



Biolnvent

**UNLEASHING IMMUNITY
TO FIGHT CANCER**

November 2024

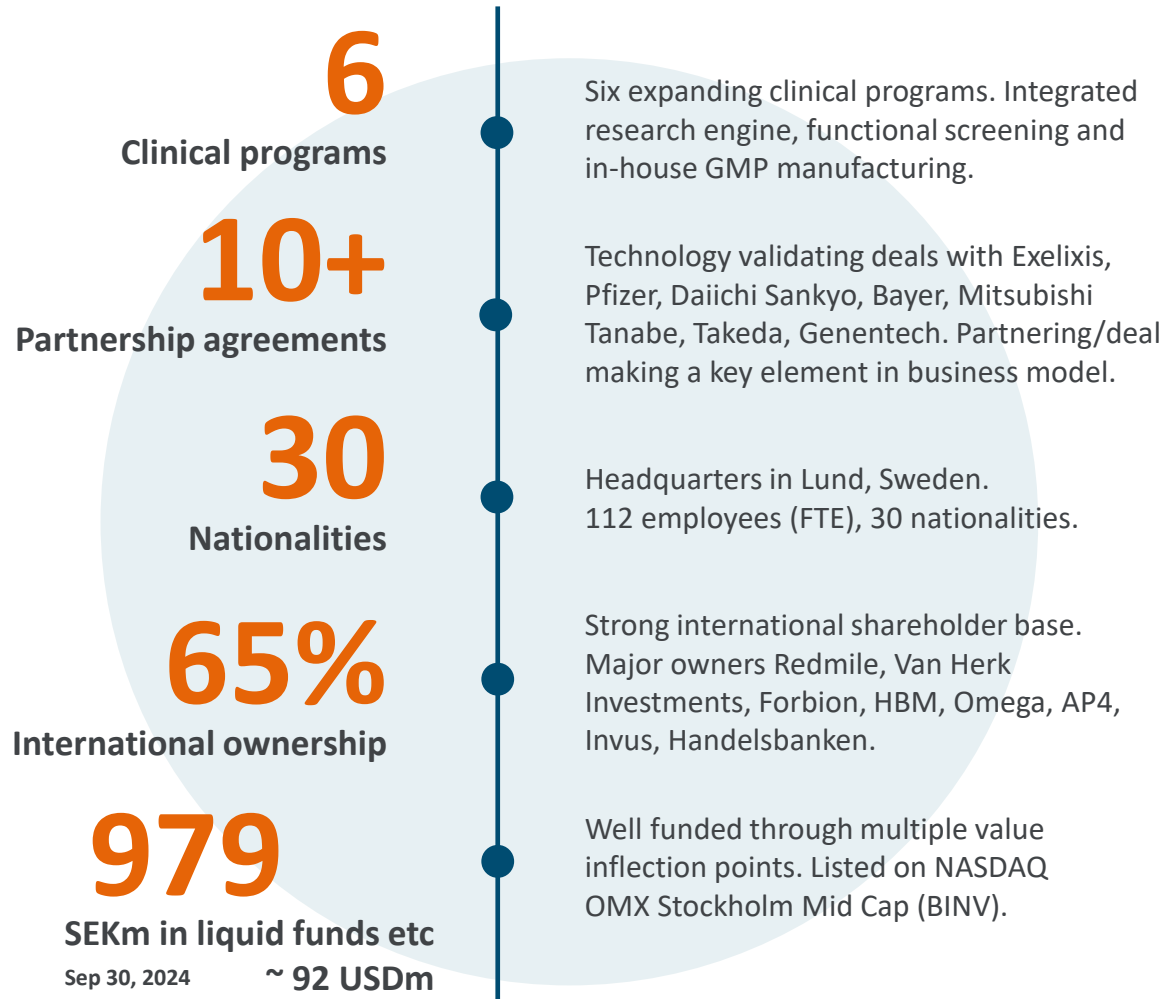
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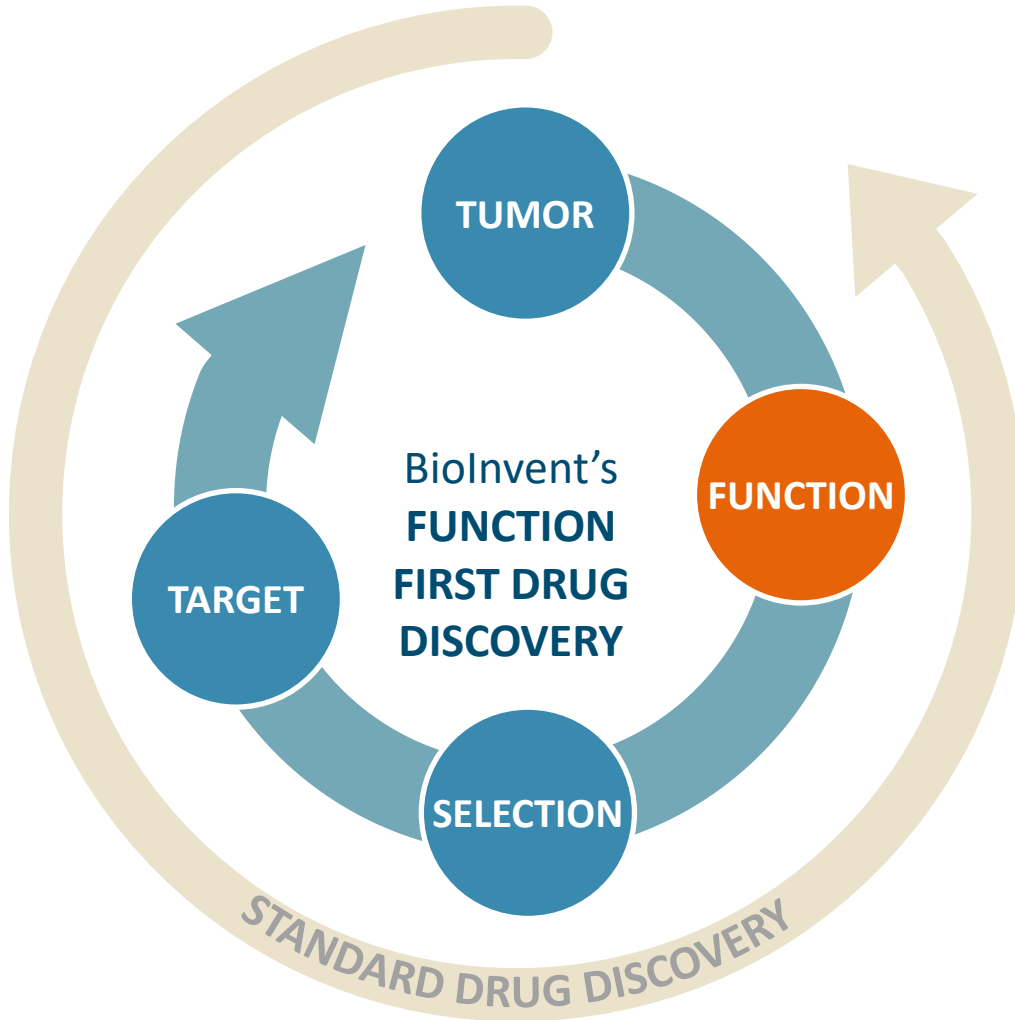
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Translating complex cancer biology into innovative antibody therapies

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

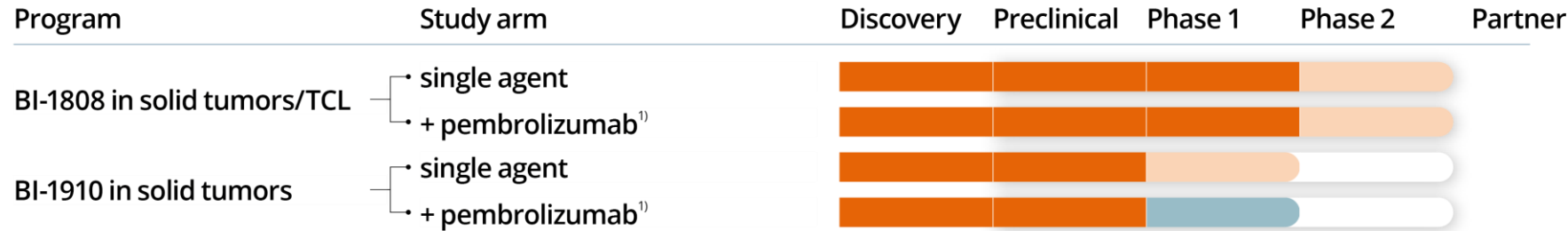


PROPRIETARY F.I.R.S.T™ PLATFORM IS THE ENGINE DISCOVERING NOVEL CANCER TREATMENTS

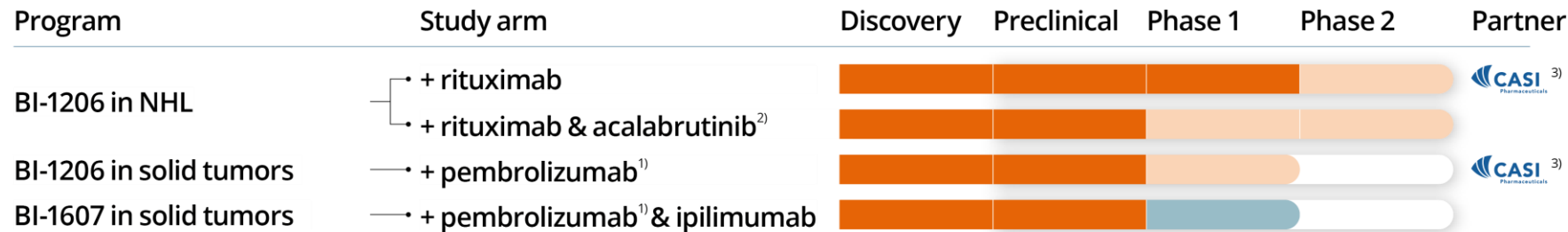
While others often focus on the targets and test function at the end, **we start from the function** (drug efficacy).

