BioInvent

UNLEASHING IMMUNITY TO FIGHT CANCER

May 2025

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6
Clinical programs

Six expanding clinical programs. Integrated research engine, functional screening and in-house GMP manufacturing.

10+
Partnership agreements

Technology validating deals with Exelixis, Pfizer, Daiichi Sankyo, Bayer, Mitsubishi Tanabe, Takeda, Genentech. Partnering/deal making a key element in business model.

30
Nationalities

Headquarters in Lund, Sweden.
114 employees (FTE), 30 nationalities.

65%
International ownership

Strong international shareholder base. Major owners Redmile, Van Herk Investments, Forbion, HBM, Omega, AP4, Invus, Handelsbanken.

742
SEKm in liquid funds etc
~ 71 USDm

Well-funded through multiple value inflection points. Listed on NASDAQ OMX Stockholm Mid Cap (BINV).

Mar 31, 2025

Translating complex cancer biology into innovative antibody therapies

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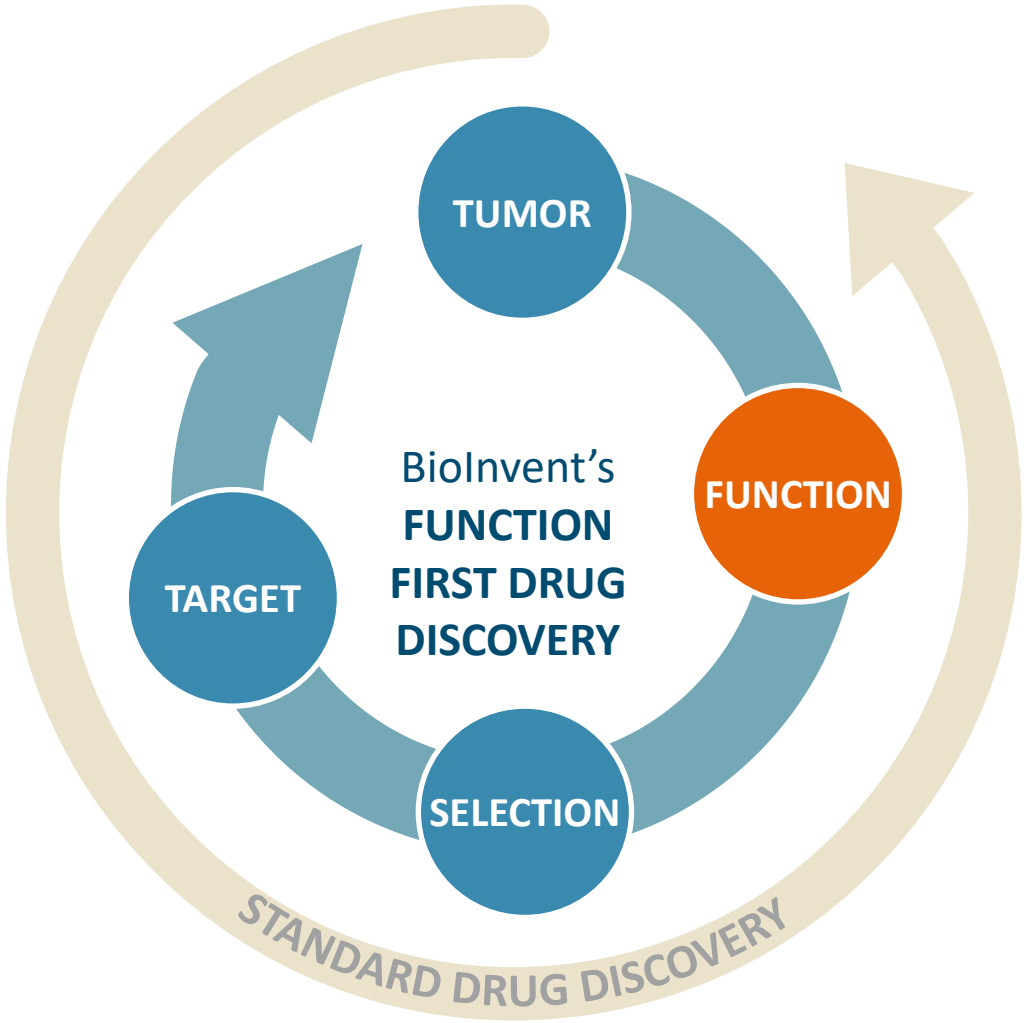
BUILDING A PIPELINE: OUR STATE-OF-THE ART ANTIBODY TECHNOLOGY



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

Program	Study arm	Discovery	Preclinical	Phase 1	Phase 2	Partner
BI-1808 in solid tumors/TCL	single agent					
	+ pembrolizumab[1]					
BI-1910 in solid tumors	single agent					
	+ pembrolizumab[1]					

FcyRIIB

Program	Study arm	Discovery	Preclinical	Phase 1	Phase 2	Partner
BI-1206 in NHL	+ rituximab					CASI[3]
	+ rituximab & acalabrutinib[2]					
BI-1206 in solid tumors	+ pembrolizumab[1]					CASI[3]
BI-1607 in solid tumors	+ pembrolizumab[1] & ipilimumab					

CTLA-4

Program	Study arm	Discovery	Preclinical	Phase 1	Phase 2	Partner
BT-001 in solid tumors	+ pembrolizumab[1]					transgene[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

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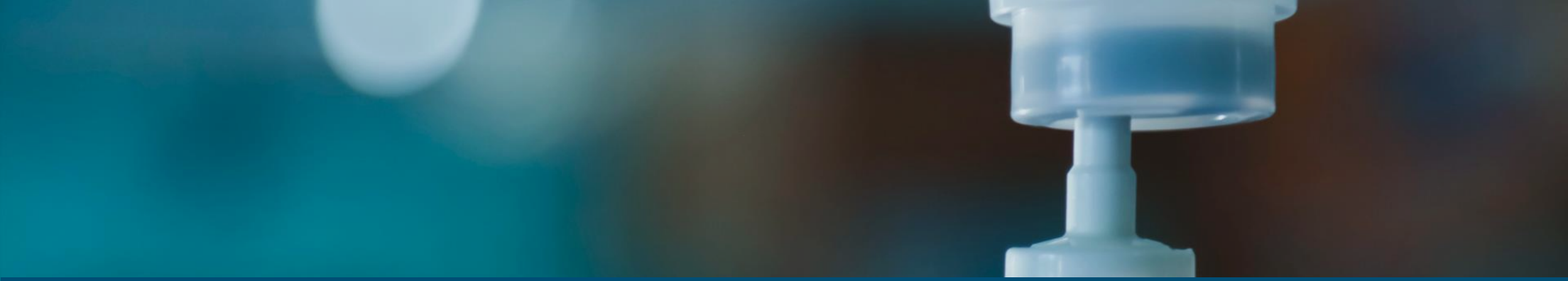

ANTI-TNFR2

BI-1808

BI-1910

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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 MoAs 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

	Phase 1: All cancer types	Phase 2a Tissue-specific cohorts
Single agent	**PART A** Dose escalation BI-1808 as single agent – administered IV Q3W mTPI2[1)] design 1000 mg ✓ 675 mg ✓ 225 mg ✓ 75 mg ✓ 25 mg ✓ **COMPLETED**	Ovarian Cancer (OC) ✓ Melanoma All tumor types TCL including CTCL **ONGOING**
Combo with pembrolizumab MSD	**PART B** Dose escalation BI-1808 in combination with pembrolizumab 200 mg Q3W mTPI2[1)] design BI-1808 1000 mg ✓ BI-1808 675 mg ✓ BI-1808 225 mg ✓ **COMPLETED**	Ovarian Cancer (OC) Melanoma All tumor types TCL including CTCL **ONGOING**

WHAT'S NEXT?

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

[1)] modified Toxicity Probability Interval 2

BI-1808: STRONG SINGLE AGENT ACTIVITY IN PHASE 1/2A

CTCL COHORT

EHA June 2024 & September 2024

- **3 partial response (PR)** currently ongoing and deepening
- **1** patient with **stable disease** (SD)
- 4 evaluable CTCL patients

SOLID TUMORS

ASCO May/June 2024

- **1 complete response (CR)** in ovarian cancer
- **1 PR** in GIST that continues to improve after more than 88 weeks (Jan 2025)
- Furthermore, **9** patients showed **SD** (26 evaluable patients)

Furthermore, promising signs of efficacy and favorable safety profile observed in **Phase 1 dose escalation** with **BI-1808 in combination with pembrolizumab*** also presented at ASCO 2024. Phase 2a dose expansion combo study ongoing.

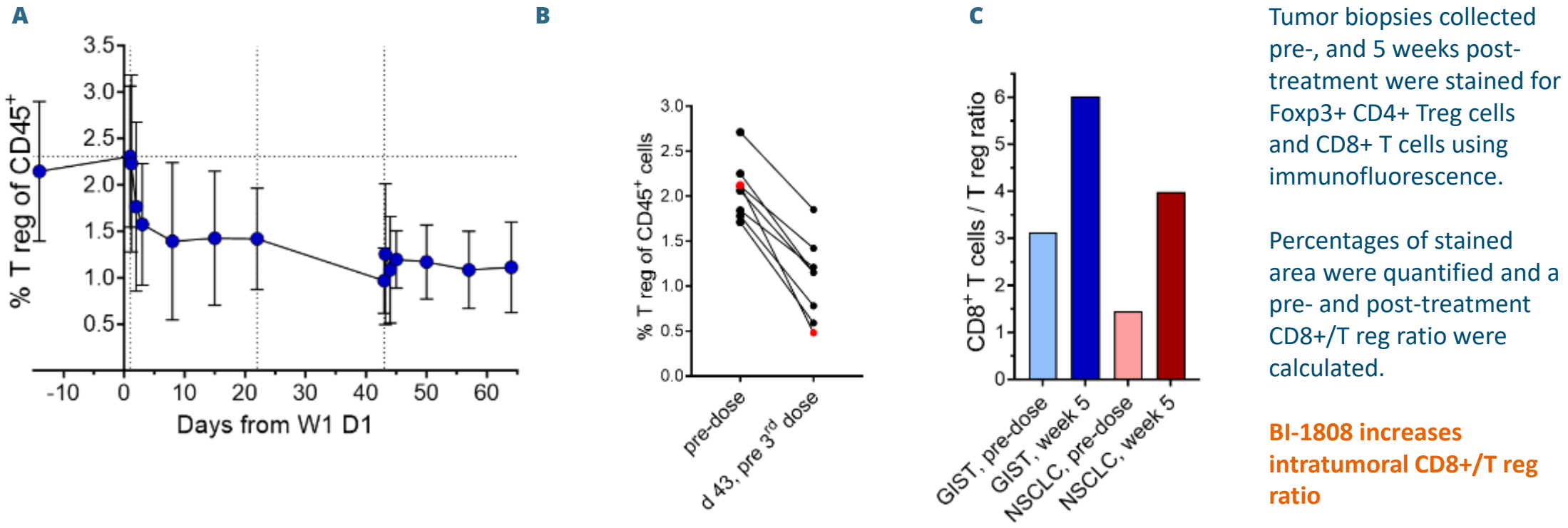
BI-1808 Orphan Drug Designation TCL (March 2025)
CTCL Fast Track Designation (April 2025)

 CTCL: Cutaneous T-Cell Lymphoma

* MSD International Business GmbH, a subsidiary of Merck & Co., Inc., Rahway, NJ, USA

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.

