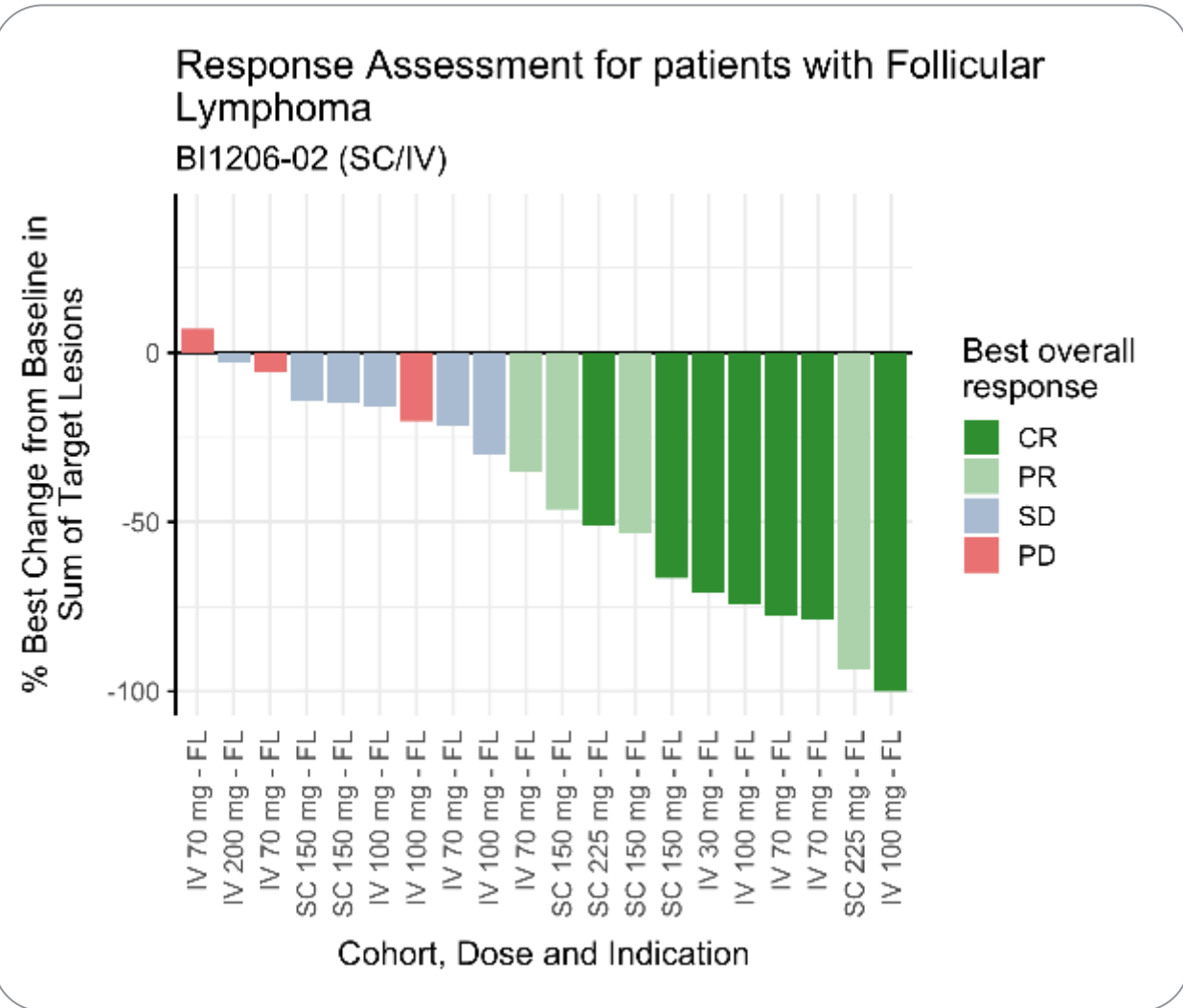


CO-ADMINISTRATION OF BI-1206 WITH RITUXIMAB LED TO HIGH RESPONSE RATES IN RELAPSED/REFRACTORY FL PATIENTS

Quality of responses particularly impressive in FL

(October 2024, SC + IV):

- 7 complete responses (CR)
- 4 partial responses (PR)
- 6 patients with **stable disease** (SD)
- Out of 20 evaluable **FL patients**
- **ORR** of 55%, **CRR** of 35%, **DCR** 85%
- **CRs** have been **long-lasting**, three of them **lasting years after** end of treatment
- **No safety or tolerability concerns**