STRONG PROPRIETARY CLINICAL PIPELINE WITH MULTIPLE VALUE DRIVERS

TNFR2



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
 ■ 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

Strong BI-1808 single agent activity in CTCL

(September 2024)

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

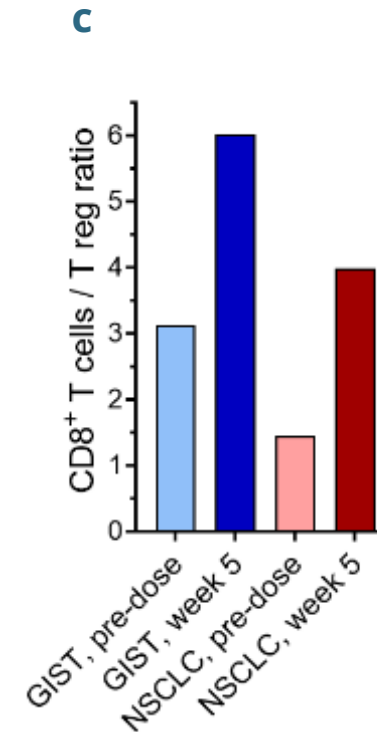
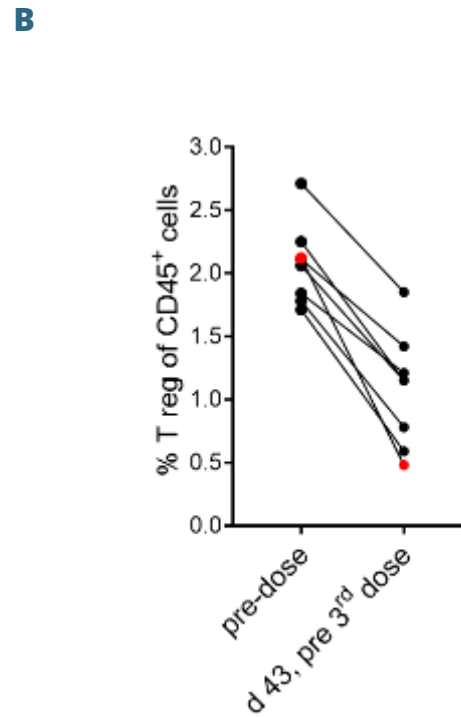
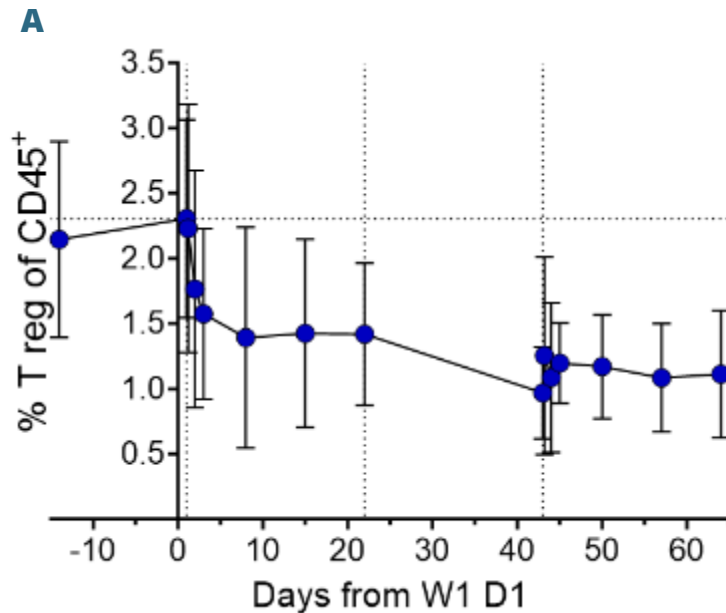
Clinical Phase 1/2a study ongoing

- CTCL data support earlier disclosed **single agent data** showing 1 complete response (CR), 1 PR and 9 patients with SD (ASCO June 2024)
- Promising signs of efficacy and favorable safety profile in Phase 1 dose escalation with **BI-1808 in combination with KEYTRUDA®** also presented at ASCO. Phase 2a dose expansion combination study with pembrolizumab has started enrollment. First Phase 2a combo data H225E.

WHAT'S NEXT?

- **Additional BI-1808 single agent Phase 2a data YE24E**

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.

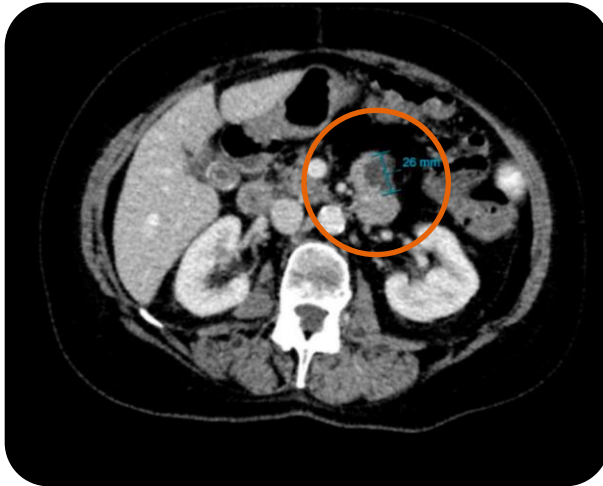
BI-1808 increases intratumoral CD8⁺/T reg ratio

Data from the 1000 mg monotherapy cohort.

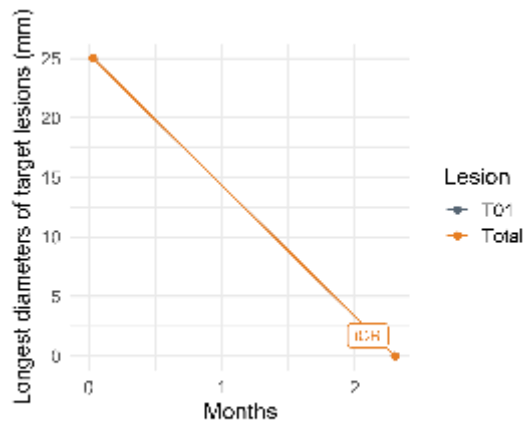
The data show substantial **T-reg depletion** compared to baseline. Panel B shows the individual patient drop in T-reg. Red dots indicate the drop in the GIST patient. (Dashed horizontal line = baseline. Dashed vertical lines = BI-1808 dosing occasions)

ASCO CASE STUDY: COMPLETE RESPONSE IN OVARIAN CANCER

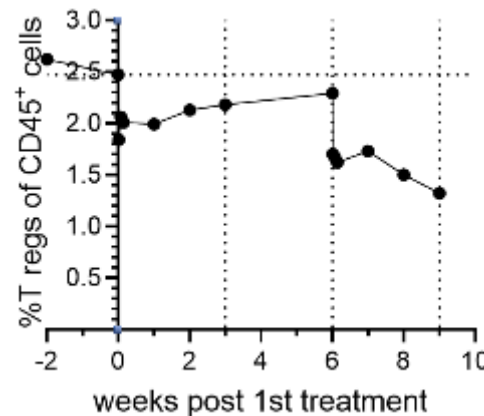
Baseline



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

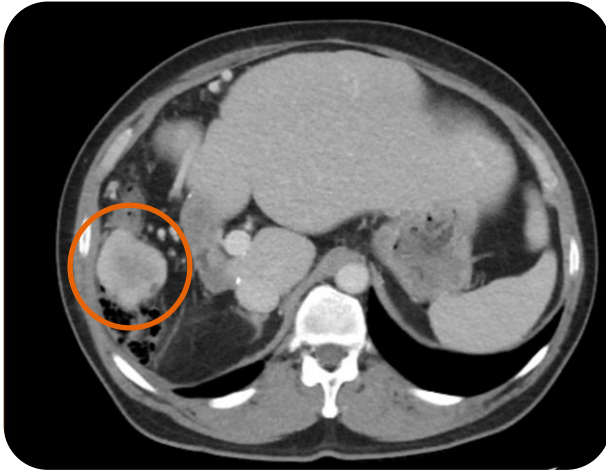
Patient had one target lesion of 25 mm and two larger non-target cystic lesions.