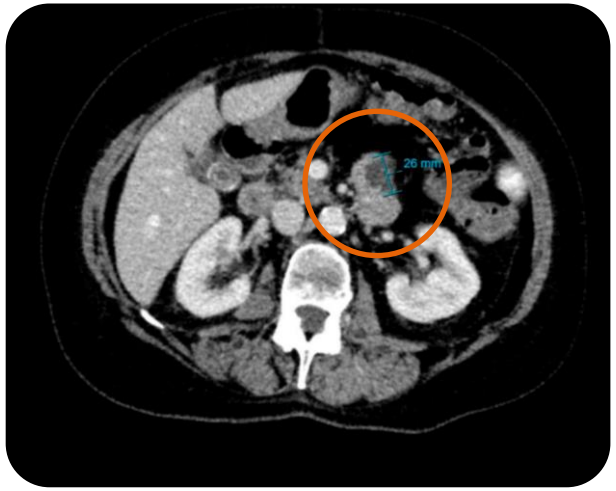
Percentages of stained area were quantified and a pre- and post-treatment CD8+/T reg ratio were calculated.

BI-1808 increases intratumoral CD8+/T reg ratio

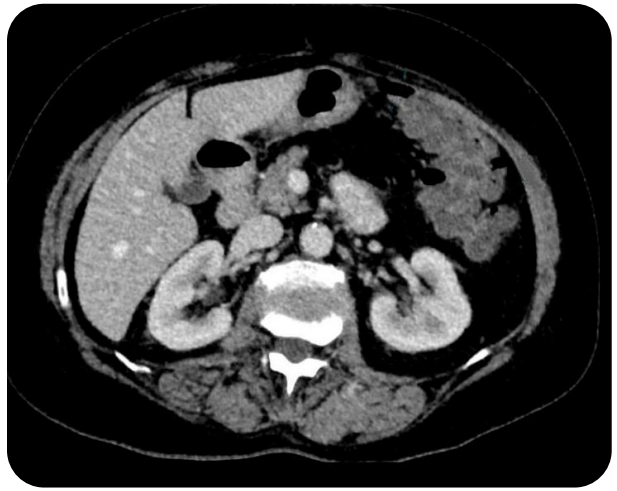
Data from the 1000 mg monotherapy cohort.
The data show substantial **T-reg depletion** compared to baseline. Panel B shows the individual patient drop in T-reg. Red dots indicate the drop in the GIST patient.
(Dashed horizontal line = baseline. Dashed vertical lines = BI-1808 dosing occasions)

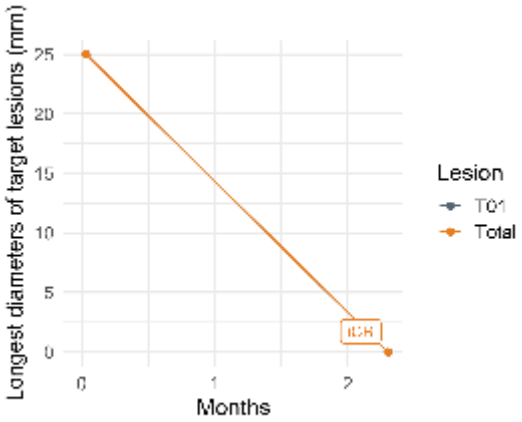
BI-1808 SINGLE AGENT CASE STUDY: COMPLETE RESPONSE IN OVARIAN CANCER

Baseline

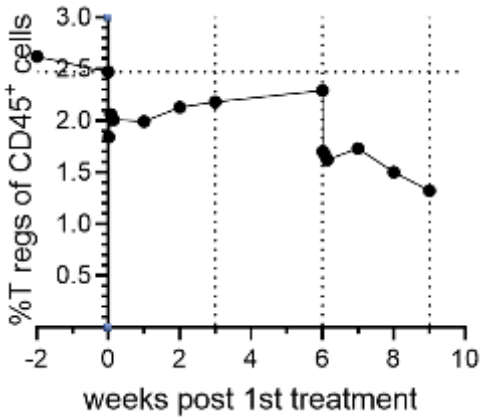


2 months





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.

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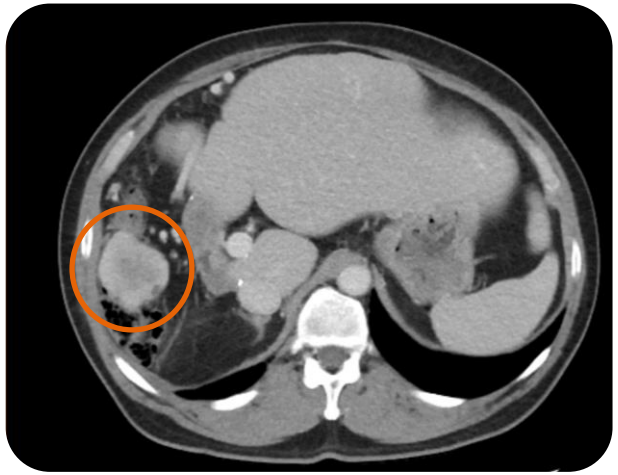
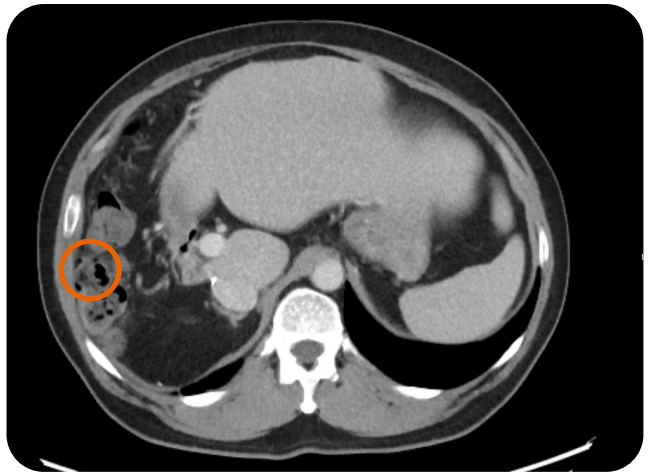
BI-1808 SINGLE AGENT CASE STUDY: ROBUST PR IN A PATIENT WITH GIST

Baseline

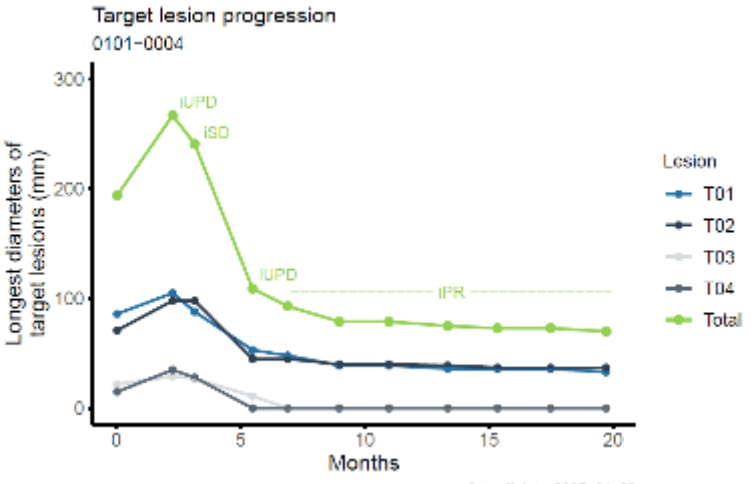


Follow-up 13 months

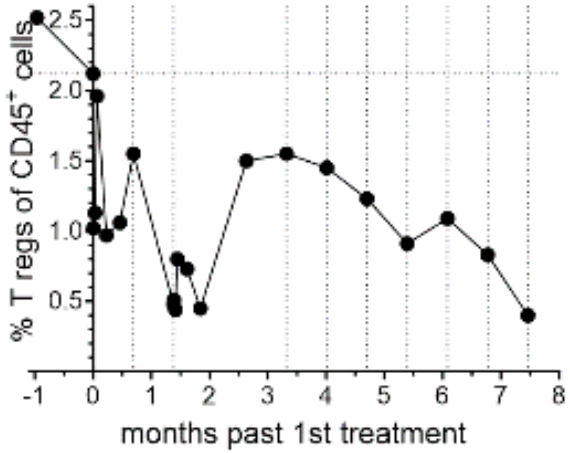


55-year-old male patient with GIST, who presented with clinical PD for more than 6 months with multiple metastatic lesions. 12 previous lines of therapy.

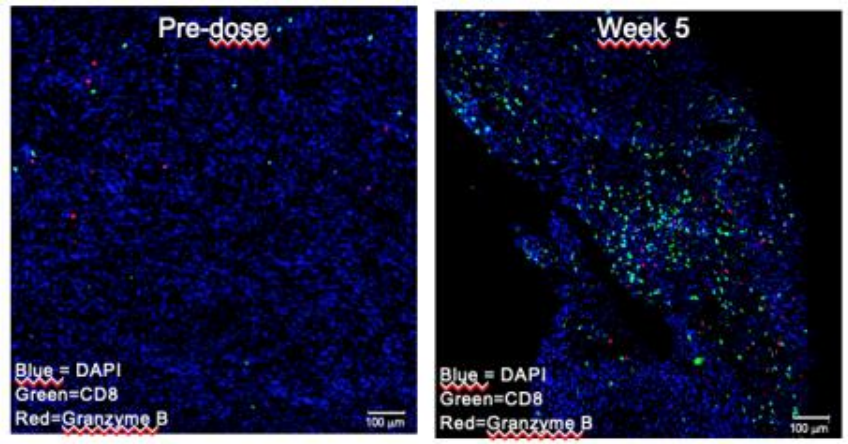
The partial response continues to improve after more than 80 weeks (Dec 2024).