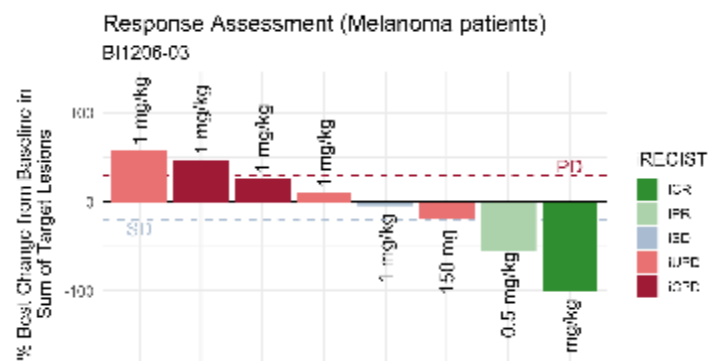
Promising efficacy signals in Phase 1

- **1 complete response (CR)** (lasting for approx. two years)
- **1 partial response (PR)** in uveal melanoma
- **8 patients with stable disease (SD)** including one long-lasting (≥ 2.5 years)
- 28 evaluable patients
- Co-administration of BI-1206 with pembrolizumab was **well-tolerated** in a **heavily pretreated population**

WHAT'S NEXT?

Further Phase 1 data BI-1206 & pembrolizumab* mid-2025E

Contact information: 18-01-206-130@icmr.gov.in
Study identifier: ICT number: 2023-206045-18-0
Clinicaltrials.gov ID: NCT054215054

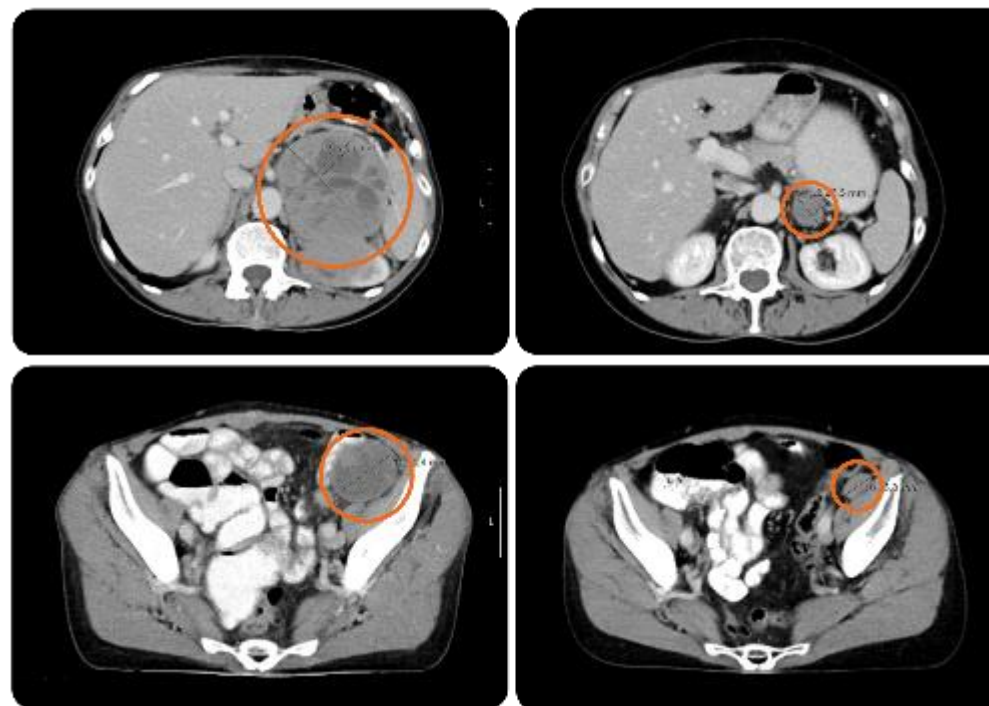
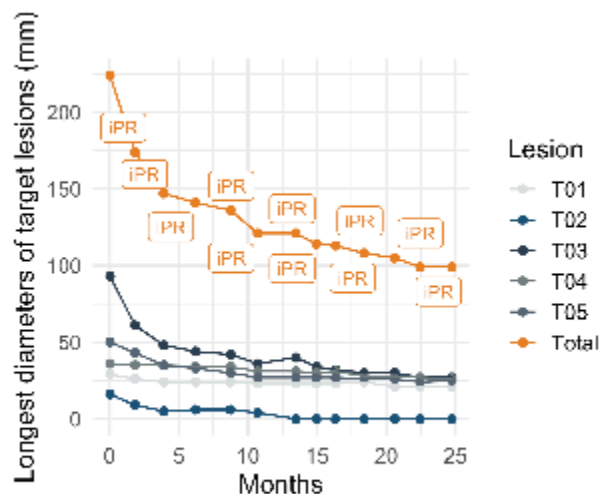