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

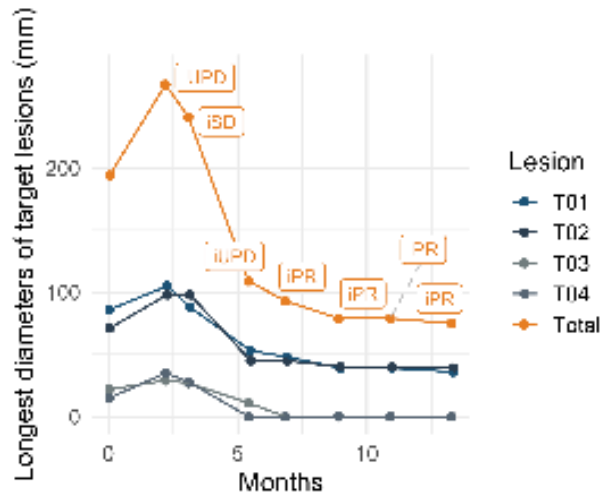
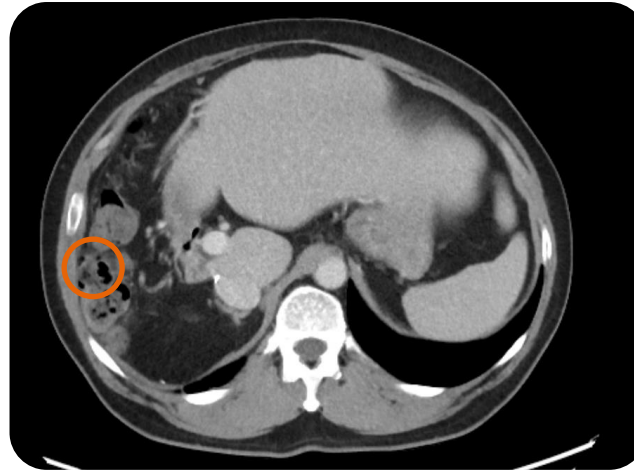
The response has been confirmed

ASCO CASE STUDY: ROBUST PR IN A PATIENT WITH GIST

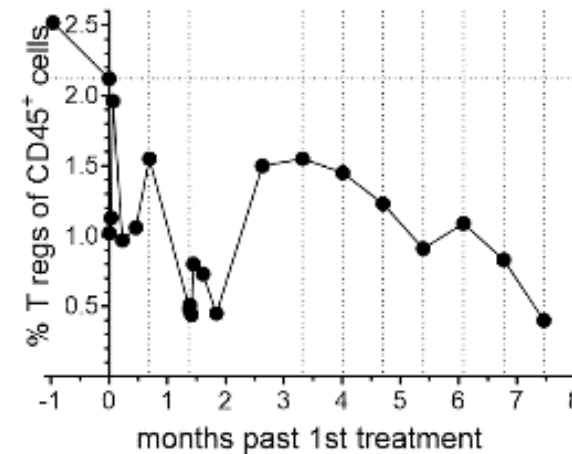
Baseline



Follow-up 13 months



Tumor assessment vs time on study



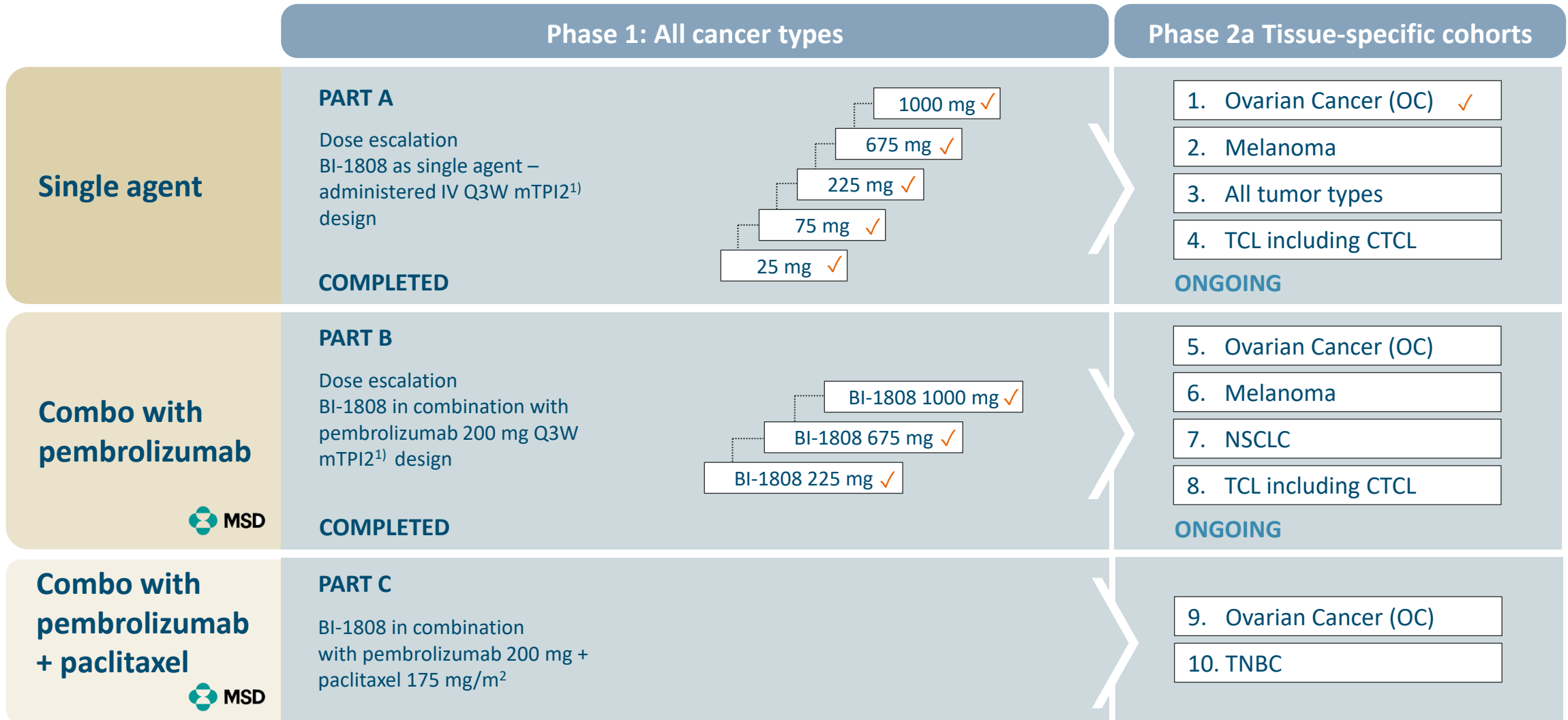
T reg levels vs time on study. Dashed lines indicate administration of BI-1808

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



BI-1910: TRIAL IN PROGRESS POSTER AT ESMO SEPTEMBER 2024

Clinical Phase 1/2a study ongoing

Part A dose escalation single agent BI-1910 at ESMO:

- Robust target occupancy in prespecified target dose range reached and evidence of immune activation observed
- Further exploration of the dose safety/tolerability margin expected to be completed before YE24

Part B dose escalation of BI-1910 in combination with pembrolizumab* planned to start H2 2024E



Trial-in-Progress 1073

A phase 1/2a first in-human phase 1 study of BI-1910, a monoclonal antibody agonistic to TNFR2, as a single agent and in combination with pembrolizumab in subjects with advanced solid tumors

Study 22-BI-1910-01 explores the safety and preliminary antitumor activity of a novel agonist to TNFR2

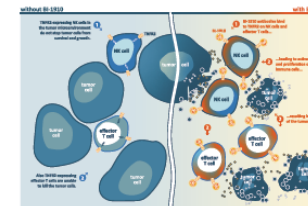
BI-1910 has demonstrated robust T-cell mediated antitumor activity in the preclinical setting, with additive effects after combination with anti-PD-1 therapy. Monotherapy dose escalation started in December 2023, and enrollment into first cohort with pembrolizumab co-treatment is expected to start in Q4 2024.

Rationale for Developing BI-1910

TNFR2 is a novel promising target for cancer immune therapy, and TNFR2 has been proposed as a costimulatory receptor for T cell activation. Early clinical development of ligand-blocking mAbs targeting TNFR2, such as BI-1808, indicate that modulating the pathway may lead to clinical responses with favourable tolerability.

We develop BI-1910, a TNFR2 targeting agonist. BI-1910 does not block the interaction between TNFR2 and its ligand TNF- α . Non-clinical in vivo data demonstrate enhancement of functional activity of TNFR2-expressing lymphocytes, including CD8⁺ and CD4⁺ T-cells, as well as NK cells, resulting in tumor regression and ultimately immune rejection.

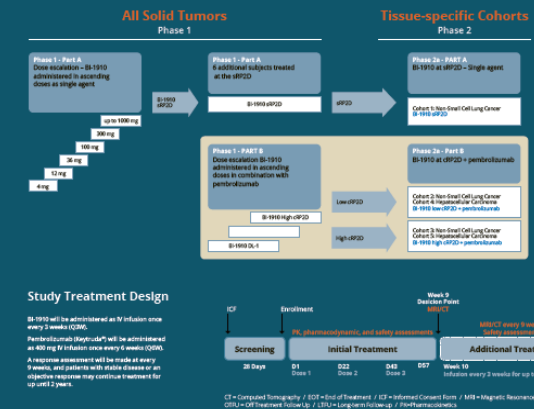
Furthermore, BI-1910 show additive effects with anti-PD-1 therapy in several murine tumor models.



