



Biolnvent

**UNLEASHING IMMUNITY
TO FIGHT CANCER**

August 29, 2024

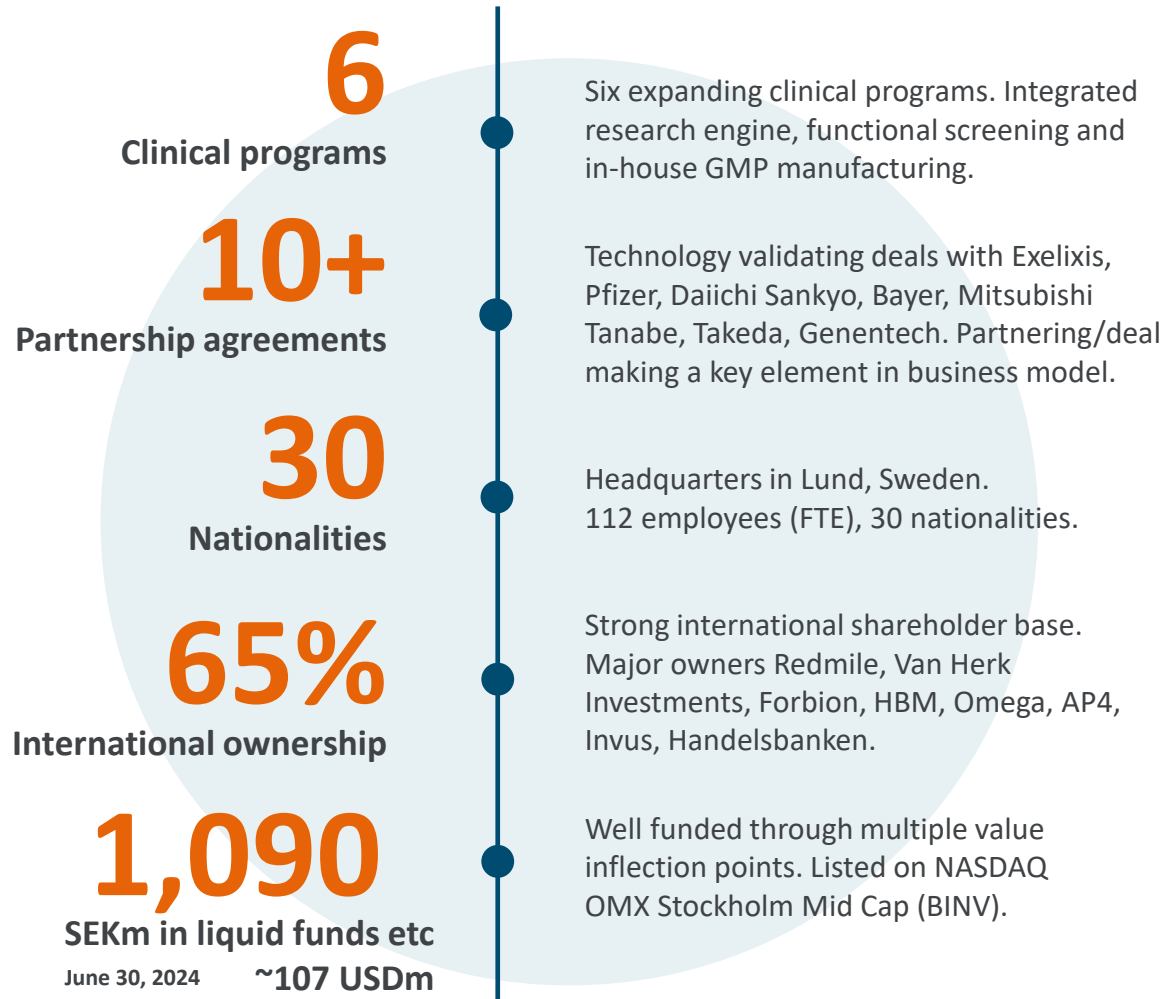
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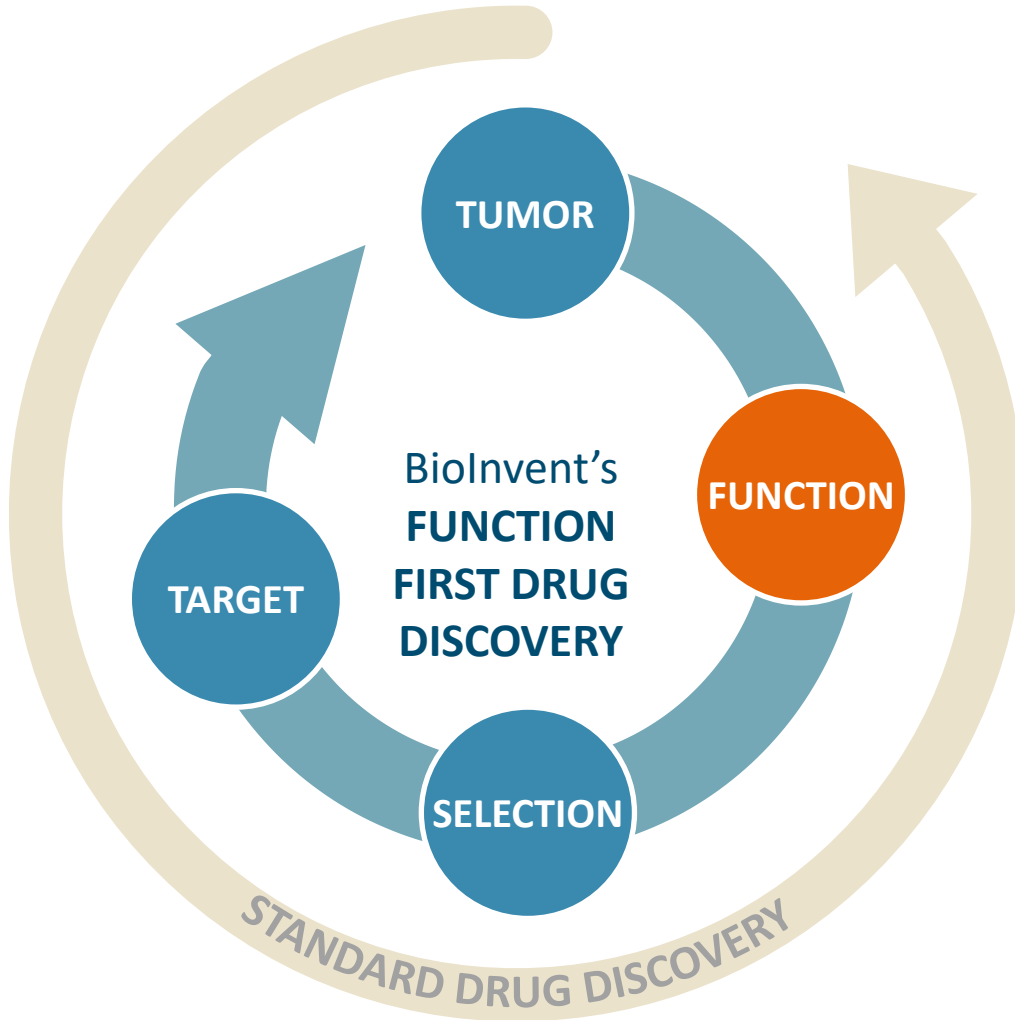
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Translating complex cancer biology into innovative antibody therapies