Co-administration of BI-1206 with pembrolizumab was well-tolerated in a heavily pretreated population, with promising responses observed in melanoma, and uveal melanoma, who previously failed anti-PD1 therapy.

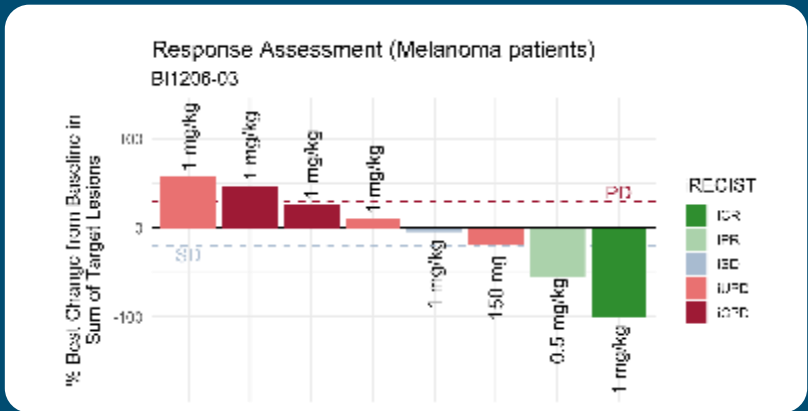
Case study: PR

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 (2years) with tumor burden reduced by 56% at end of trial.

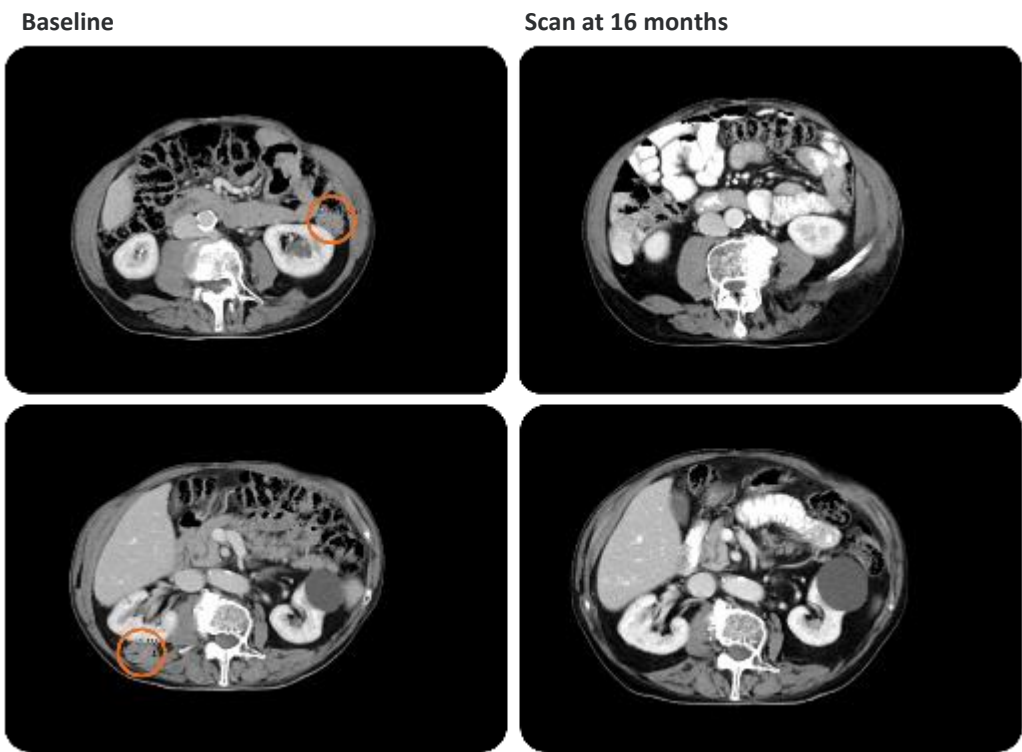
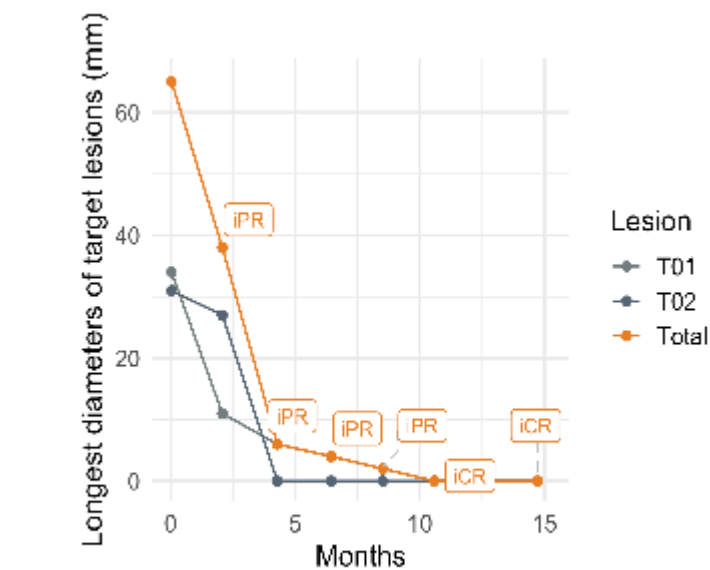