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

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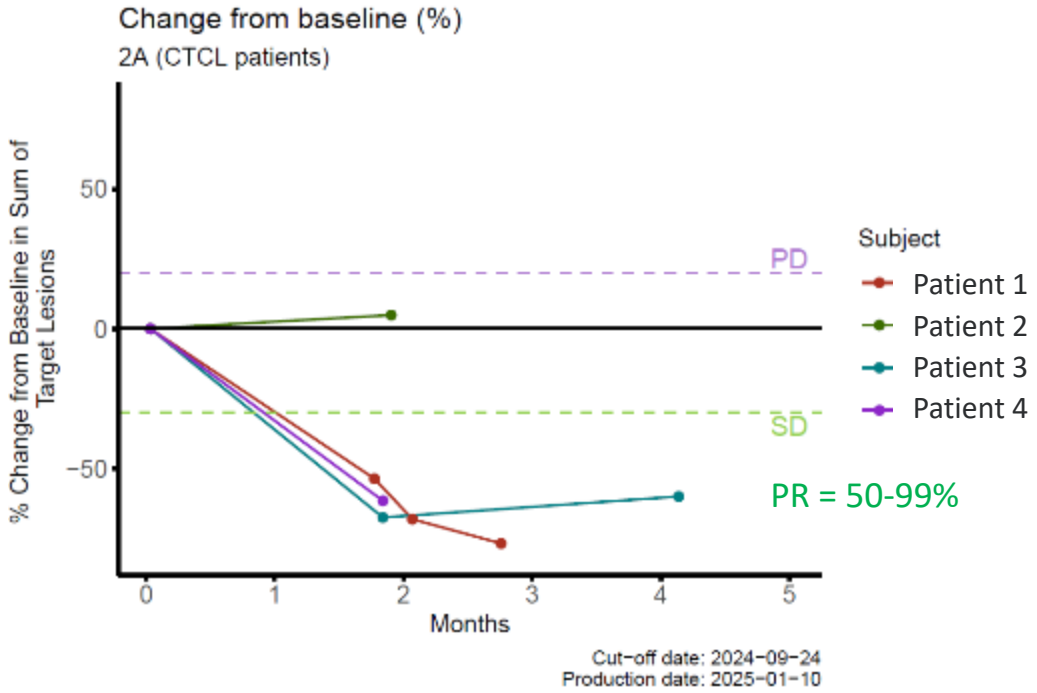
BI-1808: OUTSTANDING EARLY RESPONSES IN HEAVILY PRE-TREATED CTCL PATIENTS

- 4 patients are evaluable post treatment, out of 6 patients treated with BI-1808 single agent
- 3 exhibited partial response (50-99% decrease from baseline), with 1 patient showing stable disease

Skin Lesions *(mSWAT assessment)*

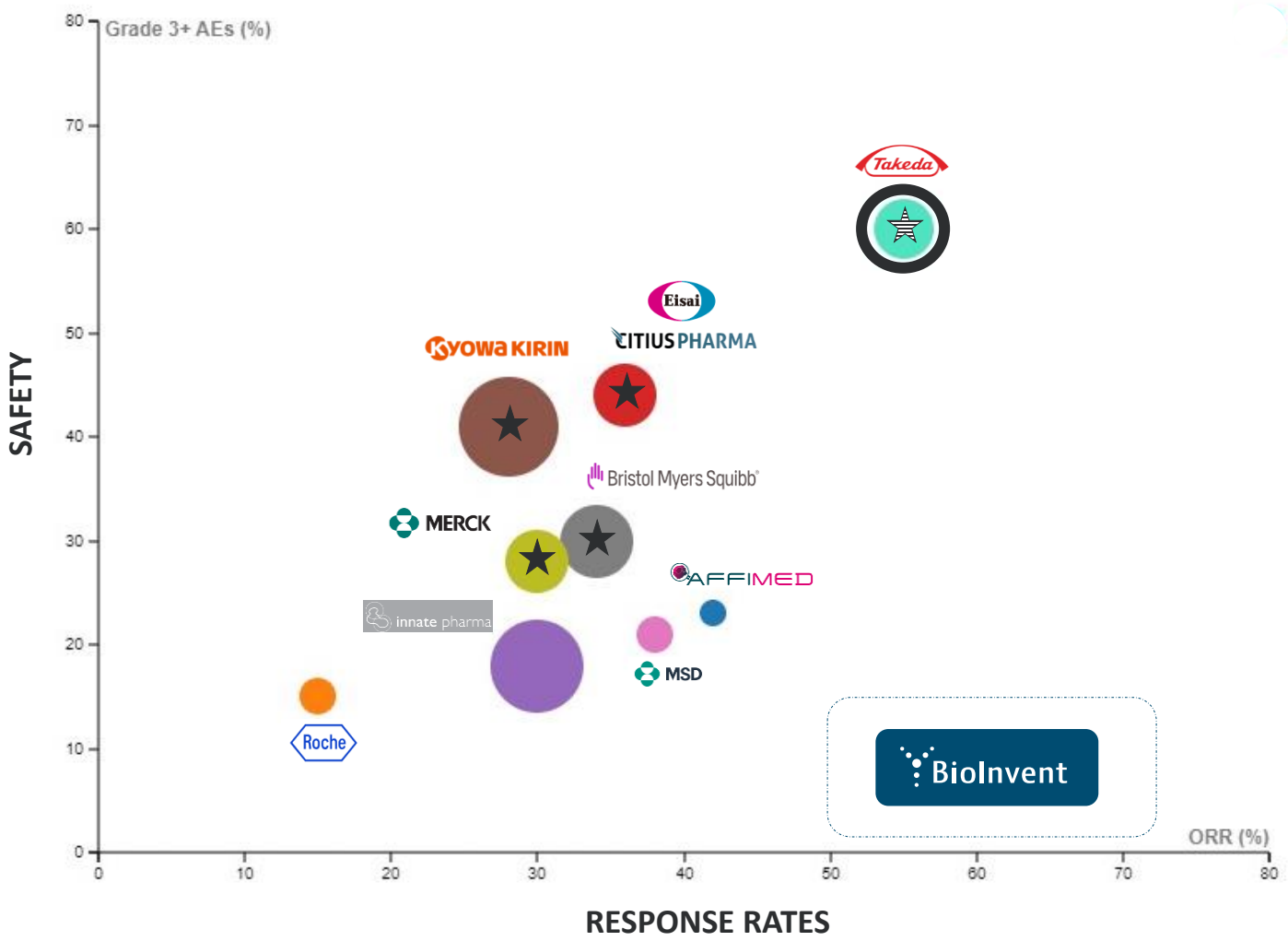


Prior Treatment in responding CTCL patients

Patient No.	Diagnose	Regimen	Prior treatment	Best prior response	BI-1808 response
3	MYCOSIS FUNGOIDES	Regimen 1	BEXAROTENE	Not Evaluable (NE)	PR
		Regimen 2	METHOTREXATE VALCHLOR GEL	Partial Response (PR)	
		Regimen 3	DURVALUMAB	Partial Response (PR)	
4	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)	
1	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

BASED ON EARLY DATA, BI-1808 LOOKS POISED TO BE BEST-IN-CLASS IN R/R CTCL LANDSCAPE



Approved

Approved for a sub-population

Black-Box warning

Patients

14.0

186.0

Treatment

- AFM13 (CD30/CD16A * tetravalent bispecific)
- Atezolimumab (PDL1 Ab) *
- Brentuximab vedotin ^ (CD30 ADC)
- Denileukin diftitox (IL2 fusion protein)
- Lacutamab (KIR3DL2 Ab)
- Mogamulizumab (CCR4 Ab)
- Pembrolizumab (PD1 Ab) *
- Romidepsin (HDAC) *
- Vorinostat (HDAC)

BI-1808 POSITIONING IN THE MARKET LANDSCAPE

CTCL

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 ≥ 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.

Solid Tumors

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 combination component with anti-PD1/L1 in several tumor types

BI-1910: PROMISING SINGLE AGENT PHASE 1 DATA (JAN 2025)

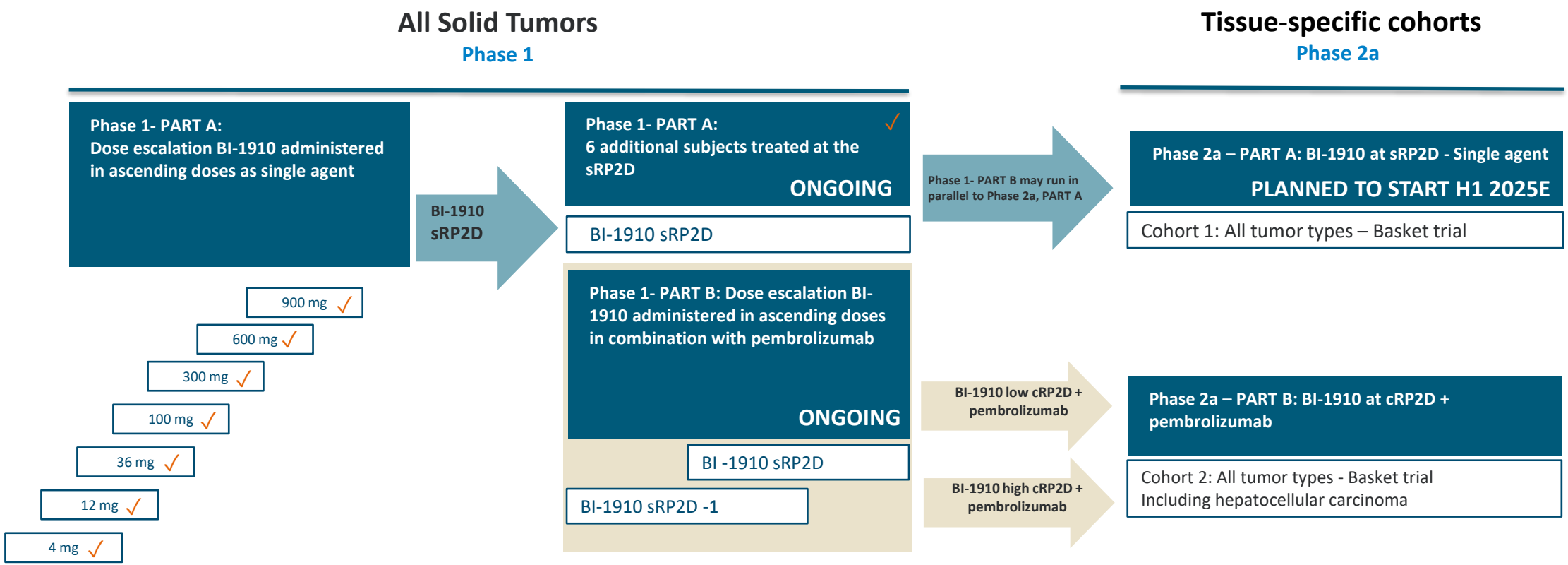
A differentiated, agonist approach to treating solid tumors

ESMO 2024 and Jan 2025 SINGLE AGENT data:

- **Stable disease** (6/12 evaluable patients) **best clinical responses**
- No notable adverse events even at the highest doses tested
- BI-1910 single agent **Phase 1** Part A **dose escalation completed** and reached a biologically active dose level
- Favorable pharmacokinetic data and a **robust target engagement**, showing evidence of induction of T-cell proliferation

* MSD International Business GmbH, a subsidiary of Merck & Co., Inc., Rahway, NJ, USA

BI-1910 STUDY DESIGN



WHAT'S NEXT?