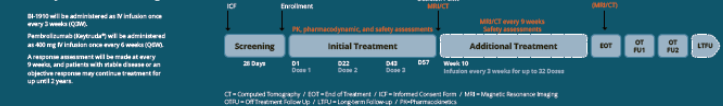
Background

Tumor necrosis factor (TNF) is a potent pro-inflammatory cytokine known to induce an inflammatory response and cell death, and TNF- α is used to treat autoimmune diseases. TNF has two receptors: TNFR1, which is broadly expressed on many different cell types, and TNFR2, with expression largely restricted to immune cells. TNFR2 is a type I transmembrane protein with typically high expression in myeloid cells and specific T cell subsets. Macrophages and Tregs constitutively express TNFR2. In effector T cells TNFR2 expression is upregulated after T cell receptor stimulation. The role of TNFR2 in inflammation is unclear, with both pro-inflammatory and immunoregulatory roles postulated.

TNFR2 is important for T reg survival, while simultaneously acting as a potent costimulatory molecule on CD8⁺ T cells thereby promoting inflammatory activity. Given the costimulatory functions of TNFR2 in different immune cells, TNFR2 has in recent years been suggested as a promising novel target for anticancer treatment. We are developing BI-1910, an agonistic human IgG2 mAb targeting TNFR2. BI-1910 agonizes T cells and mediates CD4⁺ and CD8⁺ T cell activation. It binds human TNFR2 selectively but does not block the interaction between the receptor and its ligand, TNF- α . BI-1910 combined with anti-PD-1 showed additive and tumor effect in several murine tumor models including B16 melanoma cancer, MC38 colon cancer, and CT26 colon cancer, providing rationale to clinically evaluate this antibody in combination with pembrolizumab.



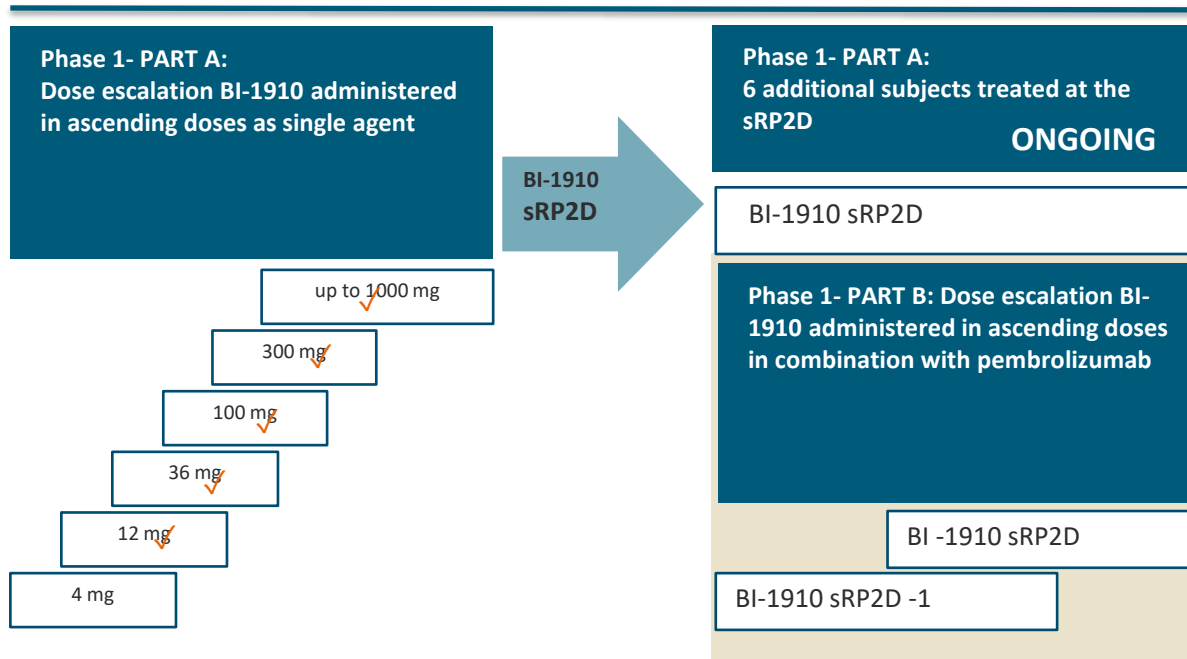
Study Treatment Design



CT = Computed Tomography / BDT = End of Treatment / ICS = Inflamed Consent Form / MR = Magnetic Resonance Imaging / CRF = Case Report Form / LTR = Long-term Follow-up / PFT = Patient Follow-up

BI-1910 STUDY DESIGN

All Solid Tumors Phase 1



Tissue-specific cohorts Phase 2a

Phase 1- PART B may run in parallel to Phase 2a, PART A

Phase 2a – PART A: BI-1910 at sRP2D - Single agent
PLANNED TO START H1 2025E

Cohort 1: non-small cell lung cancer

Phase 2a – PART B: BI-1910 at cRP2D + pembrolizumab

Cohort 2: non-small cell lung cancer

Cohort 4: hepatocellular carcinoma

BI-1910 low cRP2D + pembrolizumab

Cohort 3: non-small cell lung cancer

Cohort 5: hepatocellular carcinoma

BI-1910 high cRP2D + pembrolizumab

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

WHAT'S NEXT?

- **First Phase 1 single agent data H2 2024E**

ANTI-FC γ RIIB

BI-1206 + rituximab + acalabrutinib

BI-1206 + pembrolizumab

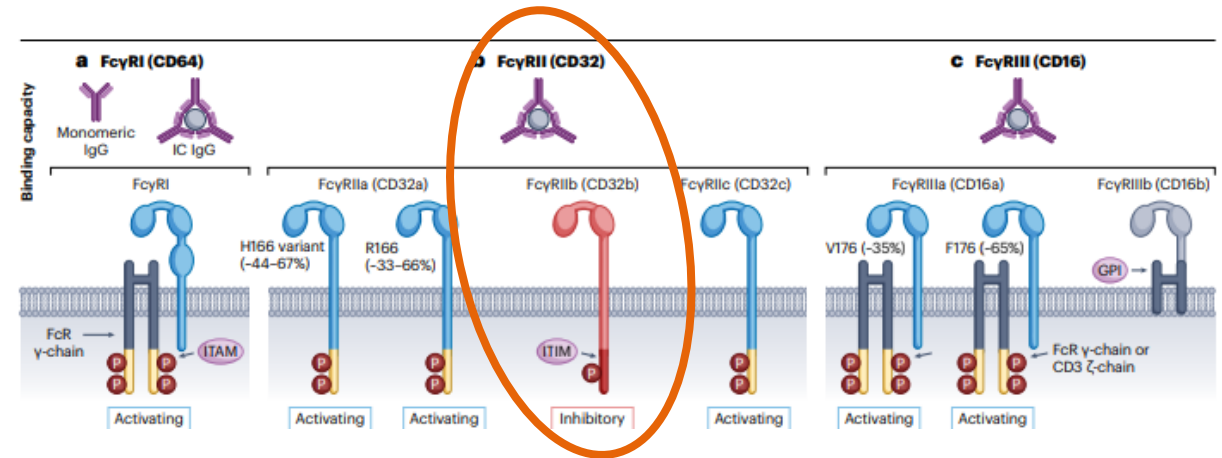
BI-1607

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**.

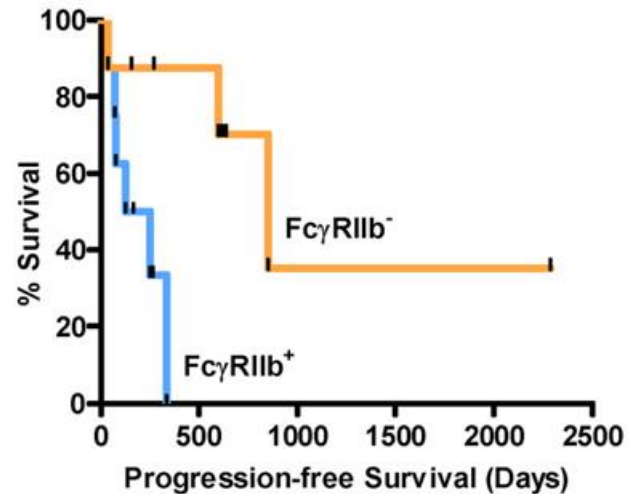
BI-1607 has a different MoA compared to BI-1206 having been engineered for reduced Fc-binding to Fc γ R.