Co-administration of BI-1206 with pembrolizumab was well-tolerated in a heavily pretreated population, with promising responses to treatment observed in melanoma, including uveal melanoma, who previously failed anti-PD1 therapy.

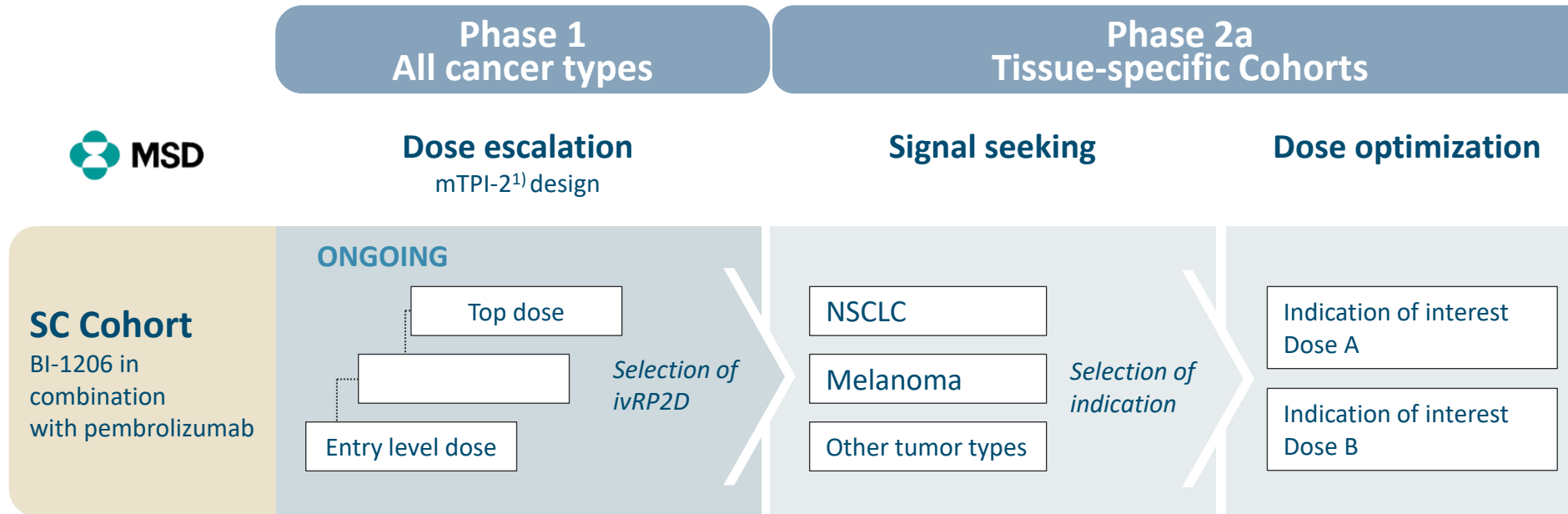


Case study: CR

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.