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

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
 ■ Upcoming



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

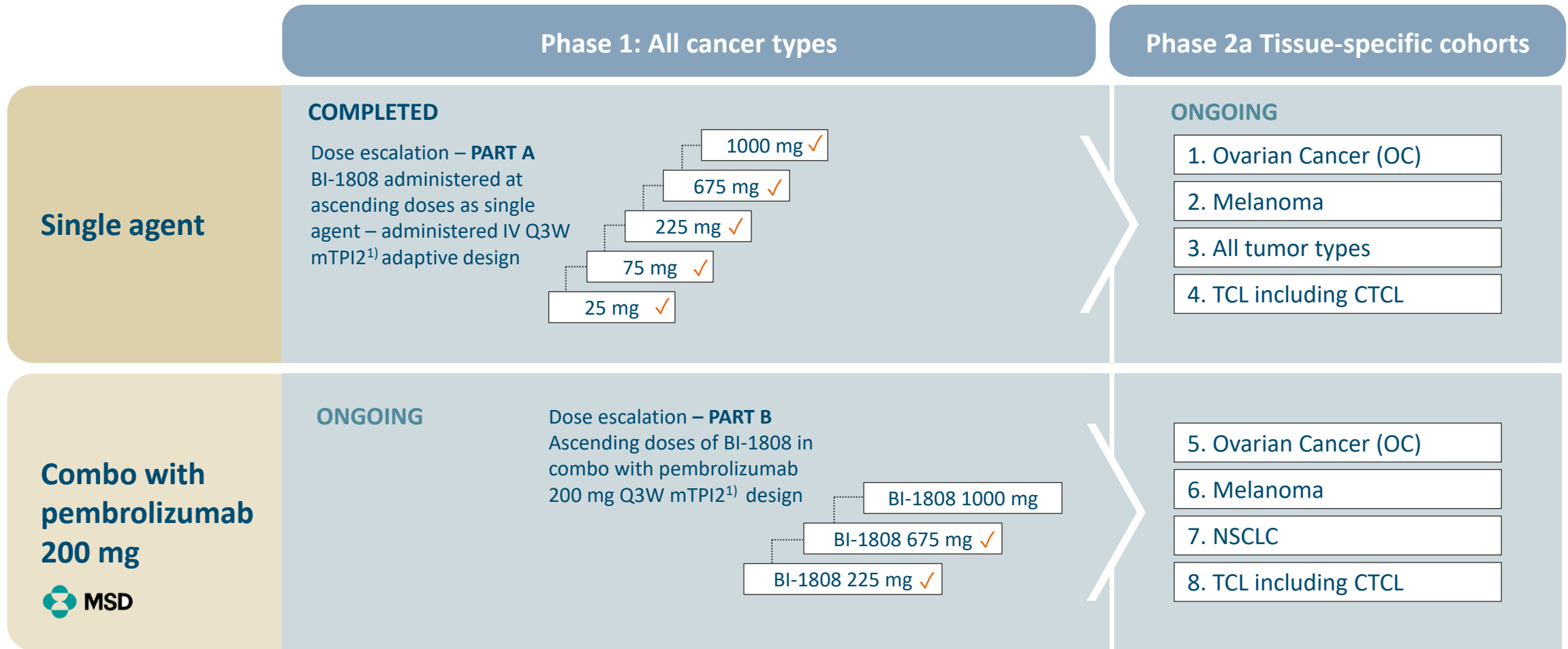
BI-1910 - an agonist mAb

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

Competitors are developing either agonists or antagonists

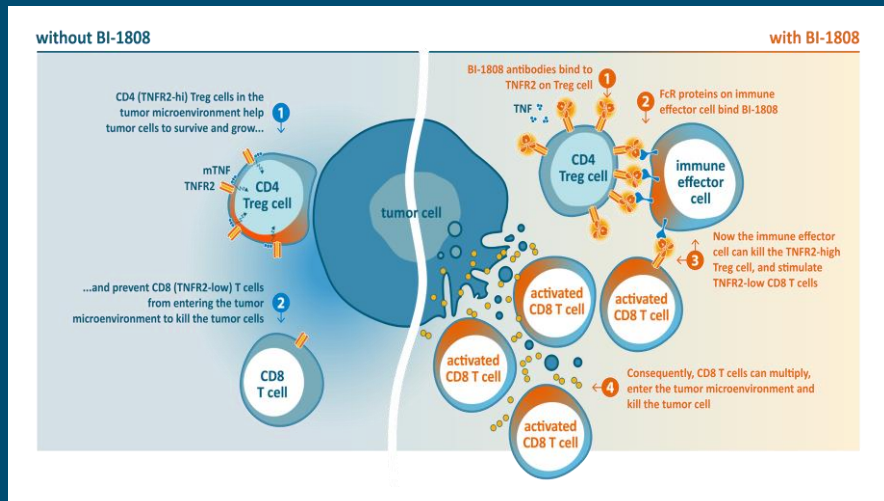
Drug Name	Company Name	Stage	Description
BI-1808	BioInvent	Phase 2	Human IgG1 Blocker/Depleter
BI-1910	BioInvent	Phase 1	Human antibody Agonist
LBL-019	Nanjing Leads Biolabs	Phase 1/2	Humanized IgG1 Blocker
SIM-0235	Simcere	Phase 1	Humanized IgG1 antibody Blocker/Depleter
HFB-200301	HiFiBiO	Phase 1	Humanized 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



ASCO 2024

BI-1808 Phase 1/2a as single agent and in combination with pembrolizumab



- BI-1808 has **single agent activity** in tumor types where immune checkpoint inhibitors have limited efficacy ("cold tumors").
- BI-1808 is safe and **well tolerated** when combined with **pembrolizumab**.
- Efficacy and safety interim data presented at ASCO in a heavily pretreated patient population.

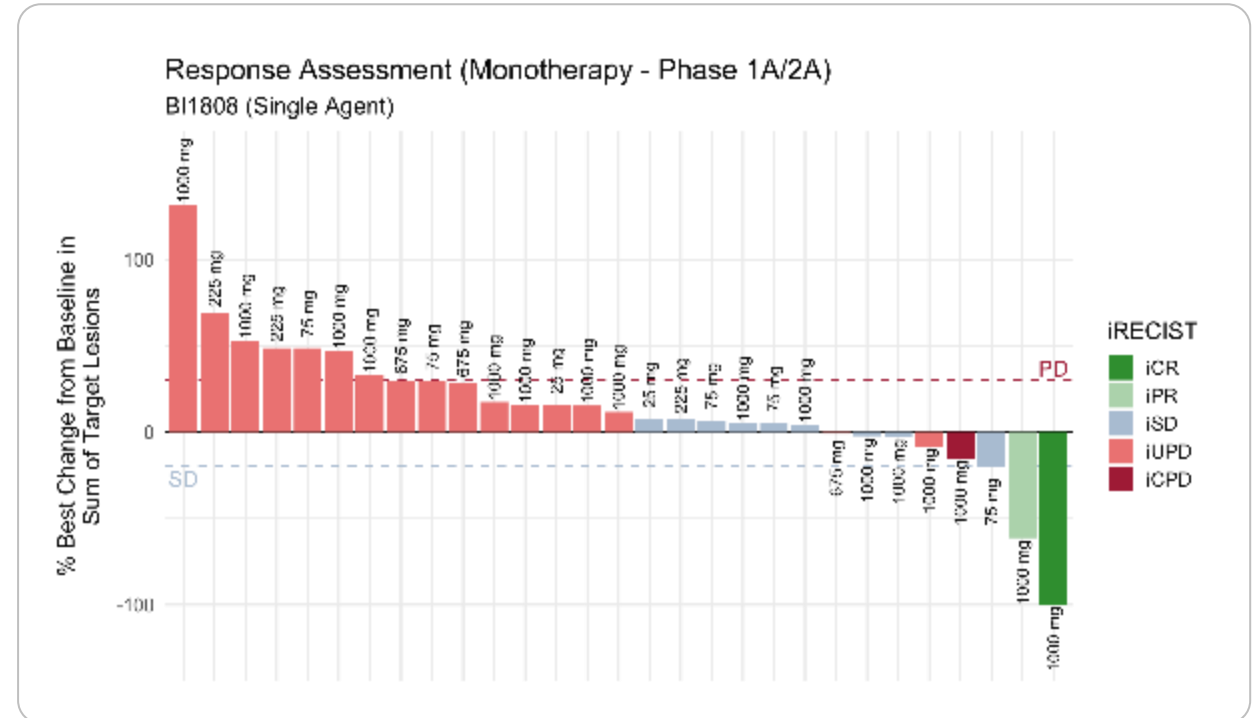


BI-1808 REPRESENTS A **NEW CLASS** OF IMMUNOMODULATORY AGENT

Single agent efficacy in ongoing Phase 1/2a study

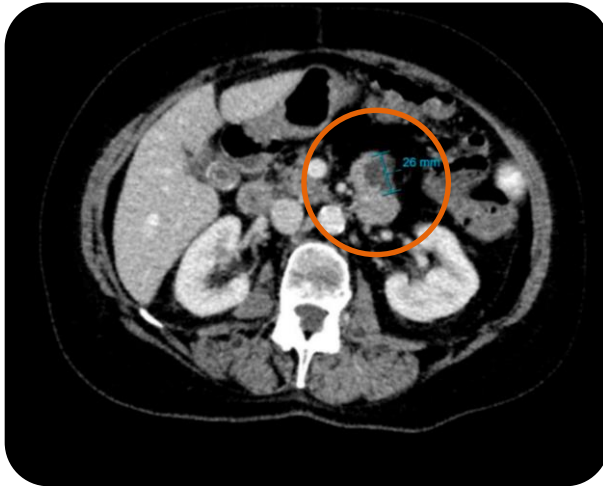
(ASCO, May 2024)

- **1 complete response (CR)** in OC
- **1 partial response (PR)** in GIST
- **9 patients with stable disease (SD)**
- **Excellent safety profile** as single agent
- **26 evaluable patients**

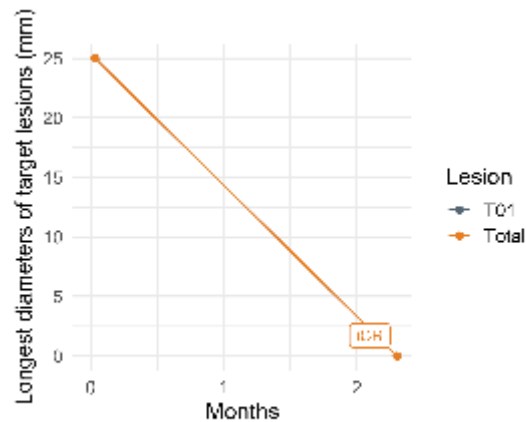


CASE STUDY: COMPLETE RESPONSE IN OVARIAN CANCER

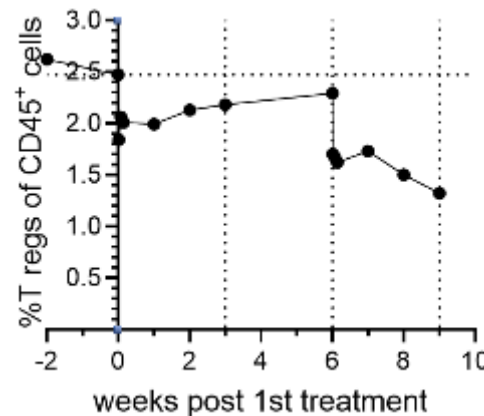
Baseline



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

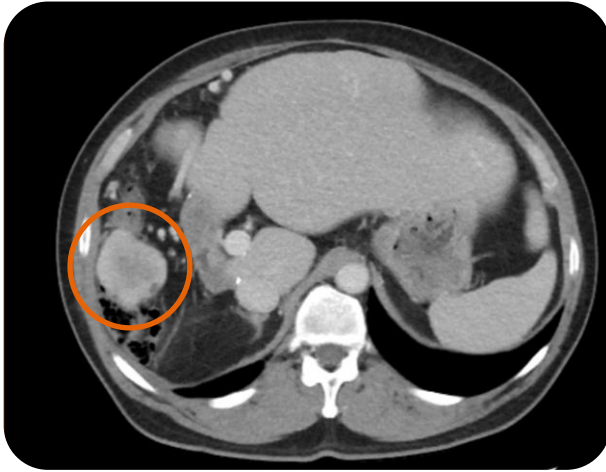
Patient had one target lesion of 25 mm and two larger non-target cystic lesions.