- **Initial Phase 2a single agent data H2 2025E**
- **Phase 1 pembrolizumab combination data H2 2025E**

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

ANTI-FcγRIIB

BI-1206 + rituximab + acalabrutinib

BI-1206 + pembrolizumab

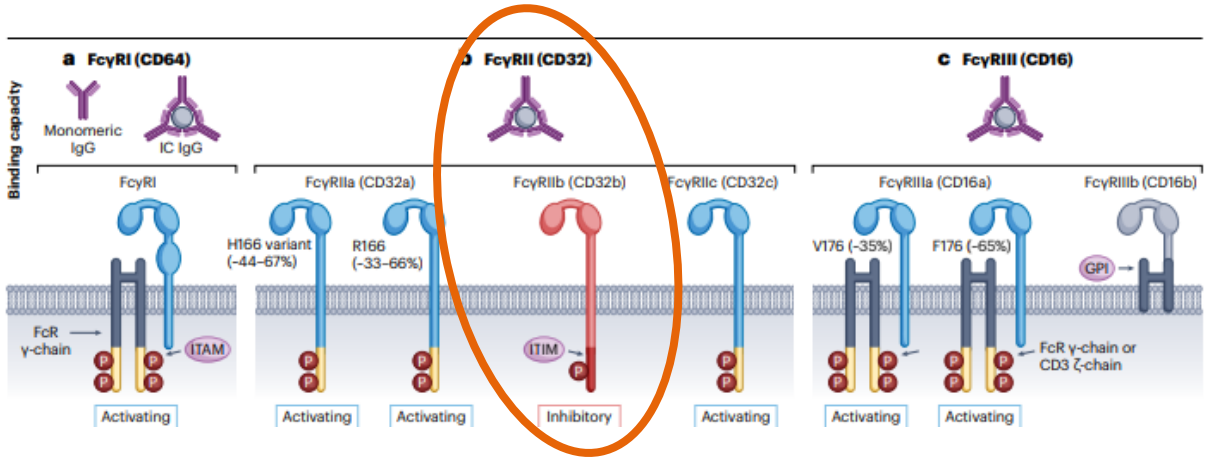
BI-1607

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 rec*eptors and immunomodulatory antibodies in cancer. *Nat Rev Cancer* **24**, 51–71 (2024). https://doi.org/10.1038/s41568-023-00637-8

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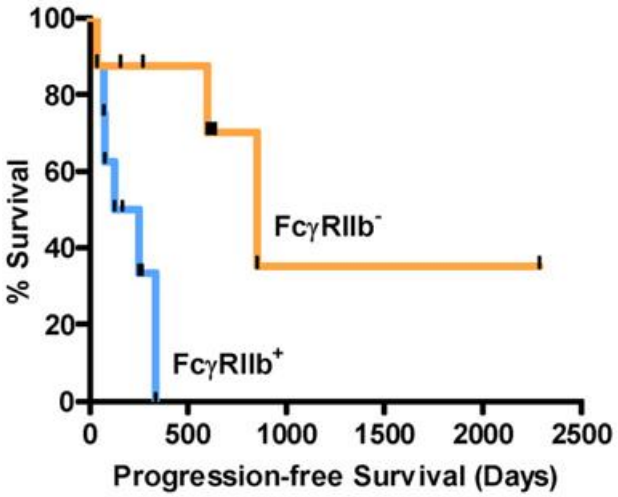
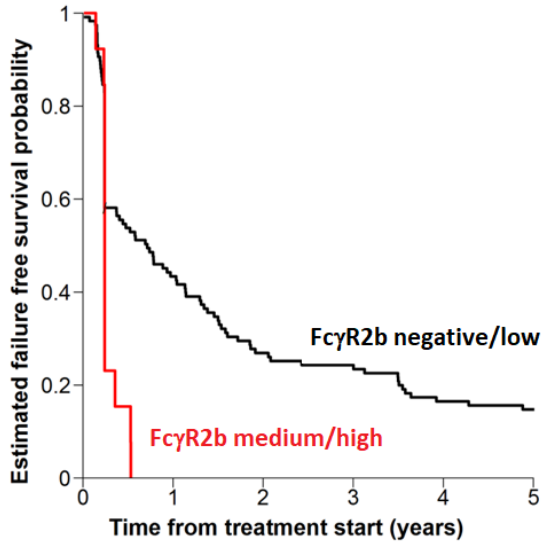
FcγRIIB EXPRESSION CORRELATES INVERSELY WITH SURVIVAL

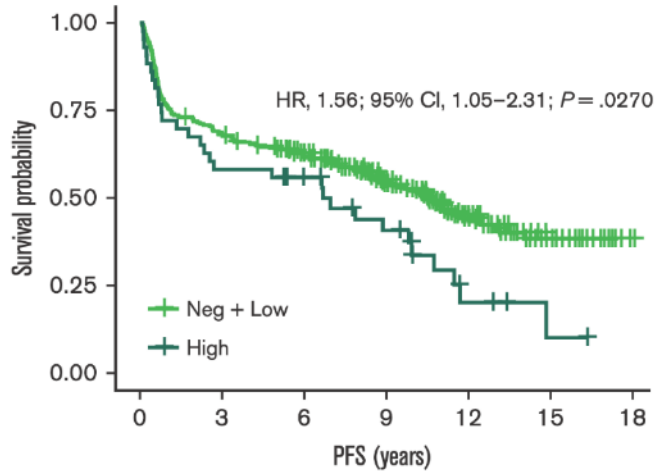
Mantle Cell Lymphoma (MCL)



Follicular Lymphoma (FL)



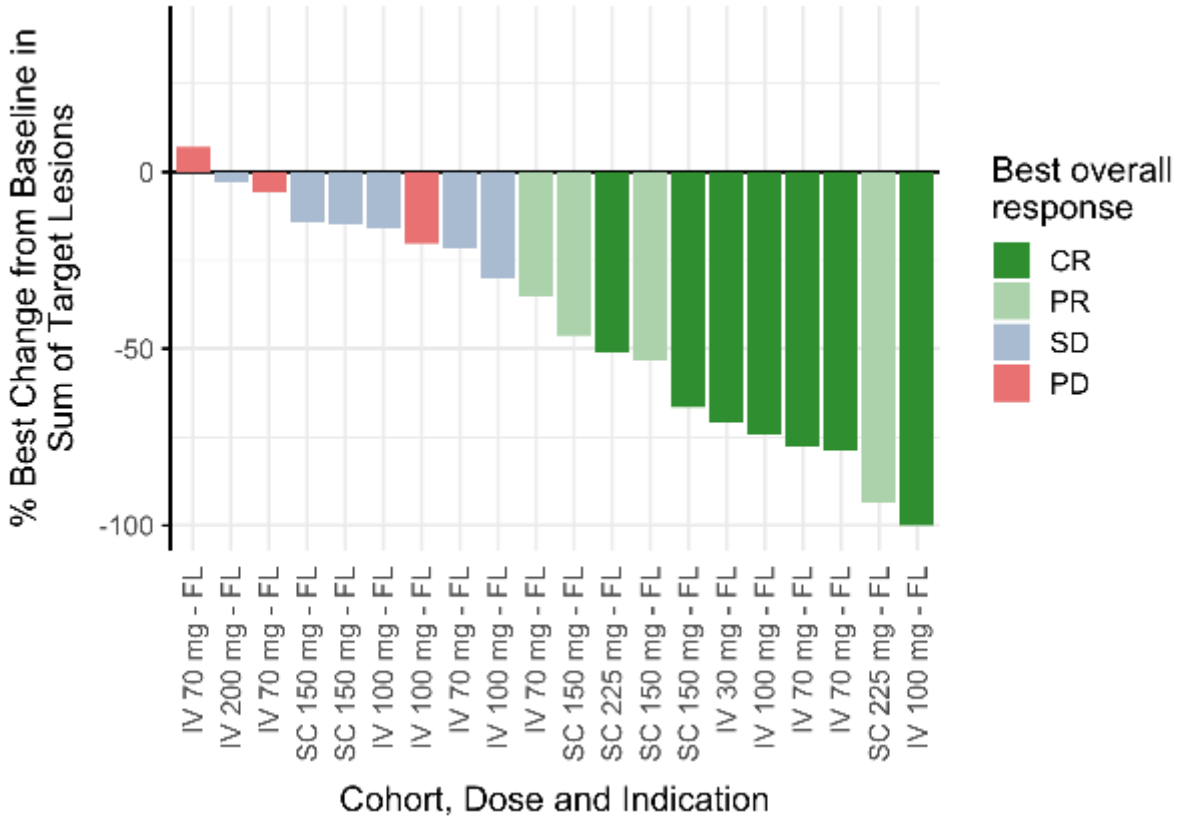
Diffuse Large B-Cell Lymphoma



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

BI-1206: PHASE 1 CLINICAL DATA IN FL PATIENTS DEMONSTRATES STRONG EFFICACY AND SAFETY SIGNALS

BI-1206 + rituximab responses in 20 relapsed/refractory FL pts



Outcomes

(October 2024, **SC + IV**)

No safety or tolerability concerns
All TEAEs were manageable
Resolved without clinical complication
SC particularly well-tolerated