PLANS FORWARD – STUDY DESIGN BI-1206 IN SOLID TUMORS (KEYNOTE-A04)

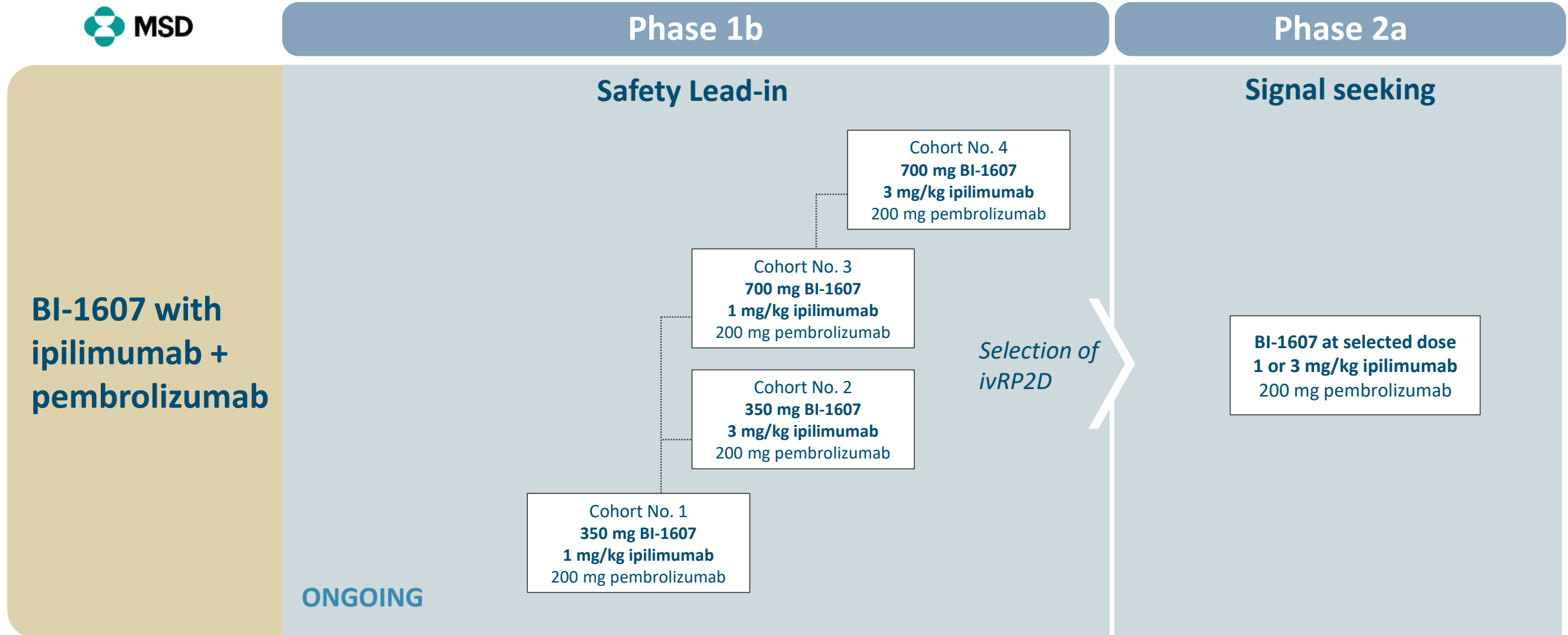


WHAT'S NEXT?