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

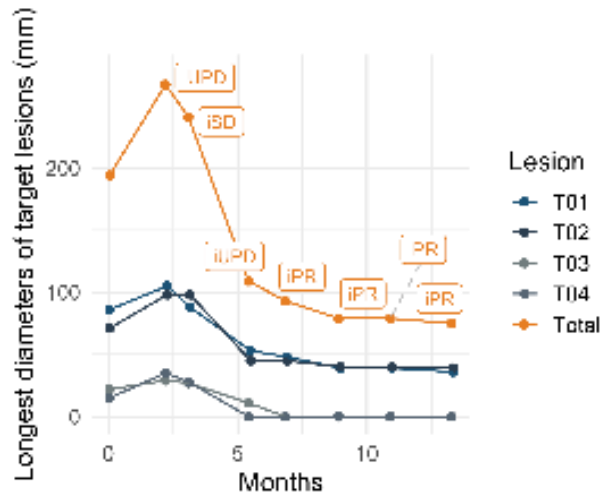
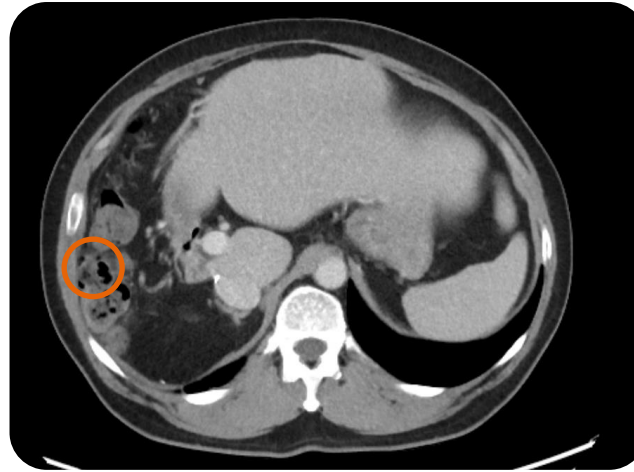
The response has been confirmed

CASE STUDY: ROBUST PR IN A PATIENT WITH GIST

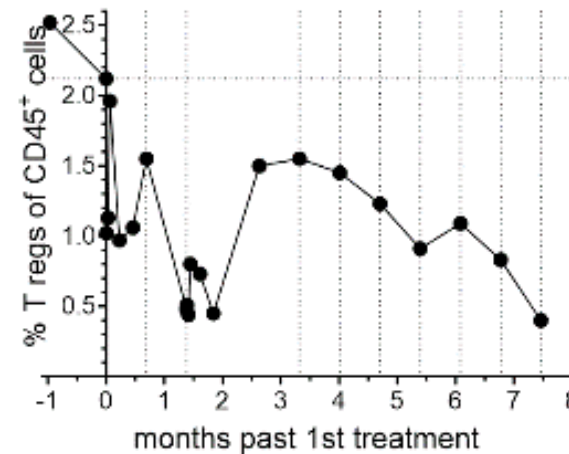
Baseline



Follow-up 13 months



Tumor assessment vs time on study



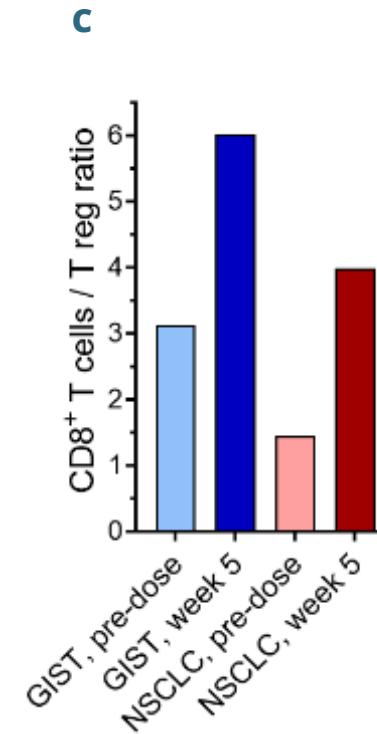
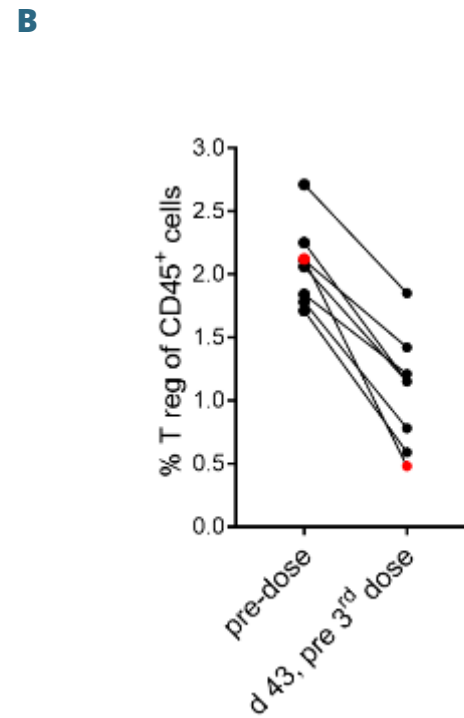
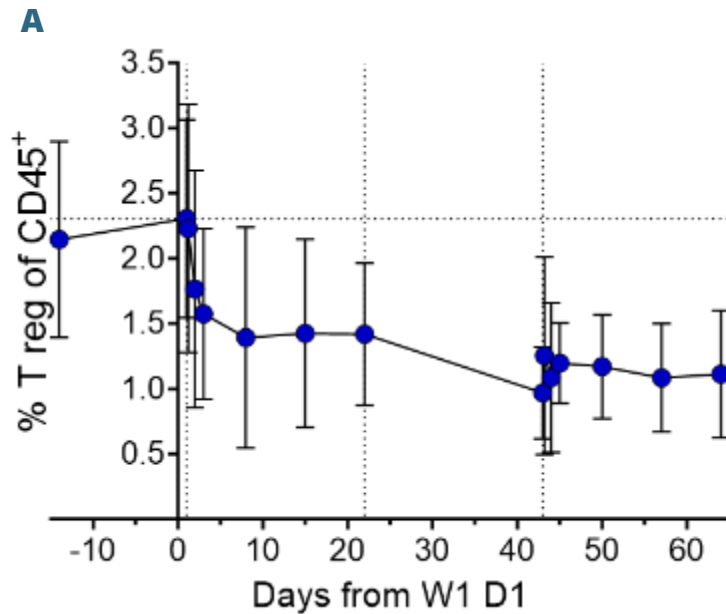
T reg levels vs time on study. Dashed lines indicate administration of BI-1808

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.**

In the most recent scan, total tumor burden is **reduced by 61%** of baseline, with BI-1808 monotherapy for 13 months and ongoing.

GIST is a gastrointestinal tumor where current immune checkpoints inhibitors show very limited activity.

BI-1808 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

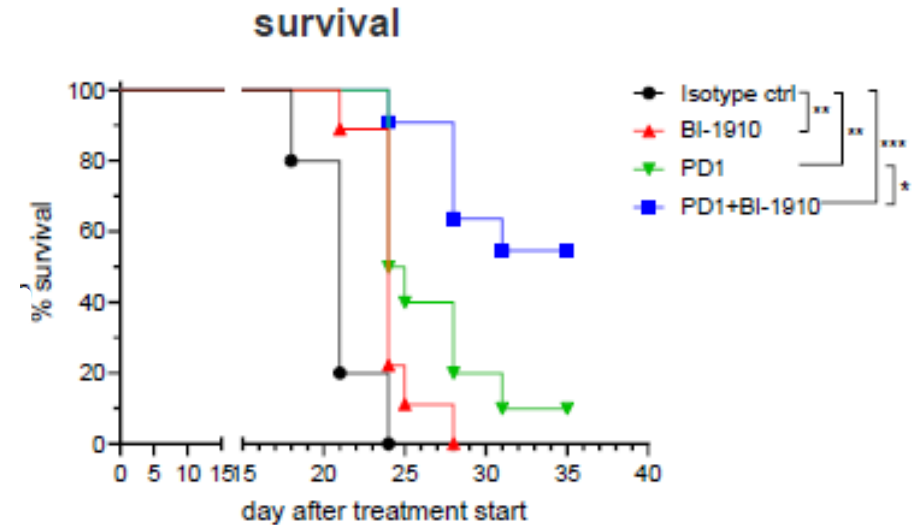
Data from the 1000 mg monotherapy cohort.

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-1910: POTENTIAL BEST-IN-CLASS TARGETING AN IDENTIFIED UNMET NEED

A differentiated, agonist approach to treating solid tumors compared to BI-1808

- Enrolment ongoing in Phase 1/2a clinical trial in the US and Europe since December 2023
- Innovative, **adaptive clinical trial** design for dose escalation
- First part evaluates **single agent** BI-1910
- Second part a dose escalation phase with BI-1910 in combination with **pembrolizumab**. Supply agreement with MSD*
- Exploratory expansion cohorts are then planned in **hepatocellular carcinoma (HCC)** and **non-small cell lung cancer (NSCLC)**.