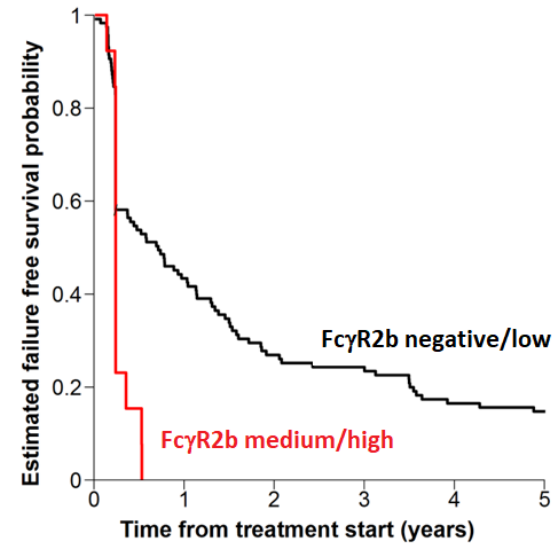
Galvez-Cancino, F., Simpson, A.P., Costoya, C. et al. Fc γ receptors and immunomodulatory antibodies in cancer. *Nat Rev Cancer* 24, 51–71 (2024). <https://doi.org/10.1038/s41568-023-00637-8>

FCGRIIB EXPRESSION CORRELATES INVERSELY WITH SURVIVAL

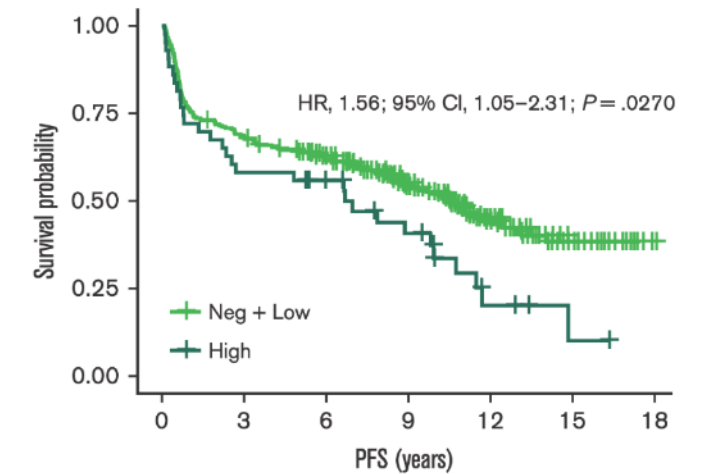
Mantle Cell Lymphoma



Follicular Lymphoma



Diffuse Large B Cell Lymphoma



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

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

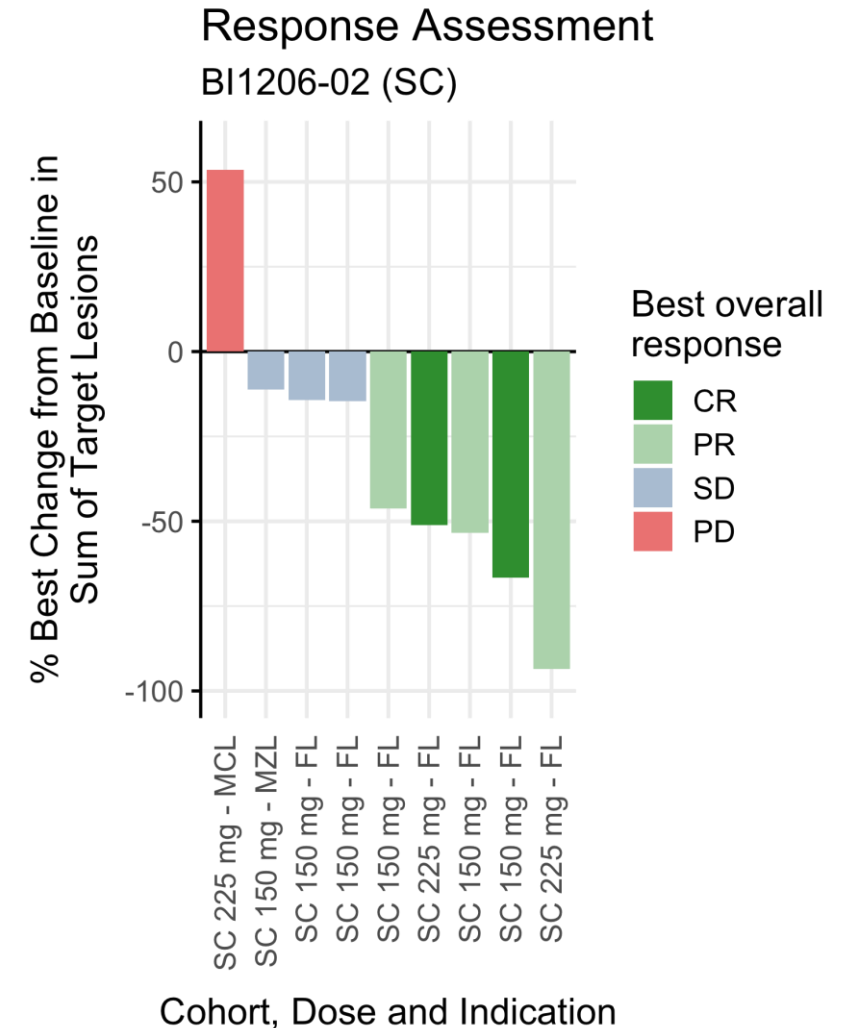
Impressive clinical efficacy data BI-1206 SC

(October 31, 2024)

- **1 additional complete response (CR)**
- **1 more partial response (PR)**
- **2 more patients with stable disease (SD)**

Together with the positive data reported at EHA 2024 (European Hematology Association) June 2024 it gives a total of:

- **2 CR**
- **3 PR**
- **3 SD**
- **Out of 9 evaluable patients**

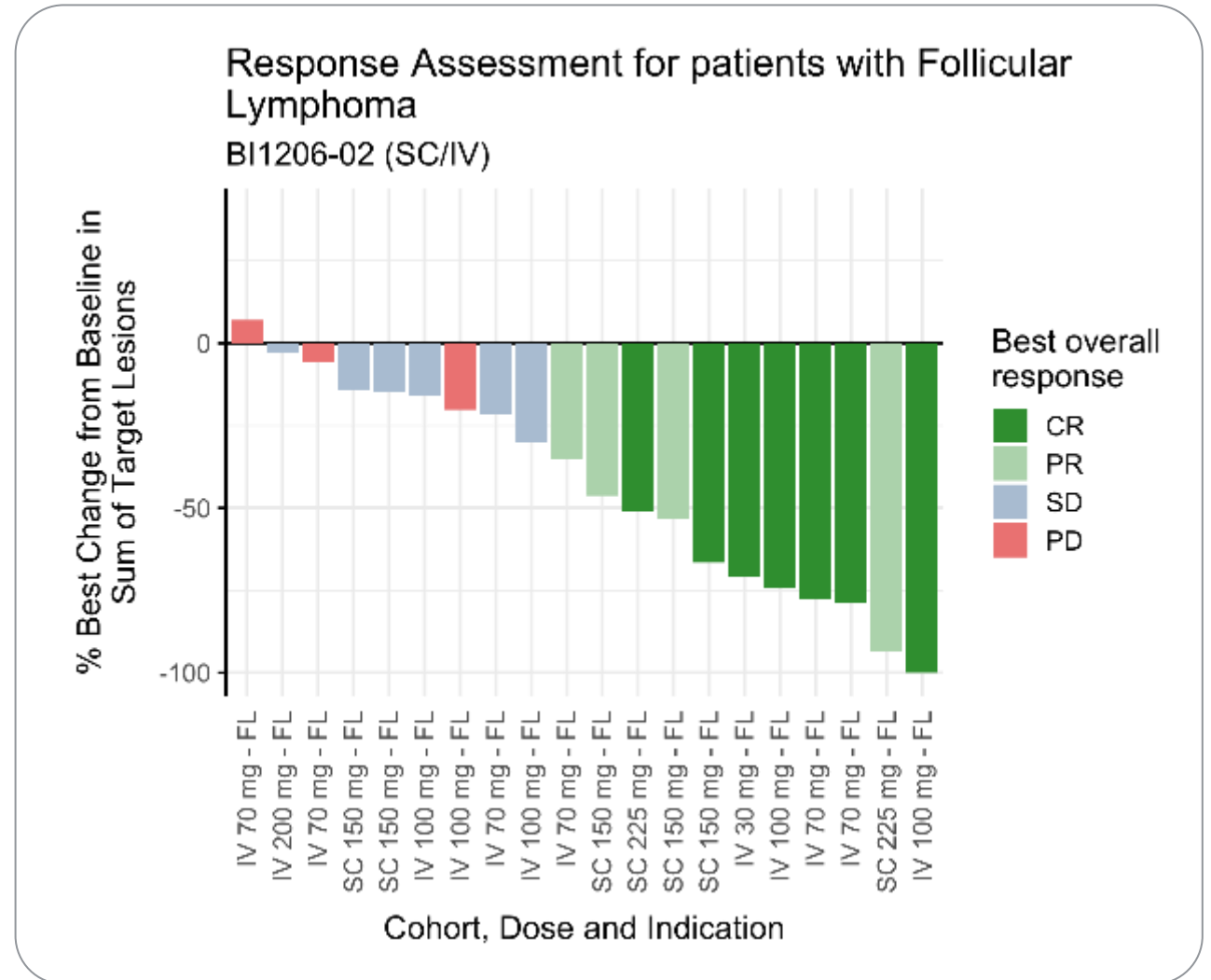


CO-ADMINISTRATION OF BI-1206 WITH RITUXIMAB LED TO HIGH RESPONSE RATES IN RELAPSED/REFRACTORY FL PATIENTS

Quality of responses particularly impressive

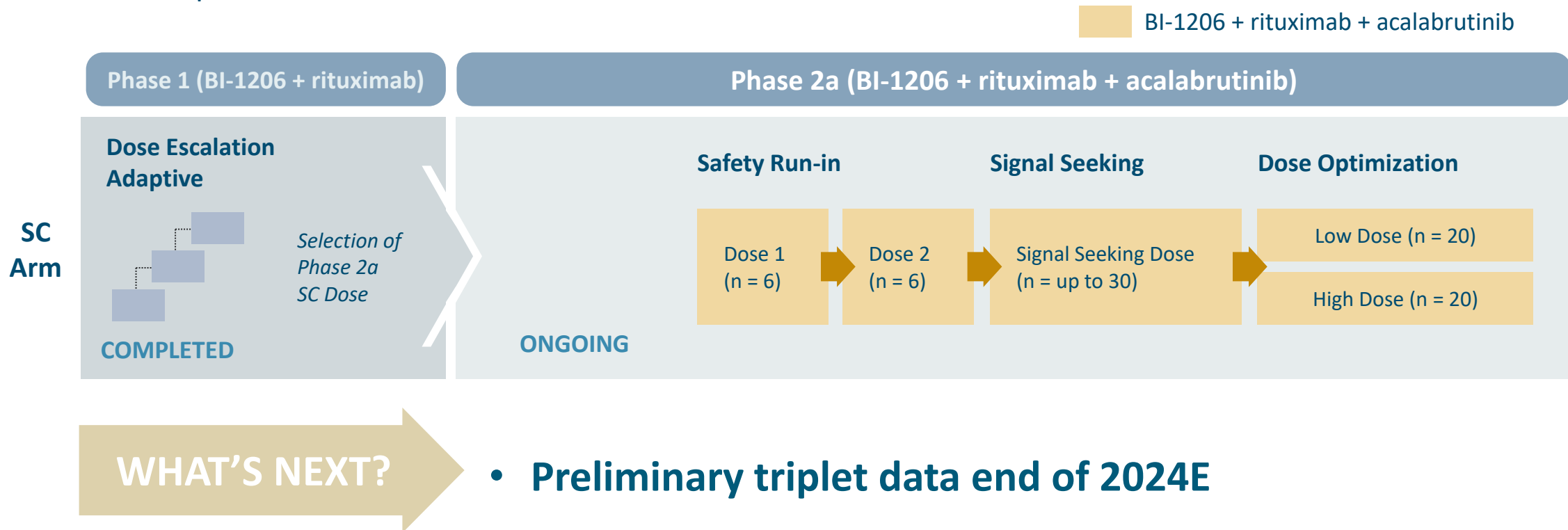
(October 2024, SC + IV):

- **7 complete responses (CR)**
- **4 partial responses (PR)**
- **5 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**



BI-1206 IN NHL: COMBINATION WITH RITUXIMAB AND ACALABRUTINIB

- **First patient enrolled** (Sep 2024) in **Phase 2a** study arm combining **BI-1206 with rituximab and acalabrutinib*** (BTK inhibitor)
- Approximately **30 patients** expected to be enrolled in Spain, Germany, the US, and Brazil
- 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



- **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**

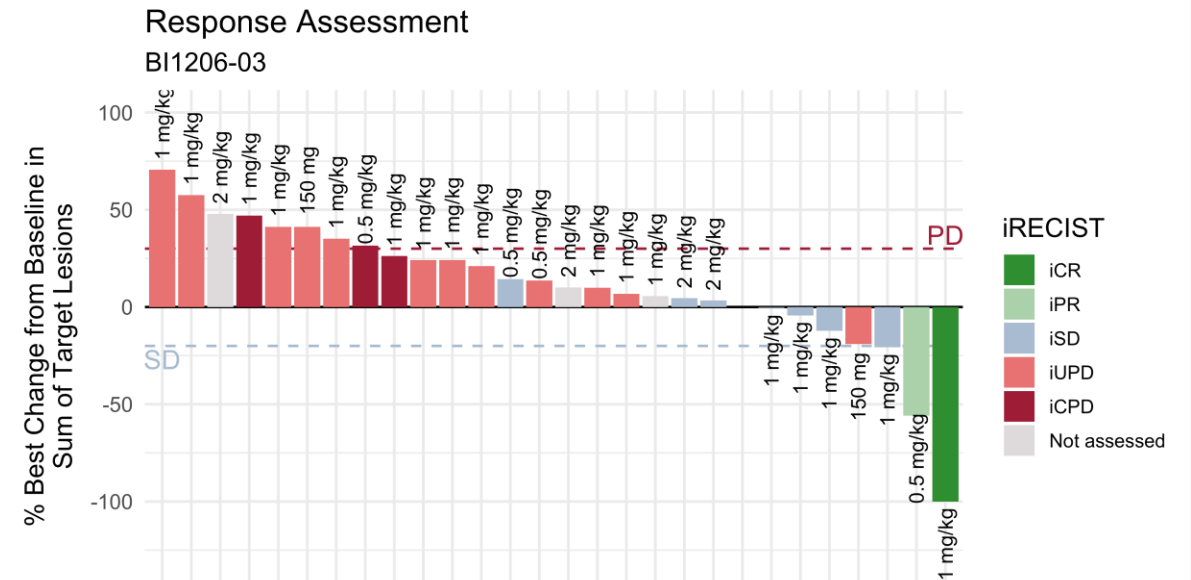
- **Further Phase 1 data BI-1206 & pembrolizumab* mid-2025E**

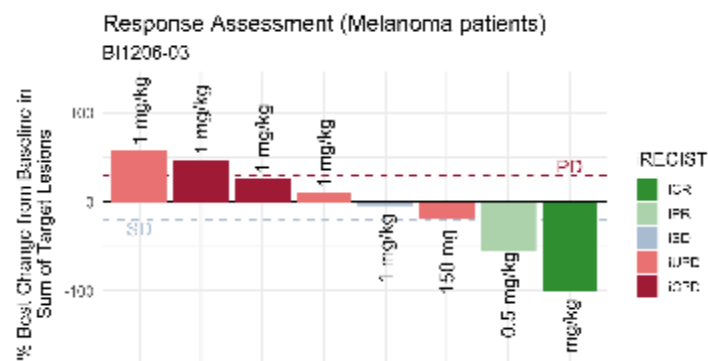
BI-1206 IN SOLID TUMORS: PHASE 1/2A STUDY ONGOING

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)



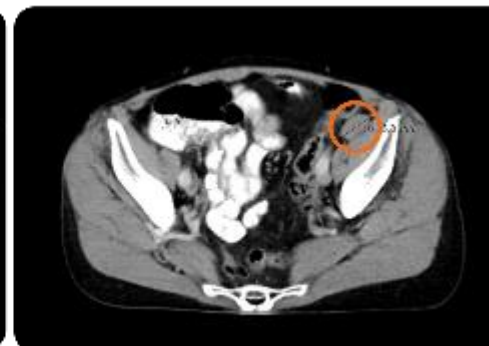
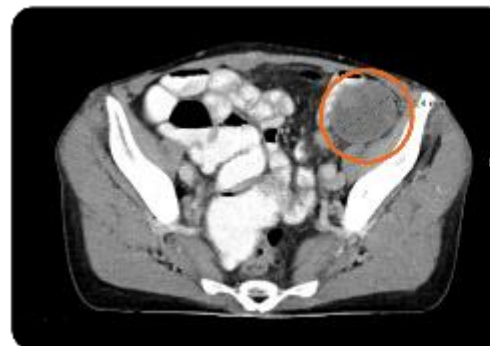
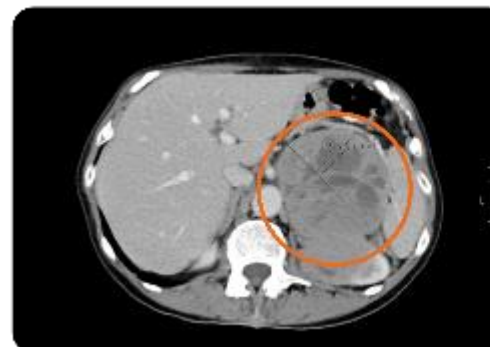
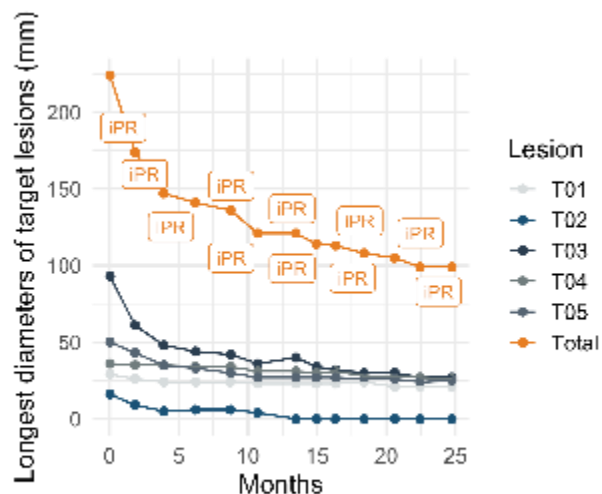


Co-administration of BI-1206 with pembrolizumab was well-tolerated in a heavily pretreated population, with promising responses observed in melanoma, and uveal melanoma, who previously failed anti-PD1 therapy.