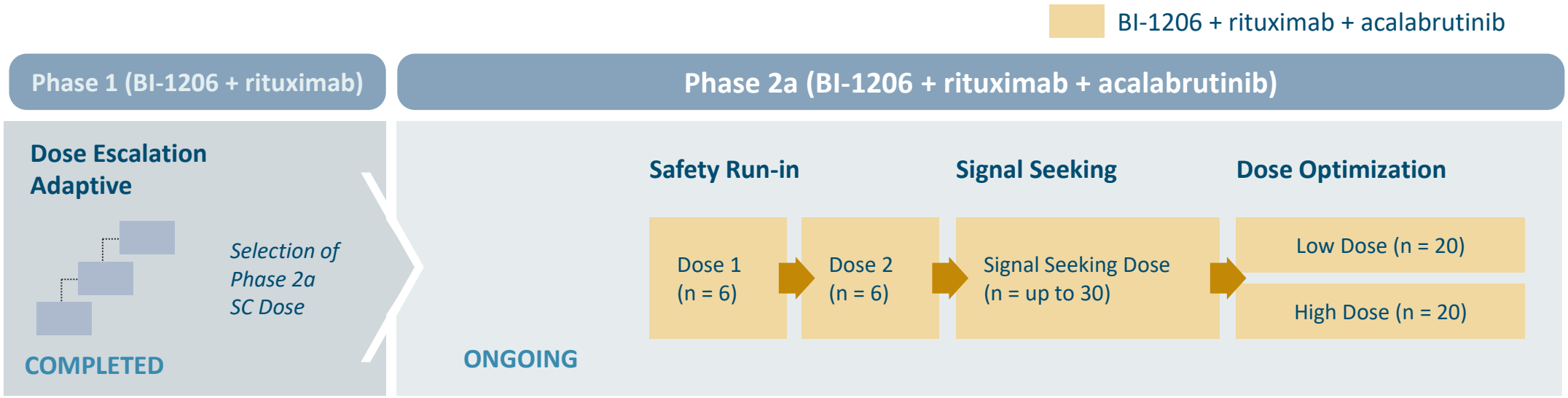
ORR of 55%, **CRR** of 35%, **DCR** 85%
7 complete responses (CR)
4 partial responses (PR)
6 patients with stable disease (SD)
CRs have been **long-lasting**, three of them **lasting years after** end of treatment

Further reading, EHA-2179, Abstract # P1135 BI-1206

TEAE: Treatment Emergent Adverse Event

BI-1206 IN NHL: COMBINATION WITH RITUXIMAB AND ACALABRUTINIB

- **Phase 1 dose-escalation** study with BI-1206 subcutaneous (SC) + rituximab **completed**
- Approximately **30 patients** expected to be enrolled in Phase 2 signal seeking part (Spain, Germany, the US, and Brazil)



WHAT'S NEXT?

Additional Phase 2a triplet data mid-2025E

 *Clinical supply agreement with AstraZeneca (LSE/STO/Nasdaq: AZN) for Calquence® (acalabrutinib)

BI-1206 IN NHL: COMBINATION WITH RITUXIMAB AND ACALABRUTINIB

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

- First two patients (as of January 2025):
  - **1 complete response (CR)**
  - **1 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

 *Clinical supply agreement with AstraZeneca (LSE/STO/Nasdaq: AZN) for Calquence® (acalabrutinib)

BI-1206 POSITIONING IN THE MARKET LANDSCAPE

Follicular lymphoma (FL)

Potential as 2nd line for the treatment of FL:

- **Highly convenient and safe**, combined with the two most successful drugs in this space, in a **chemotherapy-free** regimen:
  - Rituximab: will remain the backbone of treatment in NHL for years to come
  - Acalabrutinib: best-in-class drug for the treatment of MCL
  - SC formulation brings significant convenience. In the long-term both BI-1206 and rituximab can be administered SC (acalabrutinib is administered orally)
- ORR ≥ 75% would place the triplet as a very competitive option in the **second line**
- No cytokine release syndrome, no neurotoxicity and no safety concerns makes this triplet **ideal for the treatment of patients in community hospitals**

Solid tumors

The **largest** commercial potential of BI-1206 is for the treatment of **solid tumors**:

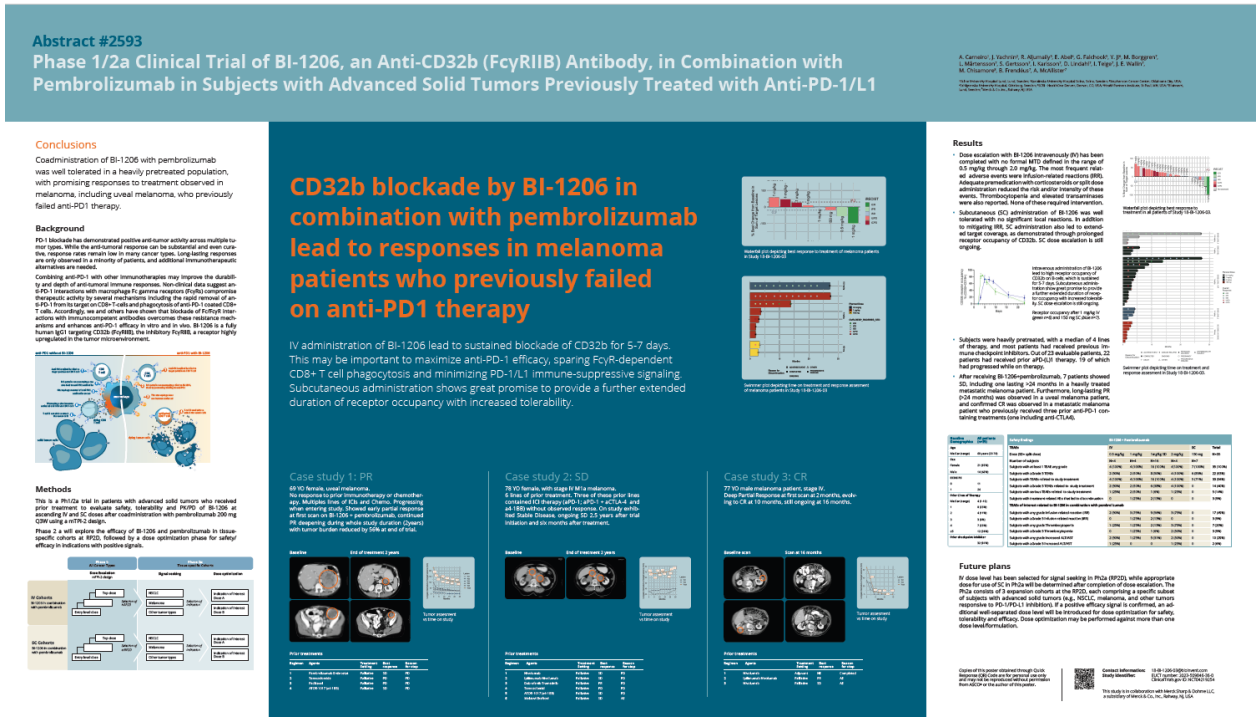
- **Enhances the activity** of pembrolizumab
- Demonstrated **synergistic activity** with anti-PD1 in preclinical models
- Strong signals observed **in heavily pretreated patients** with metastatic melanoma (cutaneous and uveal melanoma), and very likely extendable to other tumor types
- **Exceptional safety profile** makes it ideal for a combination component with anti-PD1/L1 in several tumor types

BI-1206 IN SOLID TUMORS: COMBINATION WITH PEMBROLIZUMAB

Promising efficacy signals in Phase 1

(December 2024)

- **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**



Abstract #2593

Phase 1/2a Clinical Trial of BI-1206, an Anti-CD32b (FcγRIIB) Antibody, in Combination with Pembrolizumab in Subjects with Advanced Solid Tumors Previously Treated with Anti-PD-1/L1

Conclusions

Background

Methods

CD32b blockade by BI-1206 in combination with pembrolizumab lead to responses in melanoma patients who previously failed on anti-PD1 therapy

IV administration of BI-1206 lead to sustained blockade of CD32b for 5-7 days. This may be important to maximize anti-PD-1 efficacy, sparing FcγR-dependent CD8+ T cell phagocytosis and minimizing PD-1/L1 immune-suppressive signaling. Subcutaneous administration shows great promise to provide a further extended duration of receptor occupancy with increased tolerability.