Preclinical data showcase BI-1910 anti-tumor activity and synergy with anti-PD-1. Further mode-of-action analyses demonstrate that BI-1910 increases intratumoral CD8+ T effector cells and induces long-lasting T cell memory.

WHAT'S NEXT?

Trial in progress poster at ESMO 2024. First Phase 1 single agent data H2 2024E

ANTI-FC γ RIIB

BI-1206 + rituximab

BI-1206 + pembrolizumab

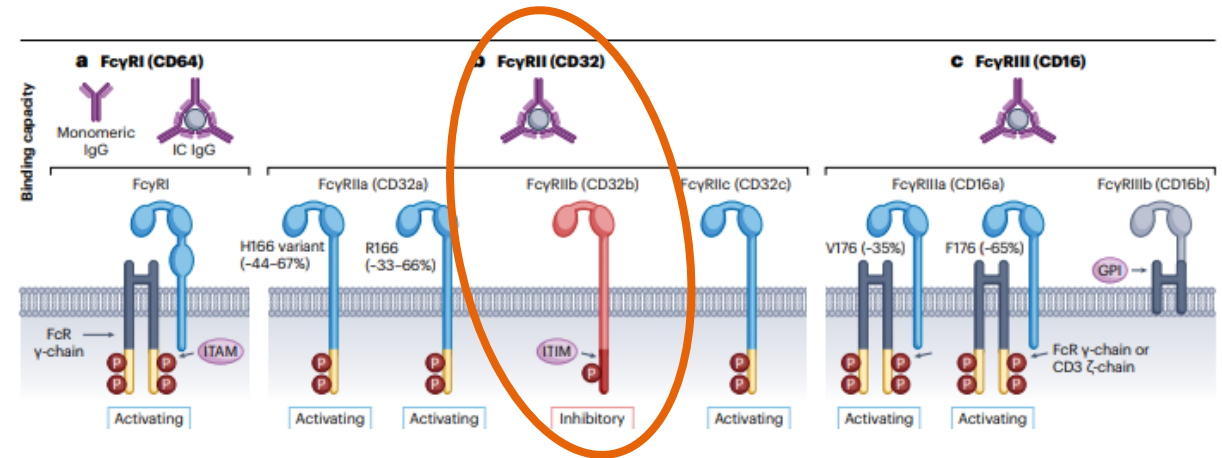
BI-1607

LEVERAGING OUR FC γ RIIB 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.

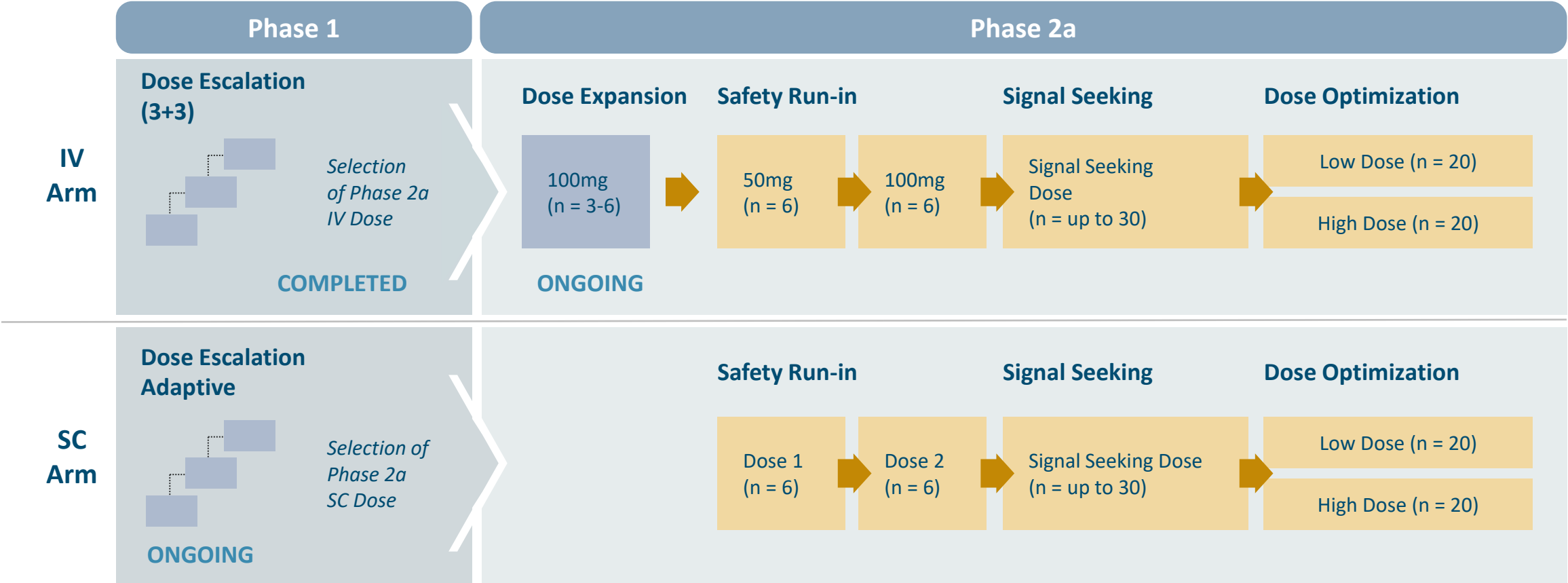


Galvez-Cancino, F., Simpson, A.P., Costoya, C. et al. Fcγ receptors and immunomodulatory antibodies in cancer. *Nat Rev Cancer* 24, 51–71 (2024). <https://doi.org/10.1038/s41568-023-00637-8>

BI-1206 IN COMBINATION WITH RITUXIMAB: OPEN LABEL PHASE 1/2A STUDY ONGOING

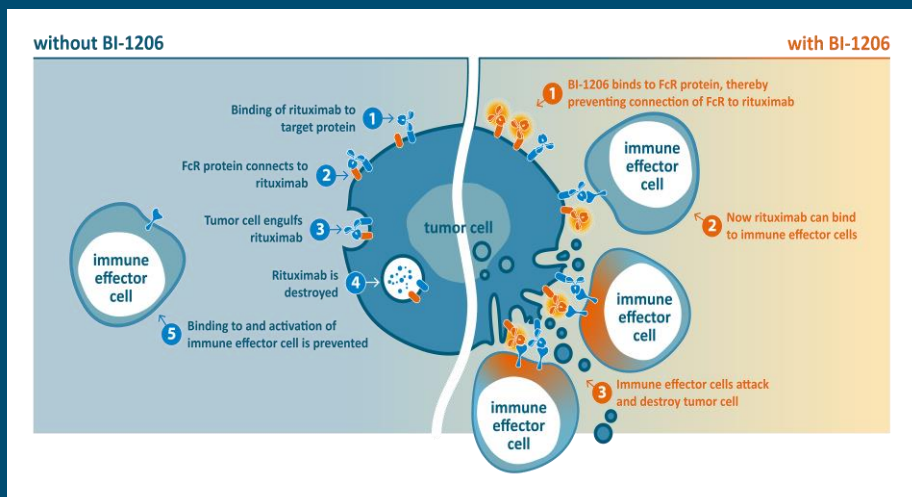
SC formulation selected for the upcoming triplet Phase 2a

BI-1206 + rituximab
 BI-1206 + rituximab + acalabrutinib



EHA 2024:

Promising preliminary results showing safety and efficacy of BI-1206 in combination with rituximab to treat indolent B-cell non-Hodgkin lymphoma.

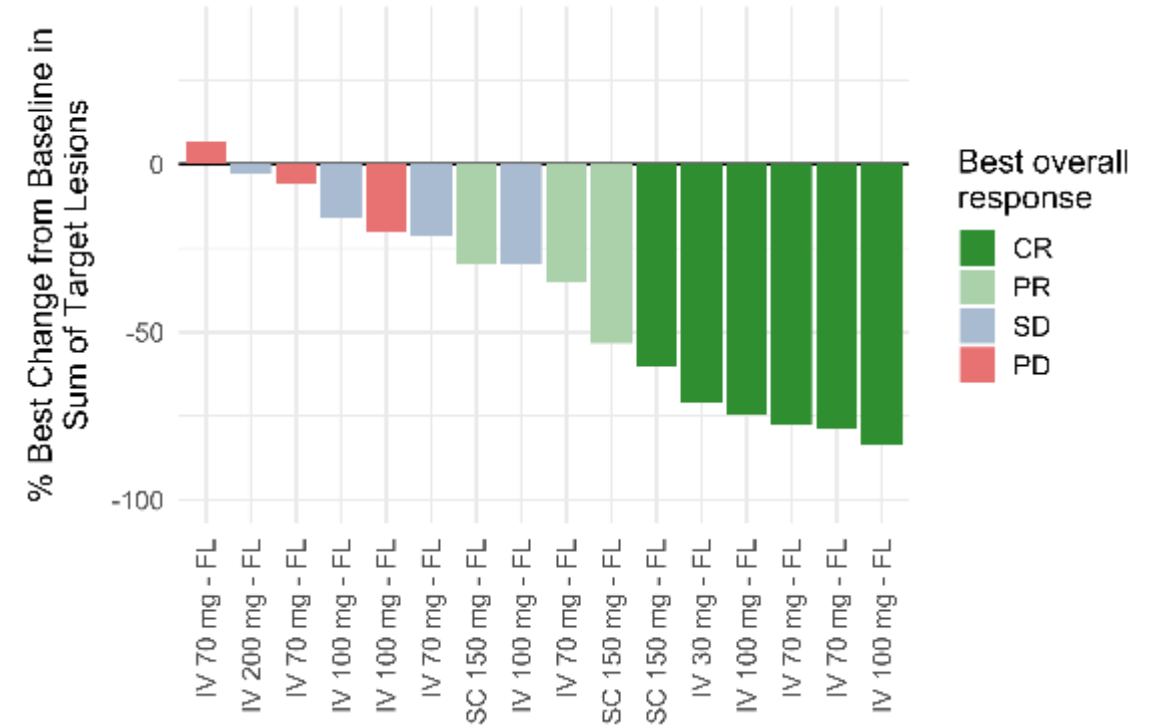


CO-ADMINISTRATION OF BI-1206 WITH RITUXIMAB LED TO HIGH RESPONSE RATES IN RELAPSED/REFRACTORY FL PATIENTS

Quality of responses particularly impressive

(May 2024, SC + IV):