Results from the Phase 1 dose escalation part mid-2025E

¹) modified Toxicity Probability Interval 2

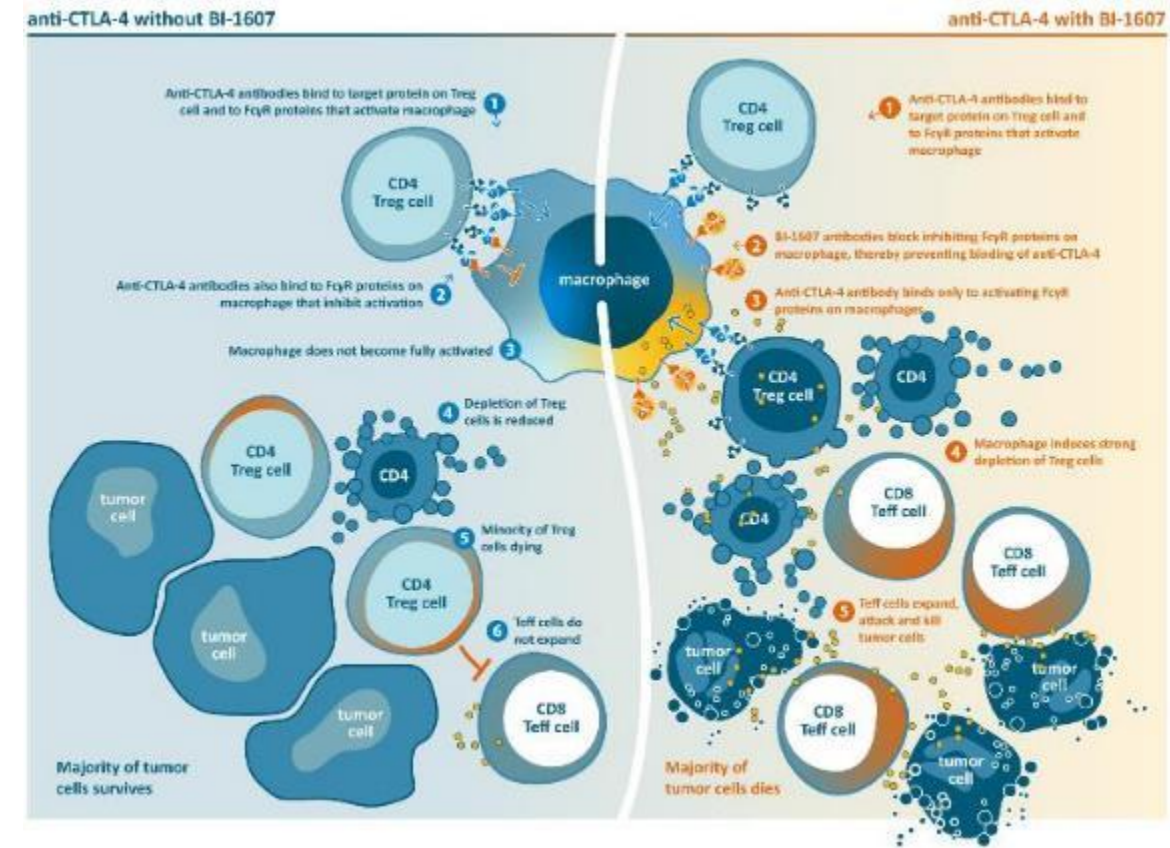
BI-1607 PHASE 1B/2A CLINICAL STUDY DESIGN



BI-1607: POSITIVE CLINICAL PHASE 1 DATA, **TRIPLET STUDY** ONGOING

First patient enrolled in Phase 1b/2a December 2024 :

- To evaluate safety and anti-tumoral activity of **two different dose levels of BI-1607** with two different dose levels of **ipilimumab (anti-CTLA-4)** (1 and 3 mg/kg) in combination with 200 mg flat dose of **pembrolizumab***
- Patients with unresectable or **metastatic melanoma**, previously treated with anti-PD-1/L1
- Includes an exploratory part assessing lower doses of anti-CTLA-4
- Preclinical studies indicate that a triple combination regimen including BI-1607 could allow the use of lower doses of ipilimumab, potentially achieving increased tolerability and higher efficacy.



WHAT'S NEXT?