Case study 1: PR

Case study 2: SD

Case study 3: CR

Results

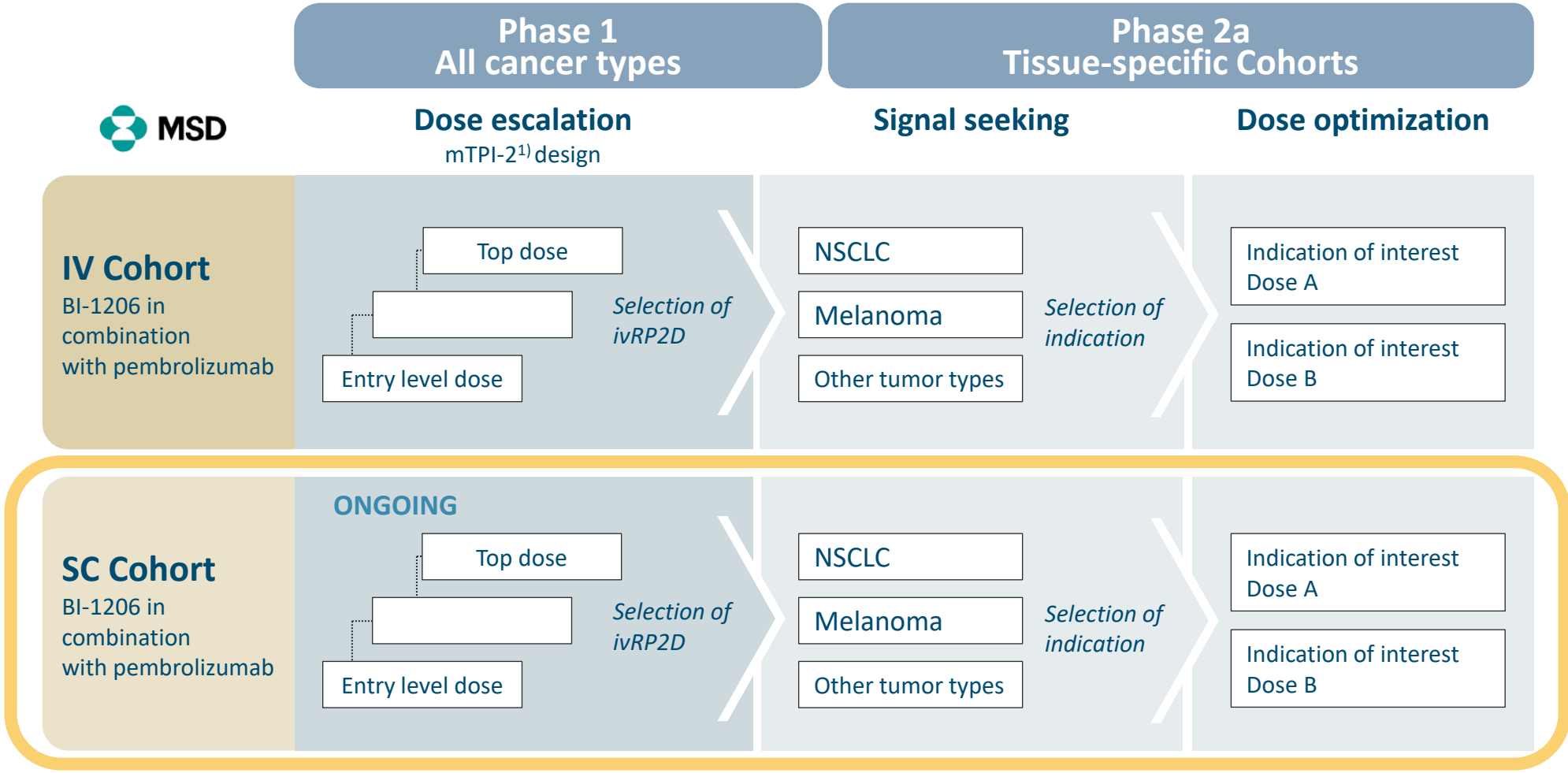
Future plans

WHAT'S NEXT?

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

* MSD International Business GmbH, a subsidiary of Merck & Co., Inc., Rahway, NJ, USA

PLANS FORWARD – STUDY DESIGN BI-1206 IN SOLID TUMORS



WHAT'S NEXT? **Results from the Phase 1 dose escalation part mid-2025E**

[1] modified Toxicity Probability Interval 2

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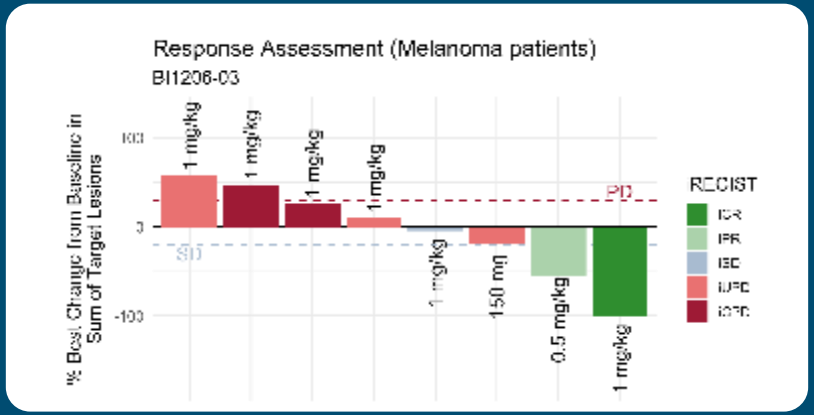
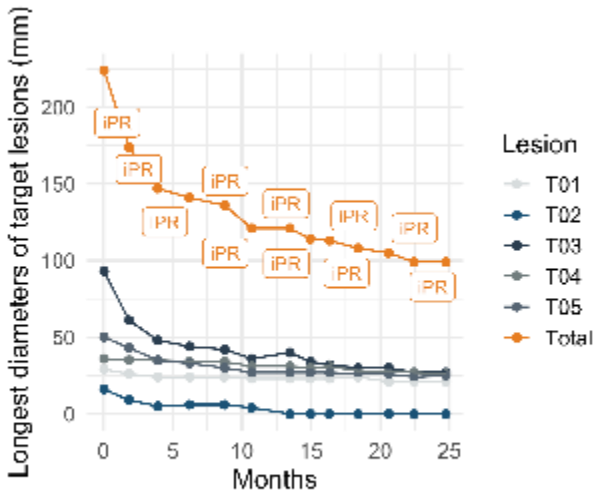


Co-administration of BI-1206 with pembrolizumab was well-tolerated in a heavily pretreated population, with promising responses observed in melanoma, and uveal melanoma, who previously failed anti-PD1 therapy.

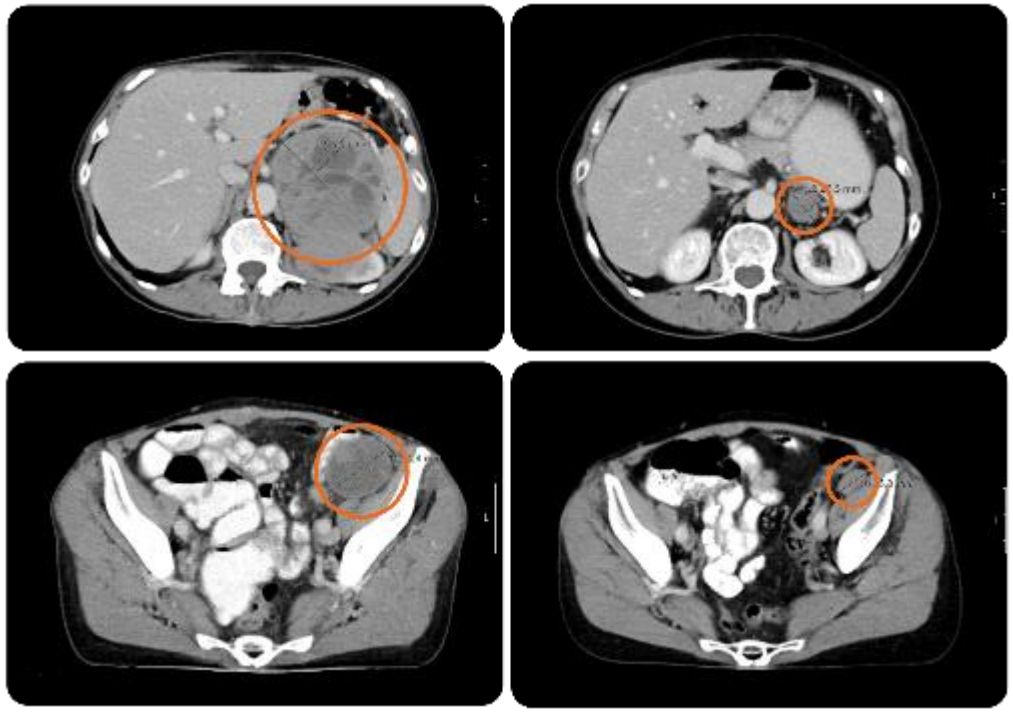
Case study: PR

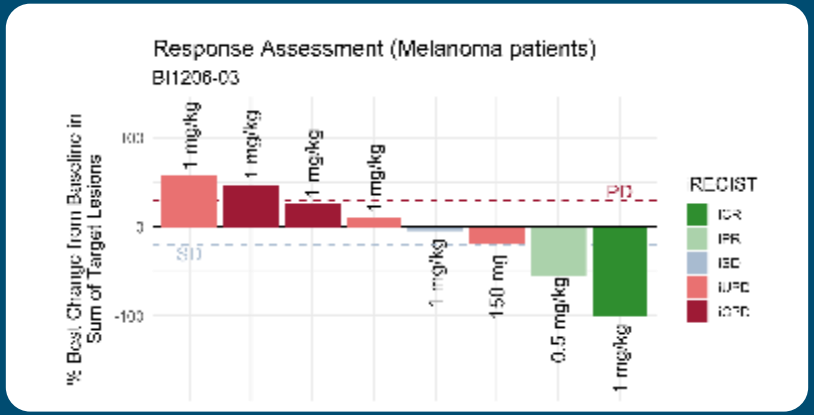
69 YO female with **uveal melanoma**.
No response to prior immunotherapy or chemotherapy. Multiples lines of ICIs and Chemo. Progressing when entering study. Showed early partial response at first scan on BI-1206 + pembrolizumab, continued PR deepening during whole study duration (2years) with tumor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



Baseline

End of treatment 2 years

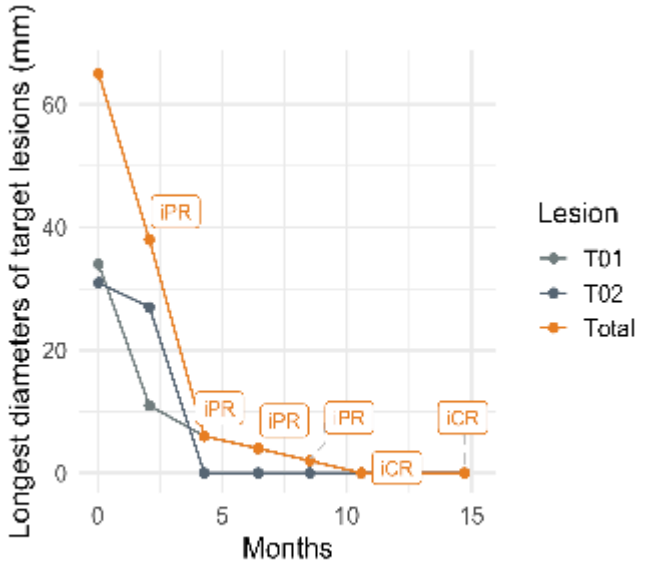




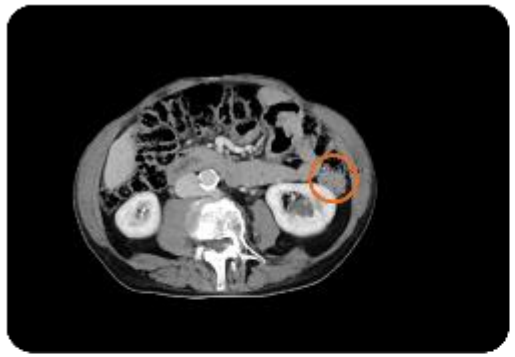
Co-administration of BI-1206 with pembrolizumab was well-tolerated in a heavily pretreated population, with promising responses to treatment observed in melanoma, including uveal melanoma, who previously failed anti-PD1 therapy.