- **6 complete response (CR)**
- **3 partial response (PR)**
- **4 patients with stable disease (SD)**
- **CRs have been long-lasting**, three of them **lasting years after** end of treatment
- **No safety or tolerability concerns**



FL: ORR of 56%, CRR of 38%

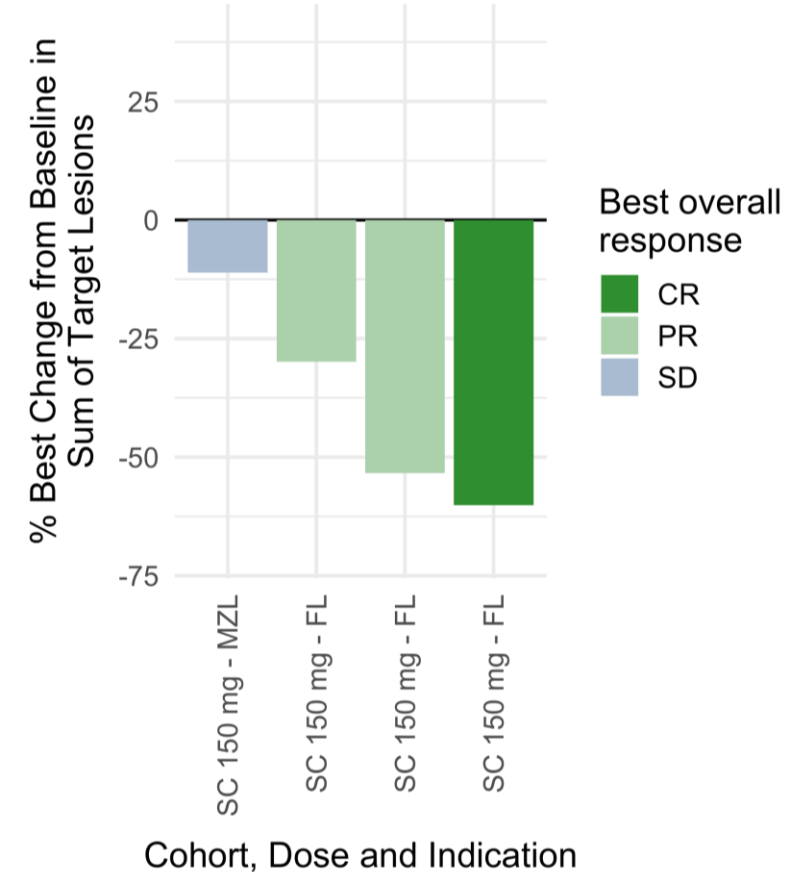
BI-1206 IN NHL: IMPRESSIVE EARLY CLINICAL EFFICACY DATA

Encouraging first data for SC arm

(May 2024):

First data for the **SC** arm presented at EHA2024:

- **1 complete response (CR)**
- **2 partial responses (PR)**
- **1 patient with stable disease (SD)**
- 4 evaluable patients.



POSITIVE INTERIM CLINICAL EFFICACY DATA FROM STUDY IN CHINA



CASI Phase 1 dose-escalation data reinforce previously reported positive efficacy data

(March 2024):

- **1 Complete Response (CR), 4 Partial Responses (PR)** out of 8 evaluable patients
- **CR** (in Marginal Zone Lymphoma (MZL) has been **long-lasting, 20+ weeks**
- **Manageable safety profile across all patients**

- **1 Complete response**
- **4 Partial responses**



**Durable CR
(20 + weeks)**

CASI Pharmaceuticals Phase 1 interim data show clinical responses from 5 patients out of 8 evaluable patients

BI-1206 IN NHL: AGREEMENT WITH ASTRAZENECA

BI-1206 in combination with rituximab and Calquence

- **AstraZeneca** to provide **Calquence** (BTK inhibitor) for combination with BI-1206 and rituximab to Phase 1/2a clinical study in patients with NHL who have progressed or are refractory to rituximab.
- The Phase 2a IV dose expansion cohort in combination with rituximab is currently enrolling patients, will look to enroll patients to be treated with the triplet.
- The Calquence expansion cohort is expected to enroll approximately 30 patients at sites in Sweden, Spain, the US, and Brazil.
- The **conveniency and safety profile** of this **triplet** will be **very competitive** in the treatment landscape of NHL.



About us Clinical programs Our Science Partners Investors

BioInvent to evaluate BI-1206 in combination with rituximab and Calquence

09 Feb 2024

- **Clinical supply agreement with AstraZeneca to support Phase 1/2a BI-1206 combination study**
- **BI-1206 to be evaluated in combination with Calquence® and rituximab in Phase 1/2a trial in non-Hodgkin's lymphoma**
- **The ongoing rituximab combination trial will be expanded to include the triplet arm**

Lund, Sweden – February 9, 2024 – BioInvent International AB ("BioInvent") (Nasdaq Stockholm: BINV), a biotech and development of novel and first-in-class immune-modulatory antibodies for cancer immunotherapy, today announce a clinical supply agreement with AstraZeneca (LSE/STO/Nasdaq: AZN) to evaluate BioInvent's anti-FcγRIIB antibody, BI-1206, in combination with Calquence (acalabrutinib), in a Phase 1/2a study in non-Hodgkin's lymphoma (NHL).

Under the terms of the supply agreement, AstraZeneca will provide Calquence, a selective inhibitor of Bruton's tyrosine kinase, in combination with BI-1206 and rituximab in the ongoing Phase 1/2a clinical study (NCT03571568) for the treatment of patients who have progressed or are refractory to rituximab.

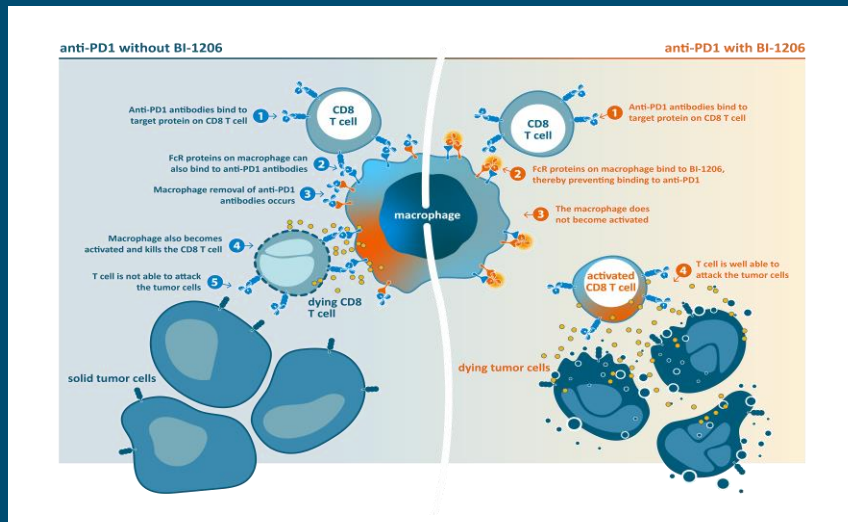
"Having already shown the benefits of combining BI-1206 with rituximab, we believe the addition of Calquence for the triplet will further improve clinical outcomes for patients with non-Hodgkin's lymphoma, including follicular lymphoma and mantle cell lymphoma," said Welschof, CEO of BioInvent. "We are extremely pleased to be entering into this supply agreement with AstraZeneca to bring a new, chemo-free, treatment option for these patients."

The Phase 1 part - intravenously (IV) administered BI-1206 - has been completed with impressive early signs of clinical activity. The Phase 1 expansion cohort is currently enrolling patients, and it will look to enroll patients to be treated with the triplet. A sub-cohort will be developed in parallel to the IV and it is expected to bring a great deal of convenience to the treatment. The Calquence expansion cohort is expected to enroll approximately 30 patients at sites in Sweden, Spain, the US, and Brazil.

ASCO 2024:

Promising Data From Phase 1/2a Study of BI-1206 In Combination With Pembrolizumab In Advanced Solid Tumors Previously Treated With Anti-PD1/L1.

- BI-1206 in combination with pembrolizumab lead to responses in melanoma patients who had previously failed on anti-PD1/PDL1 therapy.
- SC administration shows great promise and provides extended duration of receptor occupancy with increased tolerability.