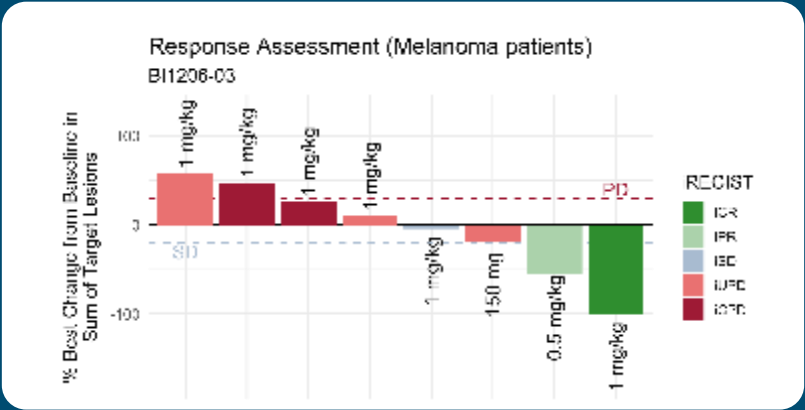
Case study: PR

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.

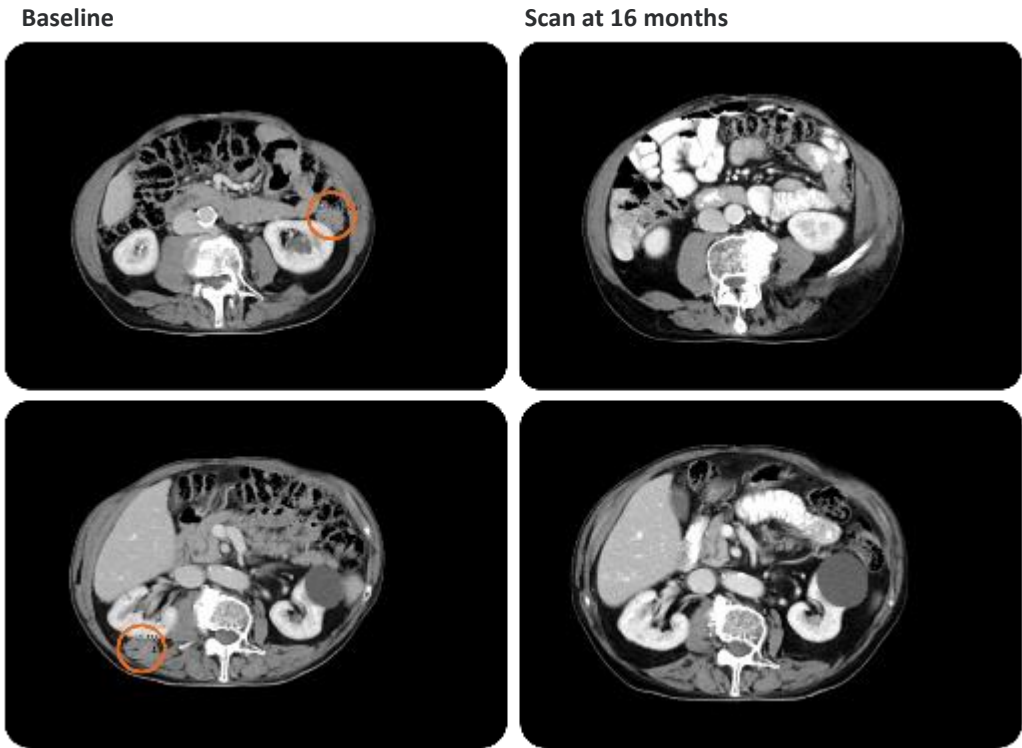
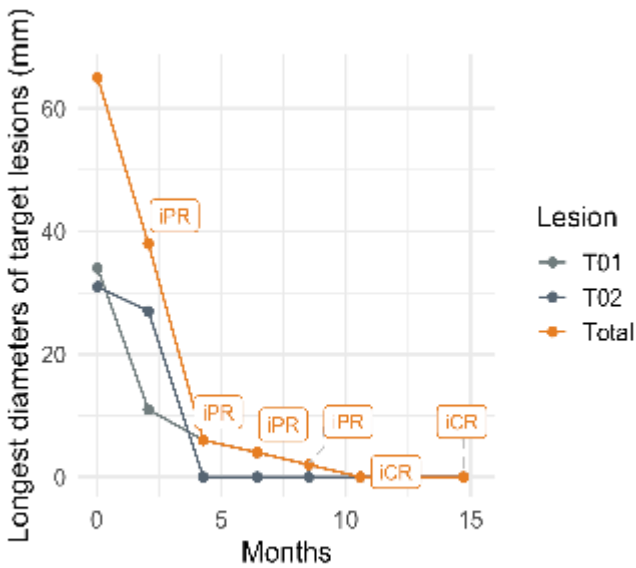


Co-administration of BI-1206 with pembrolizumab was well-tolerated in a heavily pretreated population, with promising responses to treatment observed in melanoma, including uveal melanoma, who previously failed anti-PD1 therapy.