Case study: CR

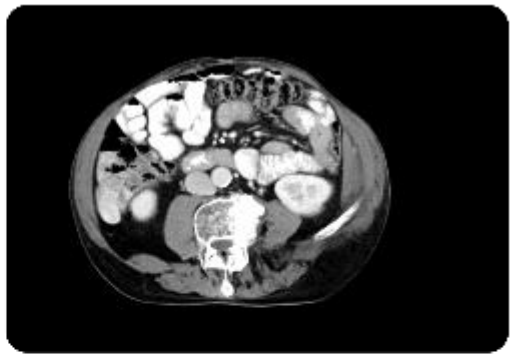
77 YO male melanoma patient, stage IV.
Deep Partial Response at first scan at 2 months, evolving to CR at 10 months, still ongoing at 16 months. Three lines of previous ICI therapy, with PR as best prior response to ipilimumab + nivolumab.

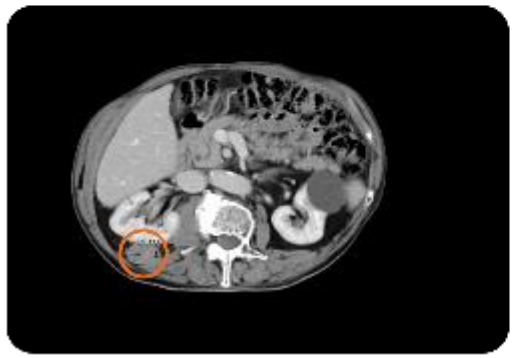


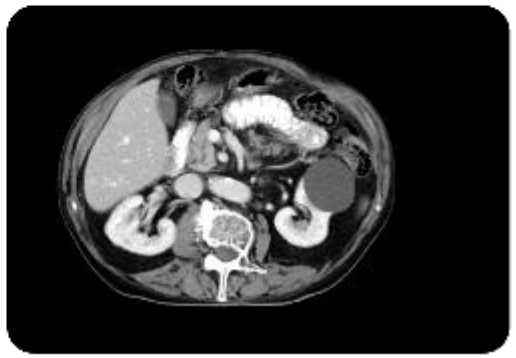
Baseline



Scan at 16 months







BI-1607 HAS THE POTENTIAL TO INCREASE EFFICACY OF OTHER ANTIBODY DRUGS

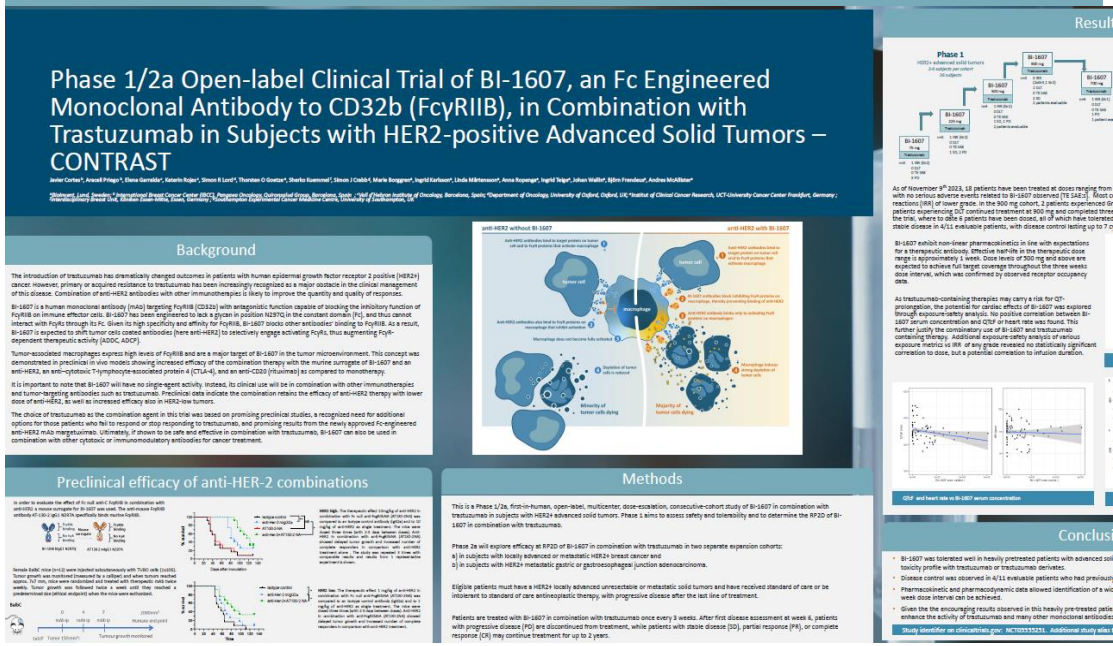
BI-1607 has an antagonistic function

Blocking the inhibitory function of immune effector cells

- Tumor-associated **macrophages** express **high levels of FcγRIIB** and a major **target of BI-1607** in the tumor microenvironment
- Given its **high specificity and affinity** for FcγRIIB, BI-1607 blocks other antibodies' binding to FcγRIIB
- Engineered for reduced Fc-binding, resulting in a **differentiated mechanism of action** vs BI-1206

Well-tolerated and stable disease in 6/11 patients

Phase 1 data of BI-1607 + trastuzumab presented at the San Antonio Breast Cancer Symposium Dec 2023.



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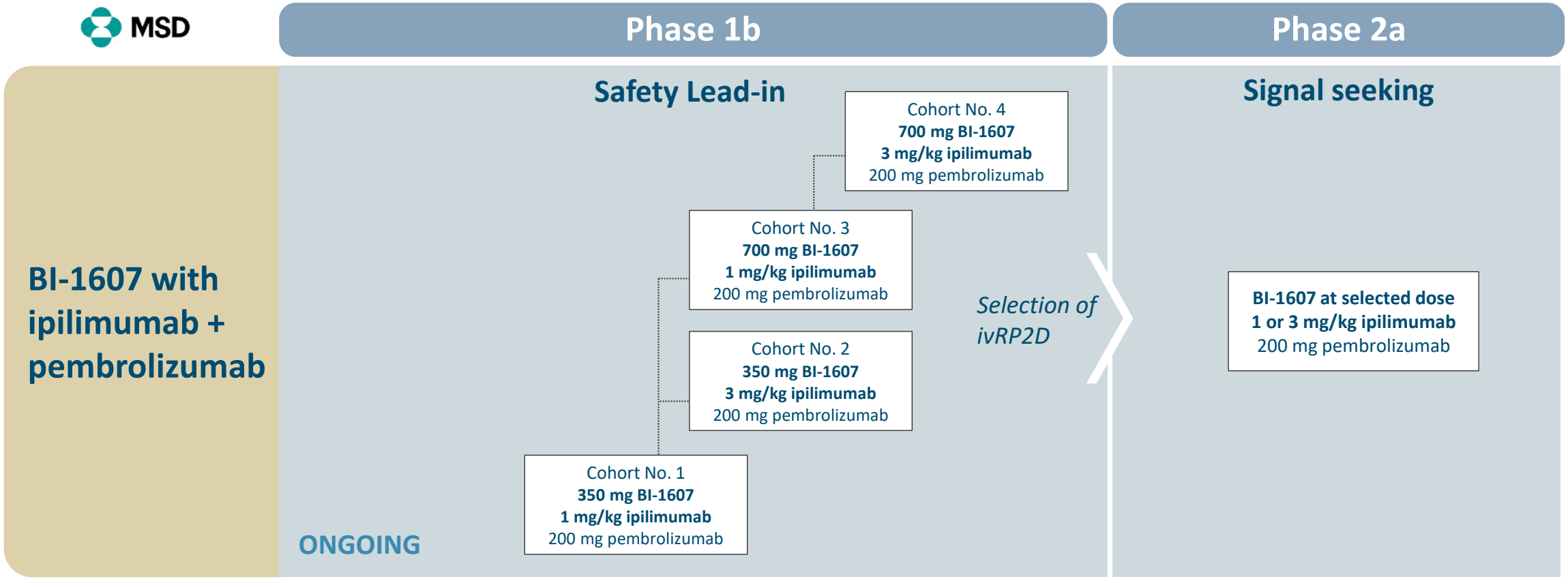
BI-1607 PHASE 1B/2A CLINICAL STUDY DESIGN



WHAT'S NEXT? **First Phase 1b data BI-1607 + ipilimumab + pembrolizumab H2 2025E**

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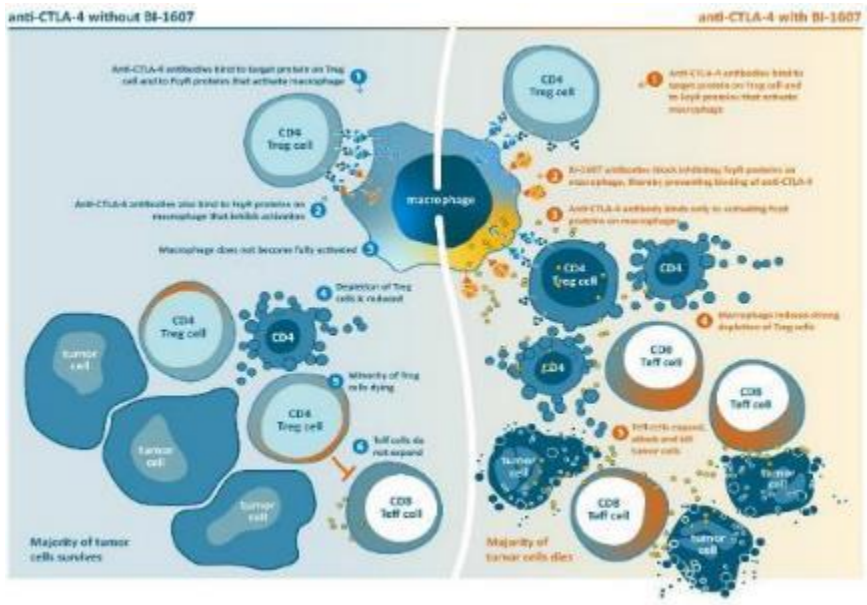
BI-1607: POSITIVE CLINICAL PHASE 1 DATA, TRIPLET STUDY ONGOING

Phase 1b/2a ongoing since Dec 2024

- Evaluating safety and anti-tumoral activity
- 2 dose levels of **BI-1607** with 2 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.