First Phase 1b/2a data H2 2025E



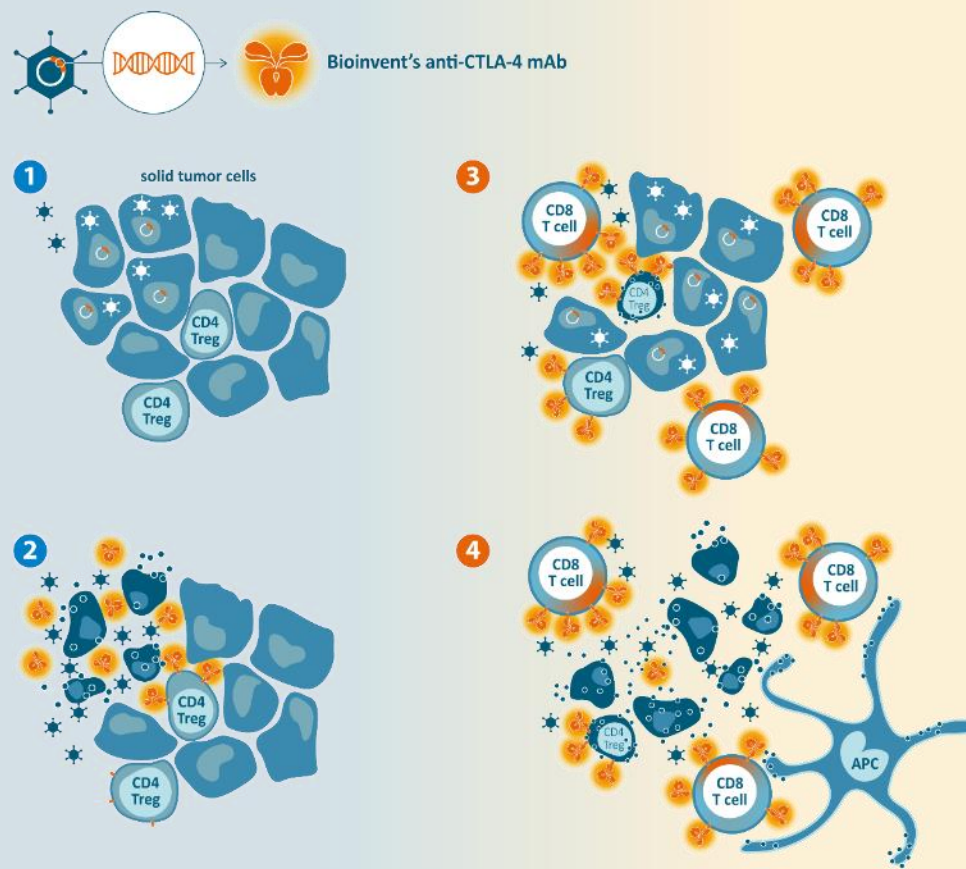
ANTI-CTLA-4

ONCOLYTIC VIRUS BT-001

BT-001: PHASE 1/2A ONGOING

50/50 PARTNERSHIP WITH TRANSGENE TO DEVELOP NEXT GENERATION ONCOLYTIC VIRUSES

mAbs and oncolytic virus attack the solid tumor together



Oncolytic virus & anti-CTLA-4 antibody combination elicits stronger antitumor response & targeted expression of anti-CTLA-4 antibody to improve safety profile

Journal for
Immunotherapy of Cancer

Vectorized Treg-depleting α CTLA-4 elicits antigen cross-presentation and CD8⁺ T cell immunity to reject 'cold' tumors

Monika Semmrich,¹ Jean-Baptiste Marchand,² Laetitia Fend,² Matilda Rehn,¹ Christelle Remy,² Petra Holmkvist,¹ Nathalie Silvestre,² Carolin Svensson,¹ Patricia Kleinpeter,² Jules Deforges,² Fred Junghus,¹ Kirstie L Cleary,³ Mimoza Bodén,¹ Linda Mårtensson,¹ Johann Foloppe,² Ingrid Teige,¹ Eric Quéméneur,² Björn Frenndéus^{1,3}

To cite: Semmrich M, Marchand J-B, Fend L, et al. Vectorized Treg-depleting α CTLA-4 elicits antigen cross-presentation and CD8⁺ T cell immunity to reject 'cold' tumors. *Journal for Immunotherapy*

ABSTRACT

Background Immune checkpoint blockade (ICB) is a clinically proven concept to treat cancer. Still, a majority of patients with cancer including those with poorly immune infiltrated 'cold' tumors are resistant to currently available ICB therapies. Cytotoxic T lymphocyte-

intratumoral VV_{car}- α CTLA-4 synergized with α PD-1 to reject cold tumors.