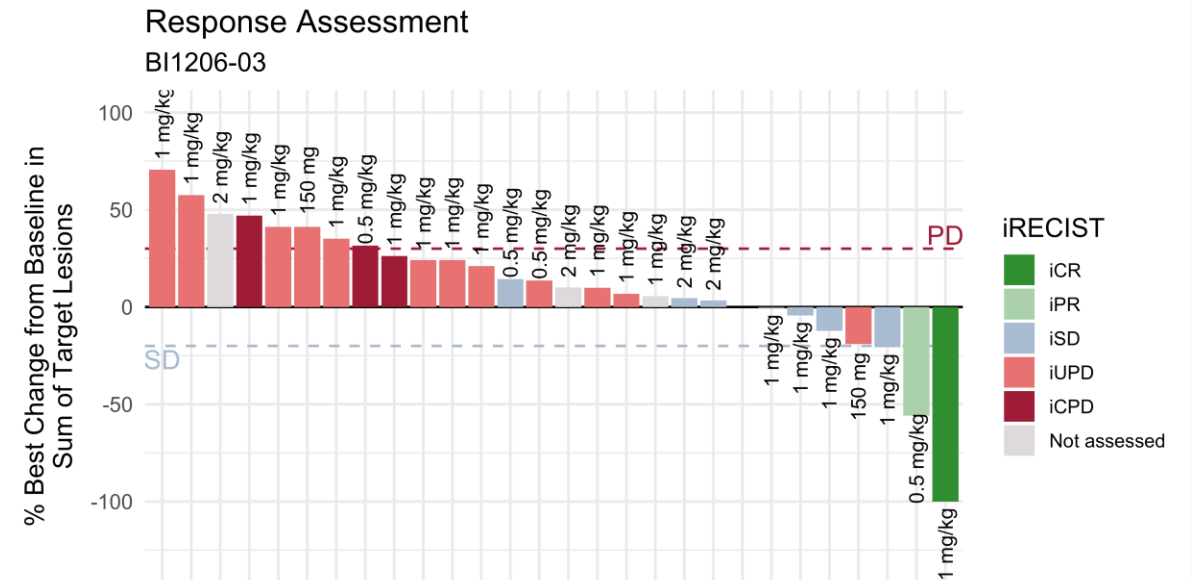


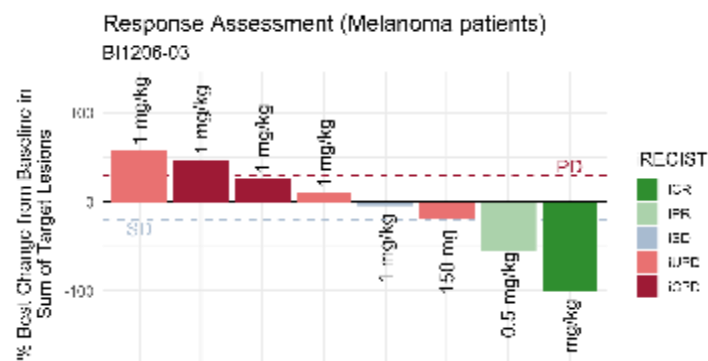
BI-1206 IN SOLID TUMORS: PHASE 1/2A STUDY ONGOING

Promising efficacy signals in Phase 1 part of study

(ASCO, May 2024):

- **1 complete response (CR)**
- **1 partial response (PR)** in uveal melanoma
- **7 patients with stable disease (SD)** including one long-lasting (≥ 2.5 years)
- 24 evaluable patients
- Co-administration of BI-1206 with pembrolizumab was **well-tolerated** in a **heavily pretreated population**
- BI-1206 is being evaluated as both an intravenous (IV) and subcutaneous (SC) administration and has the potential to overcome resistance to immune checkpoint inhibition (CPI)



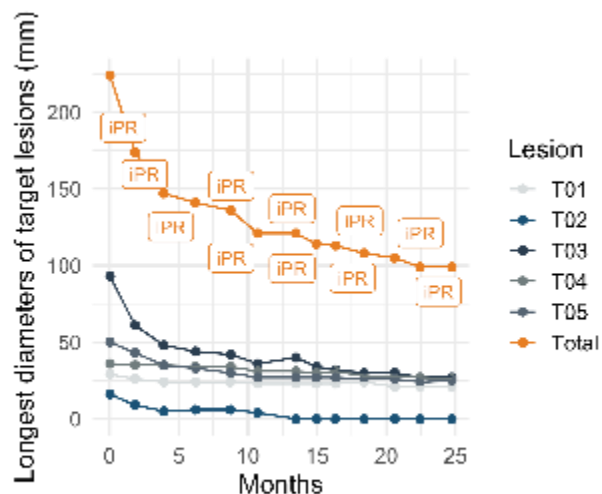


Co-administration of BI-1206 with pembrolizumab was well-tolerated in a heavily pretreated population, with promising responses observed in melanoma, and uveal melanoma, who previously failed anti-PD1 therapy.

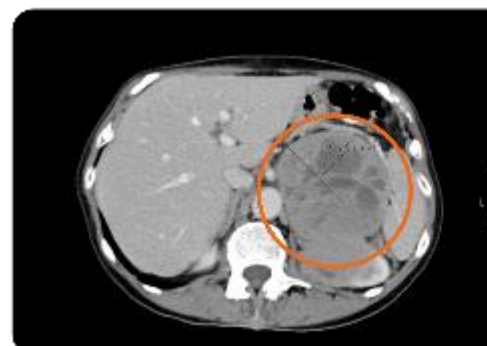
Case study: PR

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.



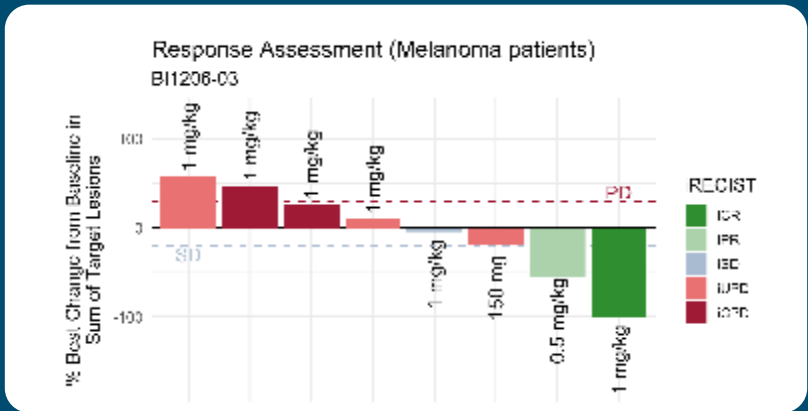
Baseline



End of treatment 2 years

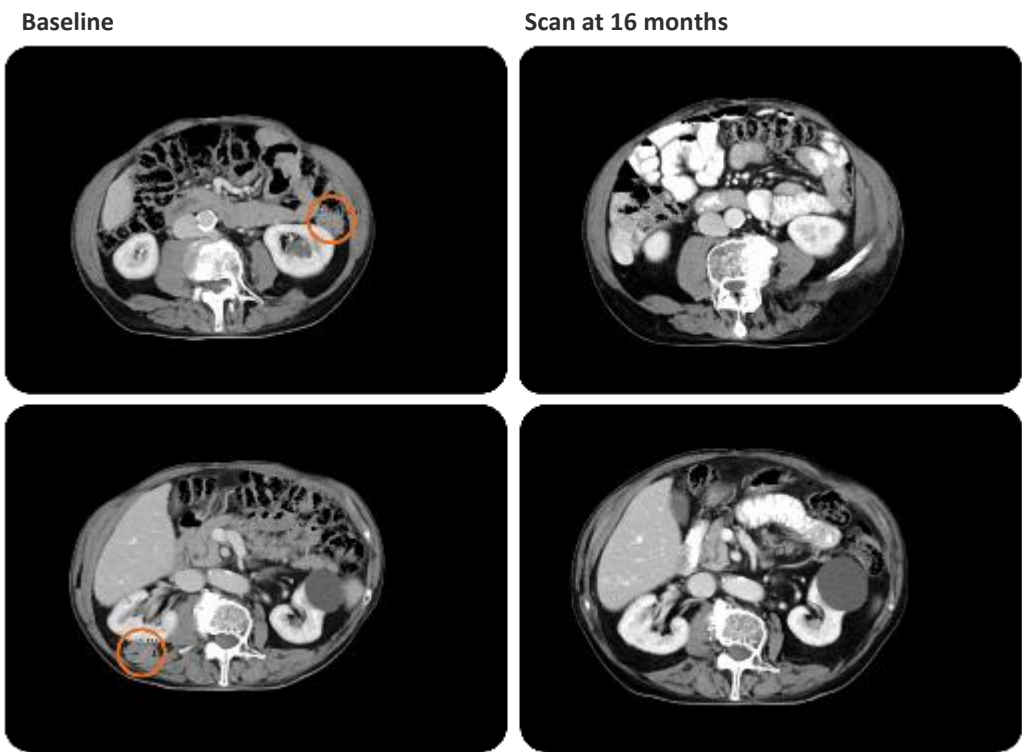
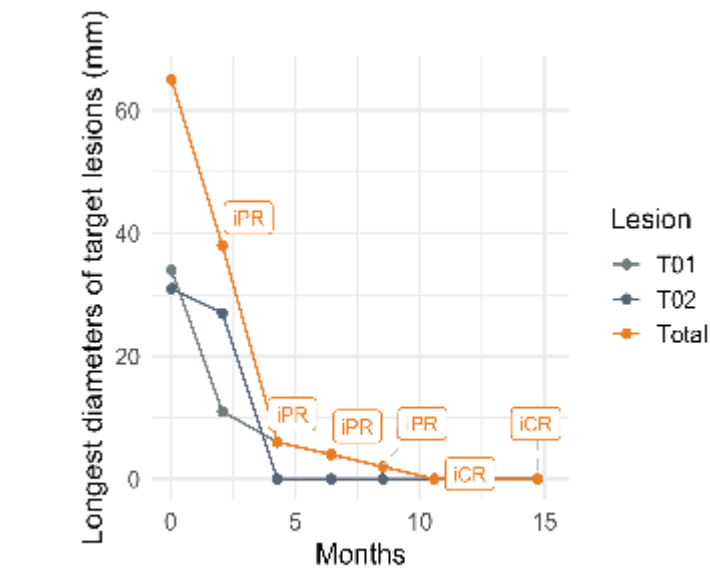


Co-administration of BI-1206 with pembrolizumab was well-tolerated in a heavily pretreated population, with promising responses to treatment observed in melanoma, including uveal melanoma, who previously failed anti-PD1 therapy.