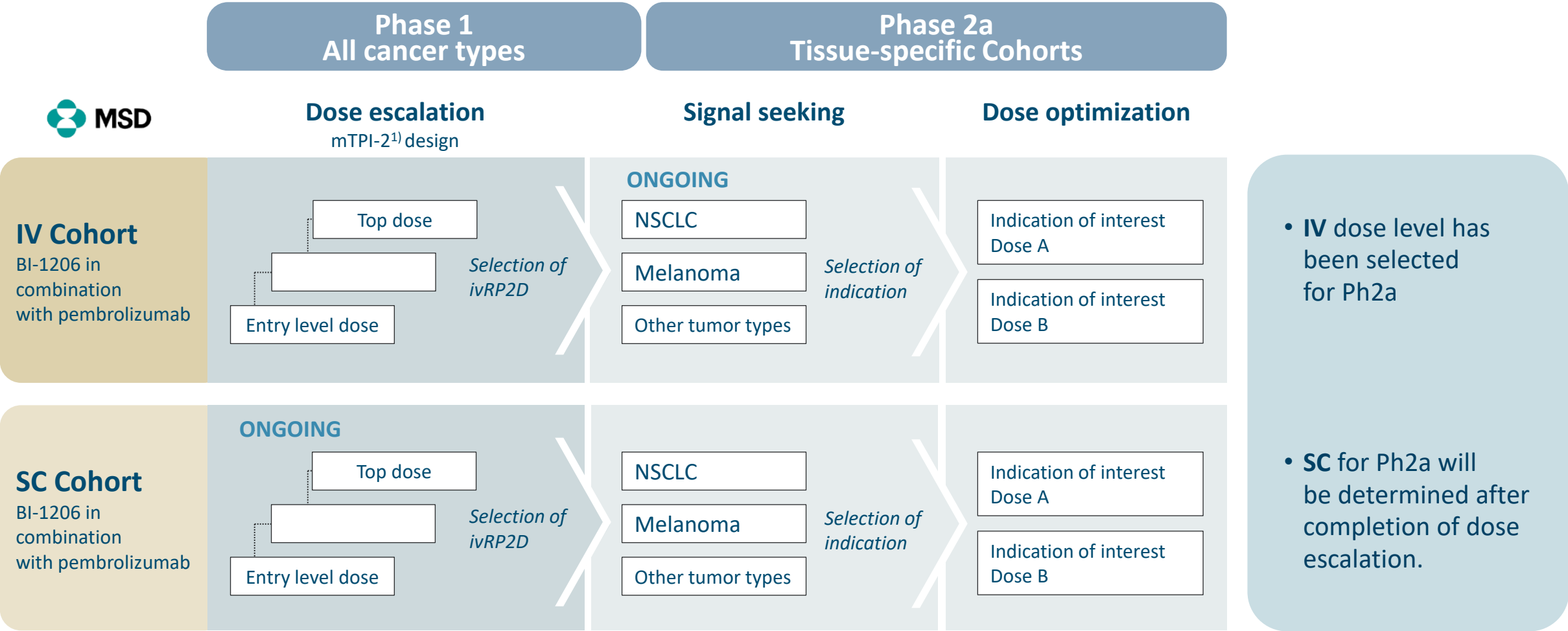


Case study: CR

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

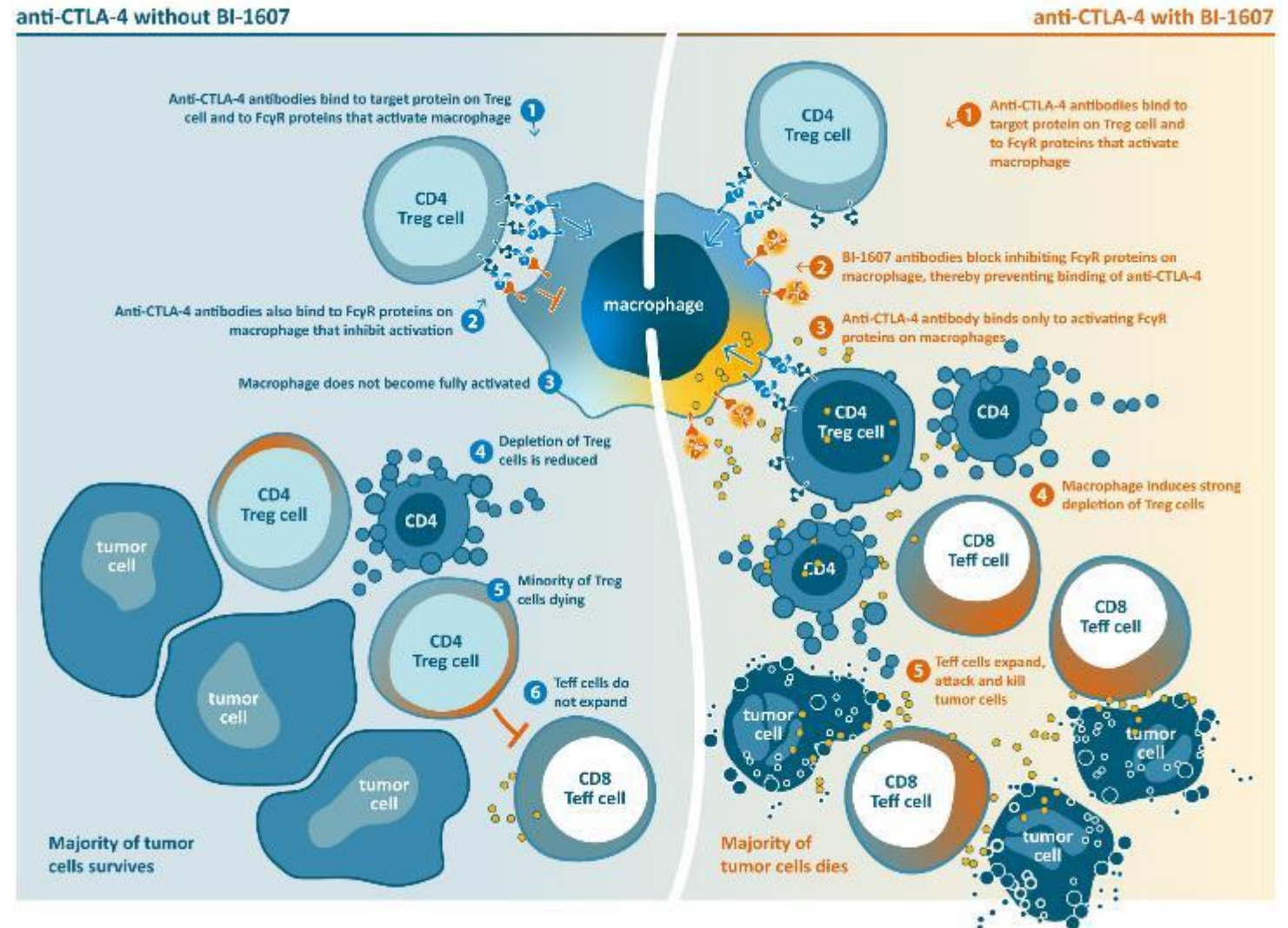


BI-1607 HAS THE POTENTIAL TO INCREASE EFFICACY OF OTHER ANTIBODY DRUGS

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



- 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)** 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?

- **Start patient recruitment for the triplet Phase 1b/2a study with first data H225E**

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

Patients are treated with ap-507 in combination with trabectedin once every 4 weeks. After first disease assessment at week 8, patients with progressive disease (PD) are discontinued from treatment, while patients with stable disease (SD), partial response (PR), or complete response (CR) may continue treatment for up to 2 years.



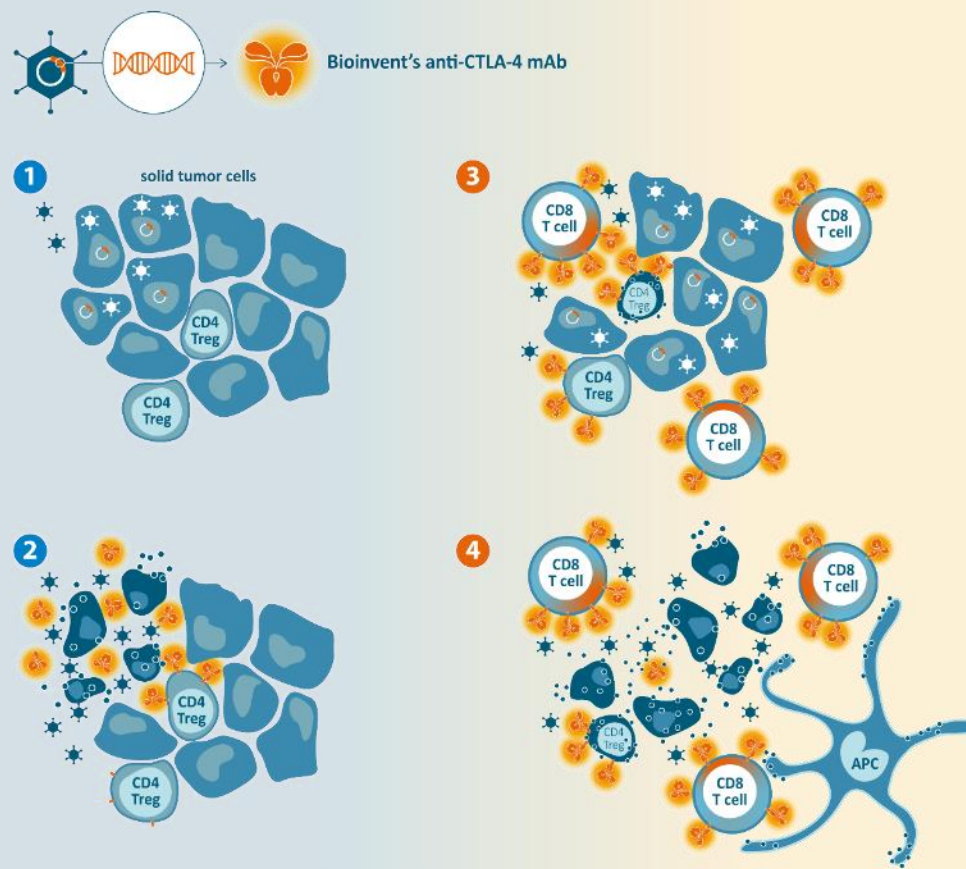
ANTI-CTLA-4

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

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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

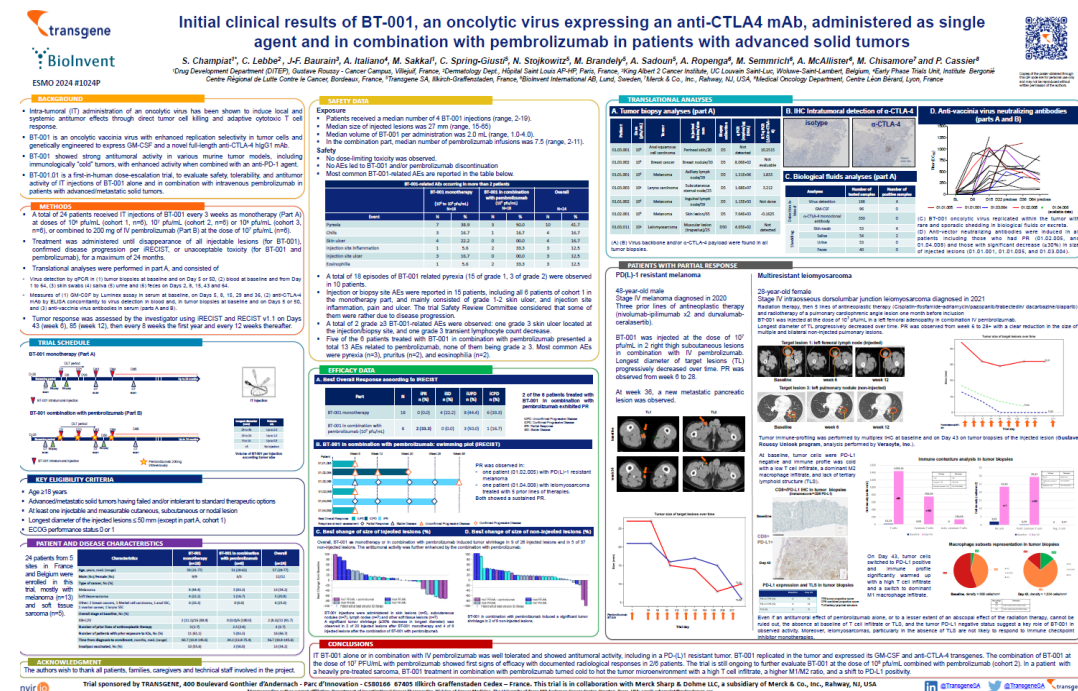


PROMISING BT-001 PHASE 1 COMBINATION DATA AT ESMO 2024

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

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 2024 - 2025

Expected key clinical milestones 2024-2025

TNFR2 platform

BI-1808
single agent Ph 2a data

BI-1910 solid tumors
single agent Ph 1 data

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

H2 2024

2025

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

**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



BioInvent

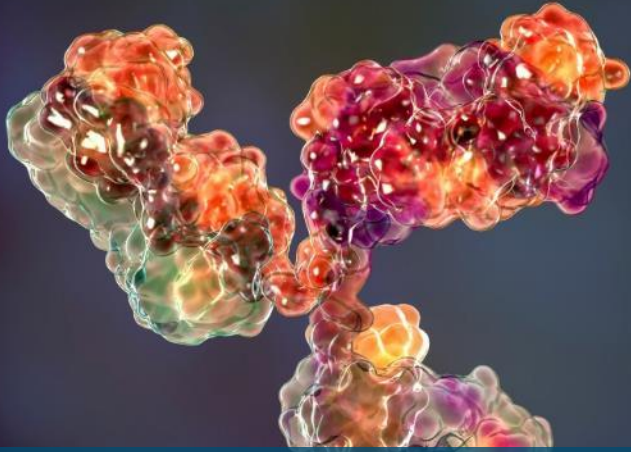
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COO

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

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.

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