* MSD International Business GmbH, a subsidiary of Merck & Co., Inc., Rahway, NJ, USA

BEST CLINICAL RESPONSES IN LEAD PROGRAMS BI-1808 AND BI-1206

(cut-off DEC 2024)

BI-1808 single agent

1 CR in Ovarian Cancer
1 PR in GIST
9 patients with SD
26 evaluable patients

CTCL cohort:
3 PR
1 patient with SD
4 evaluable patients

BI-1910 single agent

6 patients with SD
12 evaluable patients

BI-1206 + rituximab in NHL

SC formulation:
2 CR
3 PR
3 patients with SD
9 evaluable patients

IV formulation:
5 CR
1 PR
6 patients with SD
17 evaluable patients

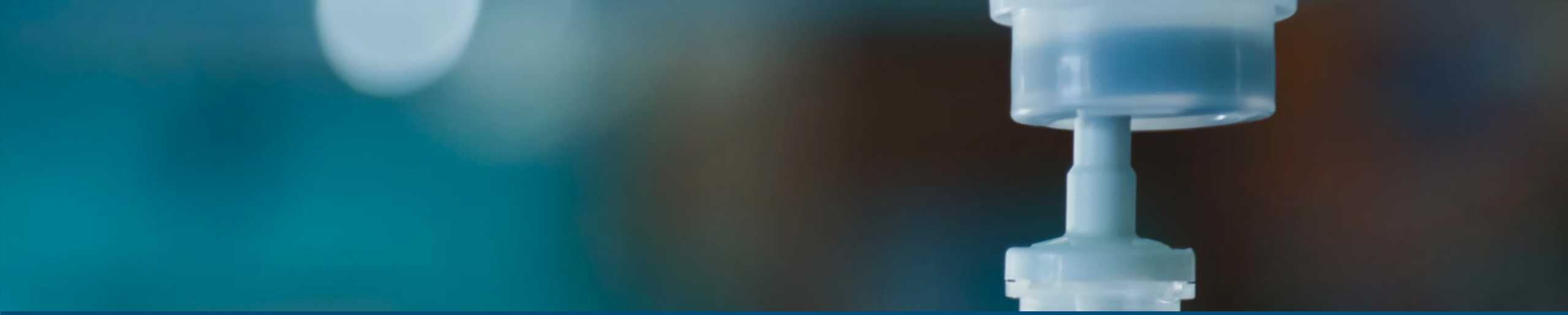
BI-1206 SC + rituximab + acalabrutinib in NHL

1 CR
1 PR
2 evaluable patients

BI-1206 + pembrolizumab in solid tumors

1 CR
1 PR
8 patients with SD
24 evaluable patients

CR = complete response PR = partial response SD = stable disease



ANTI-CTLA-4

ONCOLYTIC VIRUS BT-001

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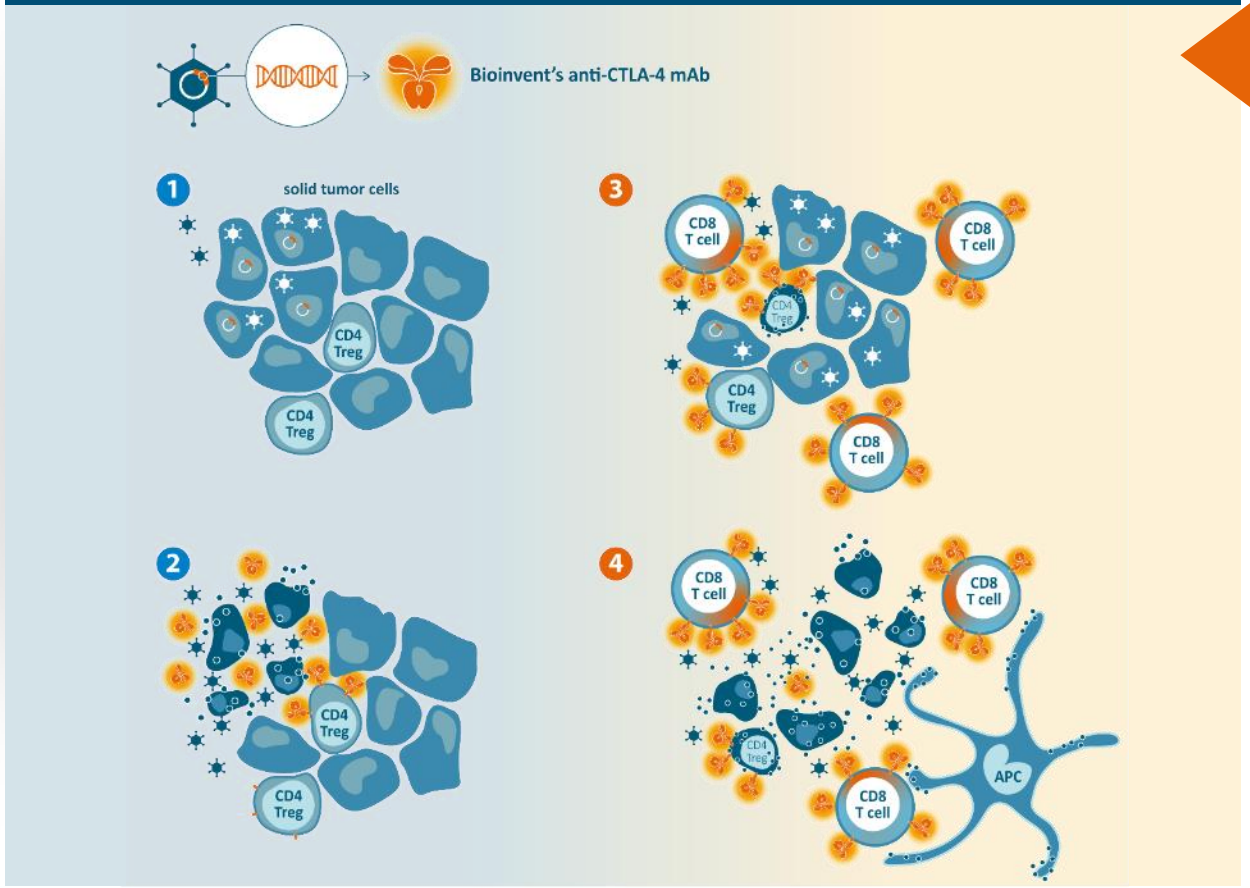
BT-001: PHASE 1/2A ONGOING 50/50 PARTNERSHIP WITH TRANSGENE TO DEVELOP NEXT GENERATION ONCOLYTIC VIRUSES

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 αCTLA-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 Frendéus [1,3]

To cite: Semmrich M, Marchand J-B, Fend L, *et al*. Vectorized Treg-depleting αCTLA-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_{GM}-αCTLA-4 synergized with αPD-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 αCTLA-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

transgene

 * doi: 10.1136/jitc-2021-003488

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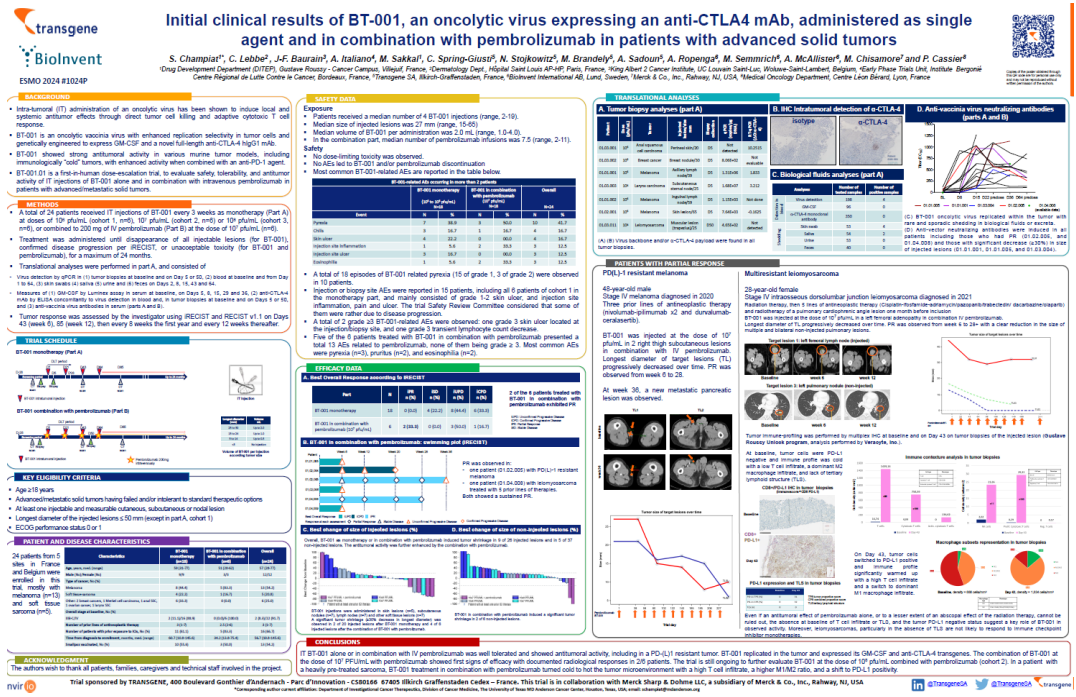
PROMISING BT-001 PHASE 1 COMBINATION DATA AT ESMO 2024

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 MSD

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

transgene

KEY CATALYSTS 2025

EXPECTED KEY CLINICAL MILESTONES 2025

	mid-2025	YE2025
TNFR2 platform		
BI-1808 in solid tumors/TCL	Single agent Ph 2a additional data	Ph 2a data with pembrolizumab
BI-1910 in solid tumors		Ph 1 single agent data Ph 1 data with pembro
FcyRIIB platform		
BI-1206 in NHL	Ph 2a data with rituximab + acalabrutinib	
BI-1206 in solid tumors	Ph 1 data with pembrolizumab	
BI-1607 in solid tumors		Ph 1b data with pembrolizumab + ipilimumab

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EXTERNAL PIPELINE (MARCH 2025)

BIOINVENT'S OUT-LICENSING AGREEMENTS FOR PROJECTS IN CLINICAL DEVELOPMENT

Program	Target	Primary indication	Phase 1	Phase 2	Phase 3	Market	Partner
MT-2990	anti-IL33	Vasculitis (ANCA)					Mitsubishi Tanabe
Mezagitamab (TAK-079)	anti-CD38	Primary Immune Thrombocytopenia					Takeda
Orticumab	anti-ApoB100	Cardiovascular					Abcentra
DS-1055	anti-GARP	Solid tumor					Daiichi-Sankyo
HMI-115	anti-PRLR	Alopecia					Hope Medicine/Bayer

BioInvent's external projects are a seal of excellence for the quality of the company's research and development capabilities.