Conclusion Our findings demonstrate in vivo proof of concept for spatial restriction of Treg depletion-optimized immune checkpoint blocking, vectorized α CTLA-4 as a highly effective and safe strategy to target CTLA-4. A

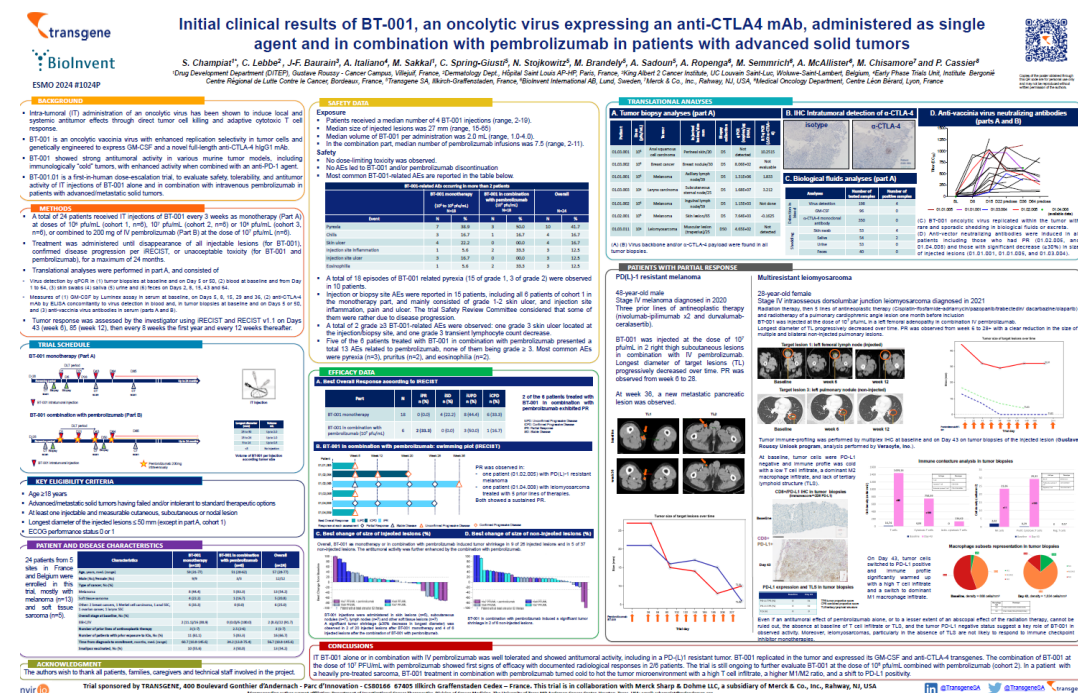
Winner of the 2022 JITC Best Oncolytic and Local Immunotherapy Paper Award



Clinical responses in 2/6 refractory patients when given in combination with pembrolizumab

Phase 1/2a open-label, multicenter, dose-escalation study of BT-001 Part B presented at ESMO September 2024

- **BT-001 induces tumor regression** in patients who **failed previous anti-PD(L)-1 treatment**
- In a patient with a **heavily pretreated leiomyosarcoma**, BT-001 was able to modulate the tumor microenvironment, turning a **“cold” tumor to “hot”**, enhancing the potential of T cell infiltration and a shift to PD(L)-1 positivity
- Early signs of efficacy with **clinical responses** observed with BT-001 in combination with KEYTRUDA® (pembrolizumab), in **2 of 6 patients** who failed previous treatment



BT-001: PHASE 1/2A OPEN-LABEL, MULTICENTER, DOSE-ESCALATION STUDY

Ongoing phase

Phase 1A Dose Escalation

BT-001 IT (18 pts)
Metastatic/advanced solid tumors
3 doses

COMPLETED

Phase 1B Dose Escalation

BT-001 IT + Pembrolizumab (12 pts)
Metastatic/advanced solid tumors
RDPB

ONGOING

Phase 2a Expansion Cohorts

BT-001 IT + Pembrolizumab
Tbd: Soft tissue sarcoma, Merkel cell carcinoma, Melanoma, Triple negative breast cancer, Non-small cell lung cancer
RDPB

PLANNED

Main Eligibility Criteria

- 1 injectable lesion 25-50mm in diameter
- ECOG 0-1
- Failed or not eligible for standard of care

Participating Countries

- France, Belgium
- IND approved in US





KEY CATALYSTS 2025

Expected key clinical milestones 2025

TNFR2 platform

BI-1808

further single agent Ph 2a data

BI-1808

pembro combo Ph 2a data

BI-1910 solid tumors

single agent Ph 2a data

BI-1910 solid tumors

pembro combo Ph 1 data

2025

**BI-1206 in NHL + ritux +
acalabrutinib Ph 2a data**

**BI-1206 (SC) solid tumors
pembro combo Ph 1 data**

**BI-1607 solid tumors
triplet Ph 1b data**

FcyRIIB platform



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