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.



PLANS FORWARD – STUDY DESIGN BI-1206 IN SOLID TUMORS

Phase 1 All cancer types

Phase 2a Tissue-specific Cohorts



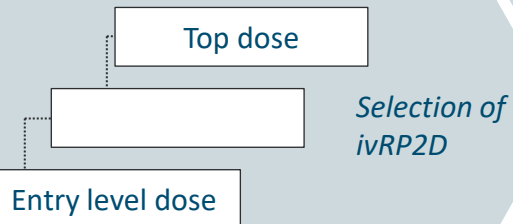
Dose escalation mTPI-2¹⁾ design

Signal seeking

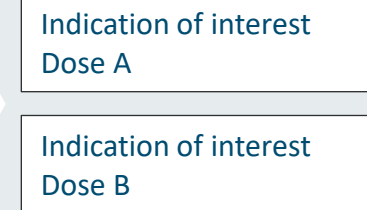
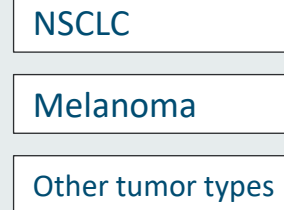
Dose optimization

IV Cohort

BI-1206 in
combination
with pembrolizumab



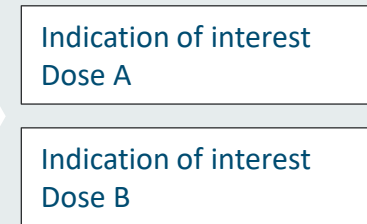
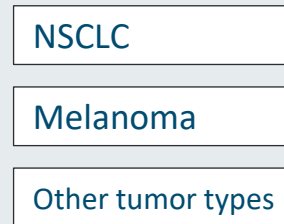
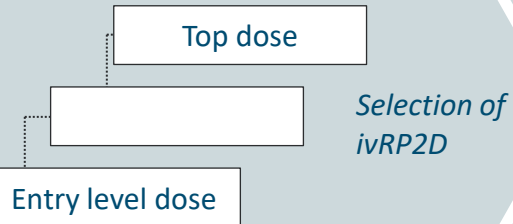
ONGOING



SC Cohort

BI-1206 in
combination
with pembrolizumab

ONGOING



- **IV** dose level has been selected for Ph2a

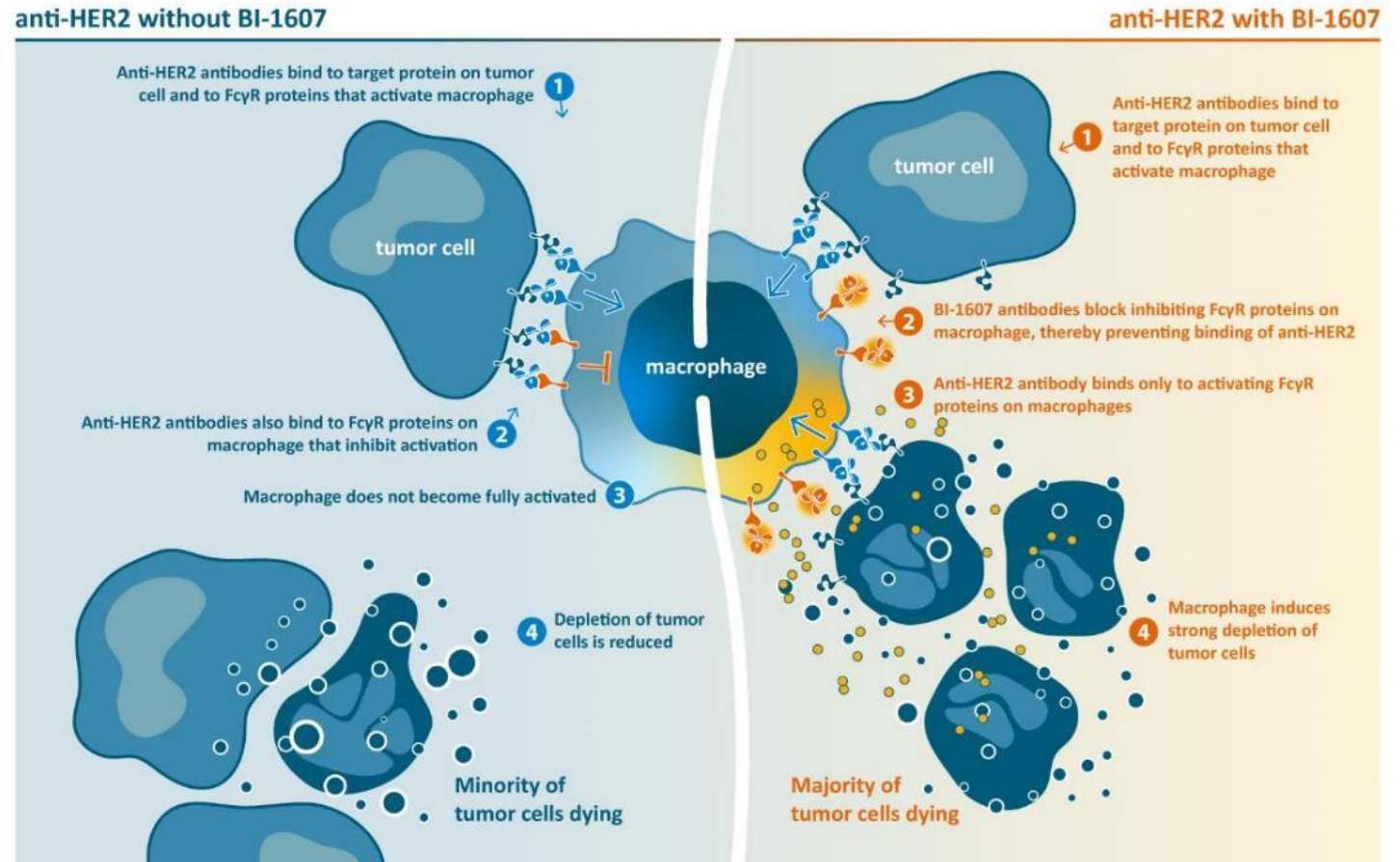
- **SC** for Ph2a will be determined after completion of dose escalation.

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

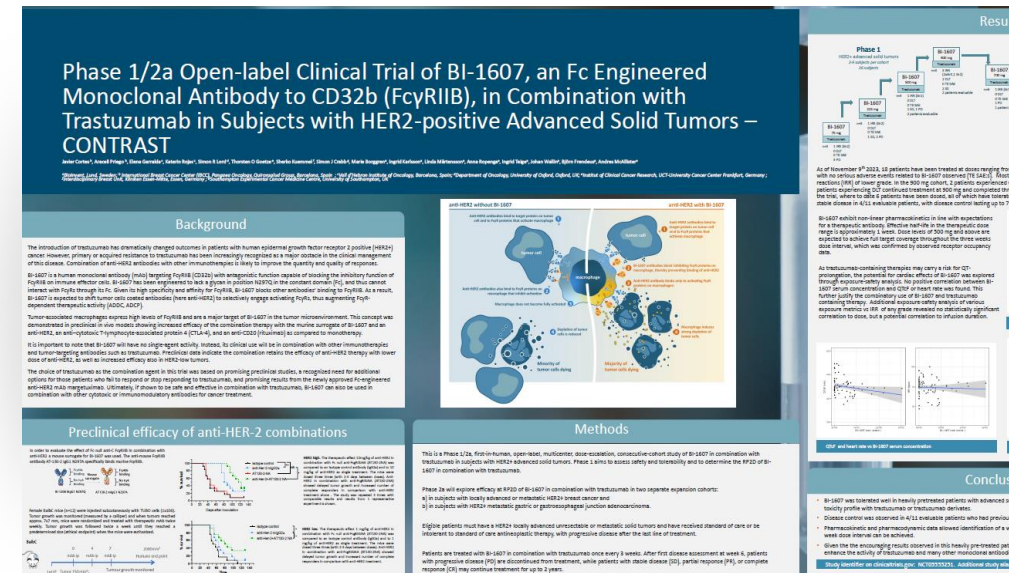


BI-1607: POSITIVE CLINICAL PHASE 1 DATA, TRIPLET STUDY IN PREPARATION

Well-tolerated and stable disease in 6/11 patients

Phase 1 data of BI-1607 in combination with trastuzumab were presented at the San Antonio Breast Cancer Symposium in Dec 2023.

- Treatment **well-tolerated**, no serious adverse events related to BI-1607 observed. 18 patients, doses ranging from 75 mg up to 900 mg flat dose
- Best clinical response **stable disease (SD)** in 6/11 evaluable patients, with disease control lasting up to 7 cycles (21 weeks)



In July 2024, a clinical trial and supply agreement with Merck was announced to support the expansion of the BI-1607 program with a new Phase 1b/2a triplet combination study. The study will evaluate two different dose levels of BI-1607 with two different dose levels of ipilimumab in combination with 200 mg flat dose of pembrolizumab in patients with unresectable or metastatic melanoma, previously treated with anti-PD-1/L1.

WHAT'S NEXT?

Preparations ongoing to initiate patient recruitment for the triplet Phase 1b/2a study



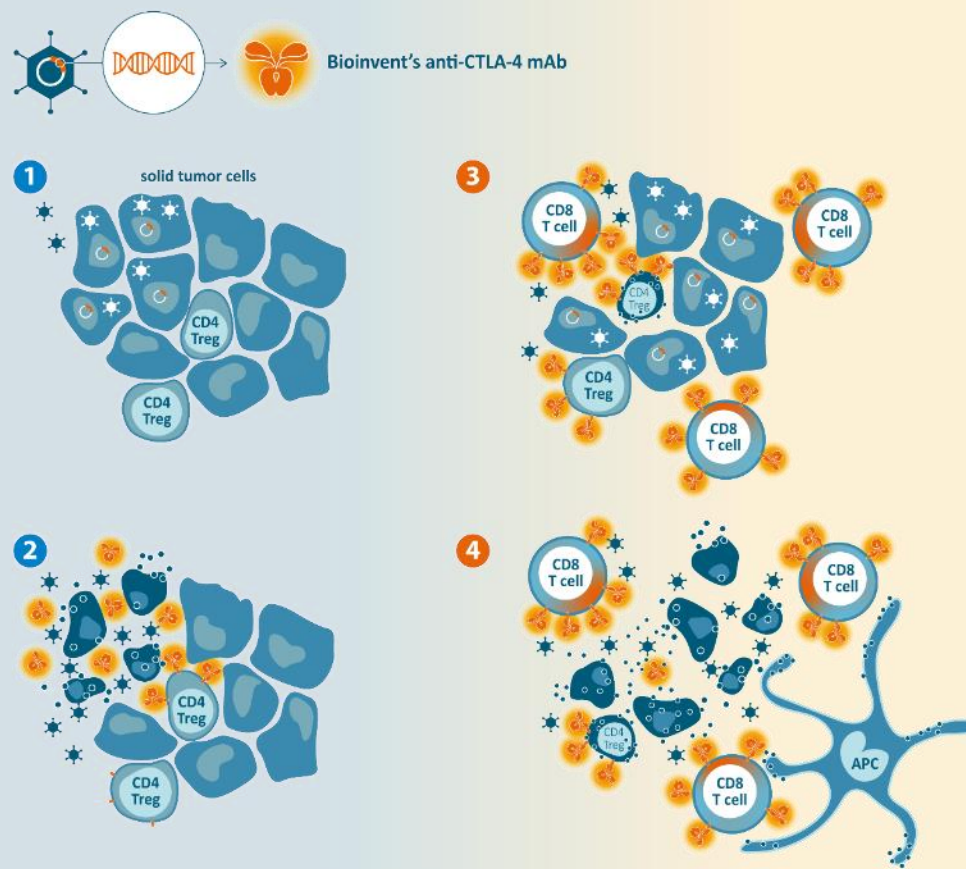
ANTI-CTLA-4

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

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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



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



POSITIVE BT-001 SINGLE AGENT PHASE 1 DATA OPENS FOR COMBINATION

Objective antitumor activity, i.e. decrease of injected lesion size of $\geq 50\%$ observed in two patients

Data from Phase 1/2a open-label, multicenter, dose-escalation study of BT-001 as single agent

- Treatment of all **Phase 1** cohorts in monotherapy completed with **no safety concerns**
- **Stabilization of injected lesions** in 11/18 patients
- In October 2023, BioInvent and Transgene announced first patient dosed in the Phase 1 part B clinical trial evaluating the **combination** of **BT-001** and MSD's anti-PD-1 therapy, KEYTRUDA® (**pembrolizumab**)



WHAT'S NEXT?

First Phase 1 data BT-001 + pembrolizumab combination at ESMO 2024



KEY CATALYSTS 2024

Expected key clinical milestones 2024

BI-1808 in solid tumors

single agent

BI-1206 in NHL

triplet (+ rituximab + acalabrutinib)

BI-1910 in solid tumors

single agent

BT-001 in solid tumors

+ pembrolizumab

YE 2024

Early Phase 2
data

H2 2024

A mix of more
complete and
early Phase 1
data



BioInvent

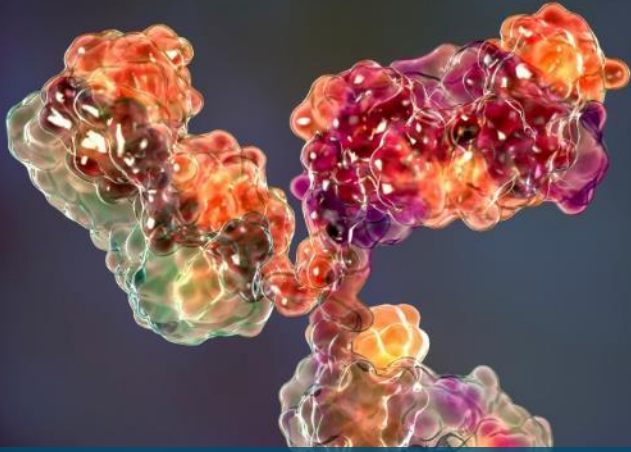
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Everything we do is based on our **extensive knowledge** of immunology, cancer biology, and antibody biology



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Stefan Ericsson
CFO



LINK Medical Research
Theradex Oncology

Marie Moores
COO

USING PARTNERSHIPS TO VALIDATE OUR CAPABILITIES AND EXPERTISE



Exclusive license agreement and clinical collaboration for BI-1206 for China/Hong Kong/Macau/Taiwan



Co-developing (50/50 share of costs and profits) of oncolytic virus BT-001 for solid tumors, leveraging BioInvent's n-CoDeR® and F.I.R.S.T™ platforms



Clinical supply (pembrolizumab) and **collaboration agreement** with MSD for BI-1206, BI-1808, BI-1910, BI-1607 and BT-001. **Supply** (Calquence®) **agreement** with AstraZeneca for BI-1206.



Mitsubishi Tanabe



Daiichi-Sankyo



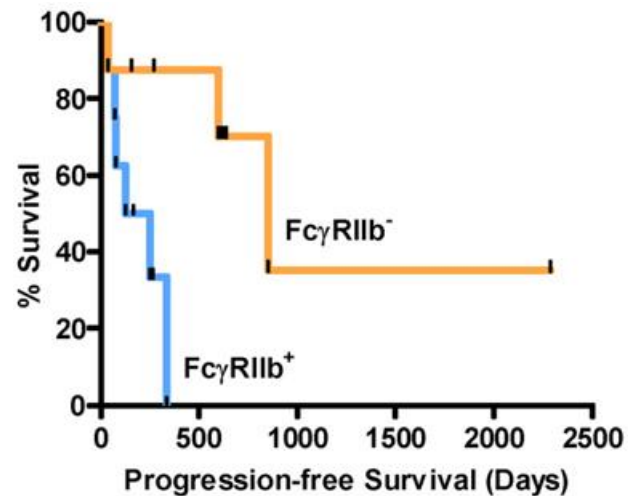
Antibody discovery partnerships using n-CoDeR® antibody library (antibodies in clinical development)



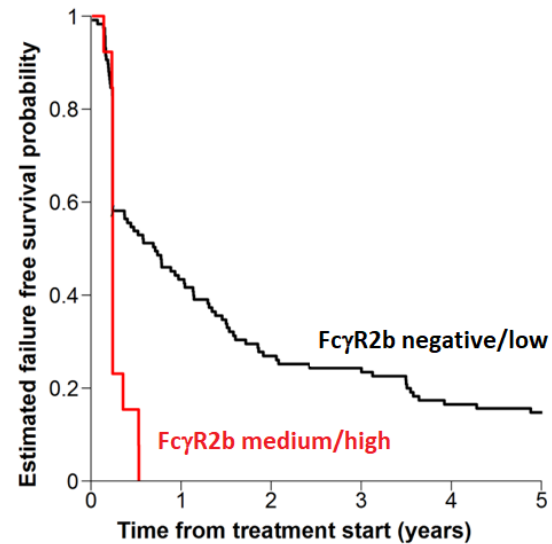
Academic/Patient organizations collaborations

FCGRIIB EXPRESSION CORRELATES INVERSELY WITH SURVIVAL

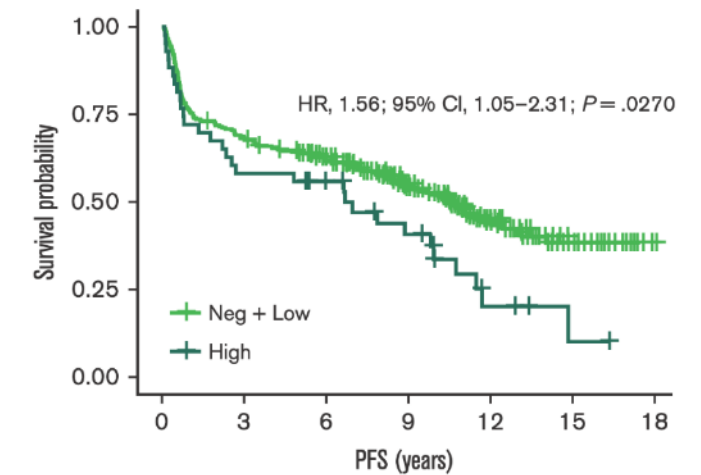
Mantle Cell Lymphoma



Follicular Lymphoma



Diffuse Large B Cell Lymphoma



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

OUT-LICENSED PROGRAMS A SEAL OF EXCELLENCE

Antibody discovery partnerships using n-CoDeR® antibody library in clinical development by licensees

- Funded and fully run by external partners, no costs involved for BioInvent
- Include development milestones and potential royalties on future sales

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	Endometriosis					Mitsubishi Tanabe
TAK-079	anti-CD38	Myasthenia Gravis					Takeda
Orticumab	anti-ApoB100	Cardiovascular					Abcentra
DS-1055	anti-GARP	Solid tumor					Daiichi-Sankyo
HMI-115	anti-PRLR	Endometriosis					Hope Medicine/Bayer

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