

A woman with blonde hair, wearing a white lab coat and green nitrile gloves, is holding a clear test tube with a blue cap. She is looking up and to the right with a focused expression. The background is a blurred laboratory with shelves containing various bottles and equipment.

 Biolnvent

UNLEASHING IMMUNITY
TO FIGHT CANCER

June 2024

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BIOINVENT IS FOCUSED ON NOVEL TREATMENTS OF CANCER

In brief

Translating
complex cancer biology
into
innovative antibody therapies

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.

29

Nationalities



Headquarters in Lund, Sweden. 109 employees, 29 nationalities.

65%

International ownership



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

1,219

SEKm in liquid funds etc
March 31, 2024 ~112 USDm

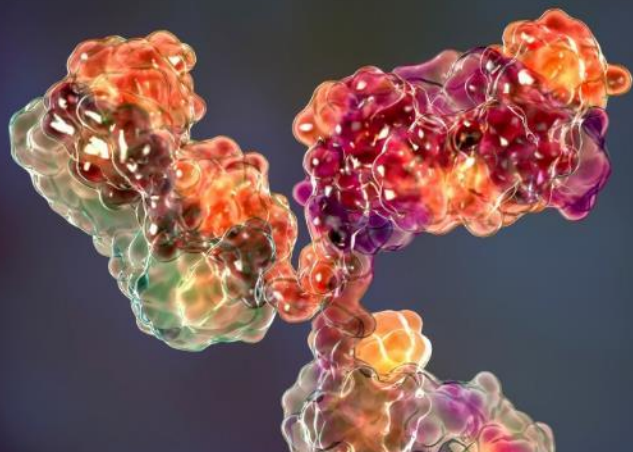


Well funded through multiple value inflection points. Listed on NASDAQ OMX Stockholm Mid Cap (BINV).

OUR SUCCESS FACTORS

Success
factors

BioInvent has one of the most exciting and unique cancer immunotherapy pipelines of any European biotech company



DISCOVERY ENGINE

Our proprietary **high-quality antibody library** and animal models deliver candidates ready for clinical development



TOP EXPERTISE

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



INNOVATIVE R&D

We have **integrated** drug development capabilities, from **early discovery**, **manufacturing** to **trial execution**

AMBITIOUS LEADERSHIP WITH LONG-STANDING INDUSTRY EXPERIENCE

Leader
ship



Affitech
Opsona Therapeutics
Axaron
APIM Therapeutics
Nextera

Martin Welschhof
CEO



UCSF
Pasteur Institute
Debiopharm
IDM
BioMerieux
Pierre Fabre

Andres McAllister
CMO



Merck KGaA
Serono International
Domain Therapeutics
Index Ventures
McKinsey & Company
Harvard Business School

Sylvie Ryckebusch
CBO



University of
Southampton

Björn Frenhéus
CSO



AGC Biologics
DAKO
Symphogen

Kristoffer Rudenholm Hansson
SVP Tech Ops



Circio
Nordic Nanovector
Photocure
Nycomed

Ingunn Munch Lindvig
SVP Regulatory



Swedish Tax Agency
Pricewaterhouse
Coopers

Stefan Ericsson
CFO



LINK Medical Research
Theradex Oncology

Marie Moores
COO

USING PARTNERSHIPS TO VALIDATE OUR CAPABILITIES AND EXPERTISE

Partners



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 and BT-001. **Supply** (Calquence®) **agreement** with AstraZeneca for BI-1206.



Mitsubishi Tanabe



Daiichi-Sankyo



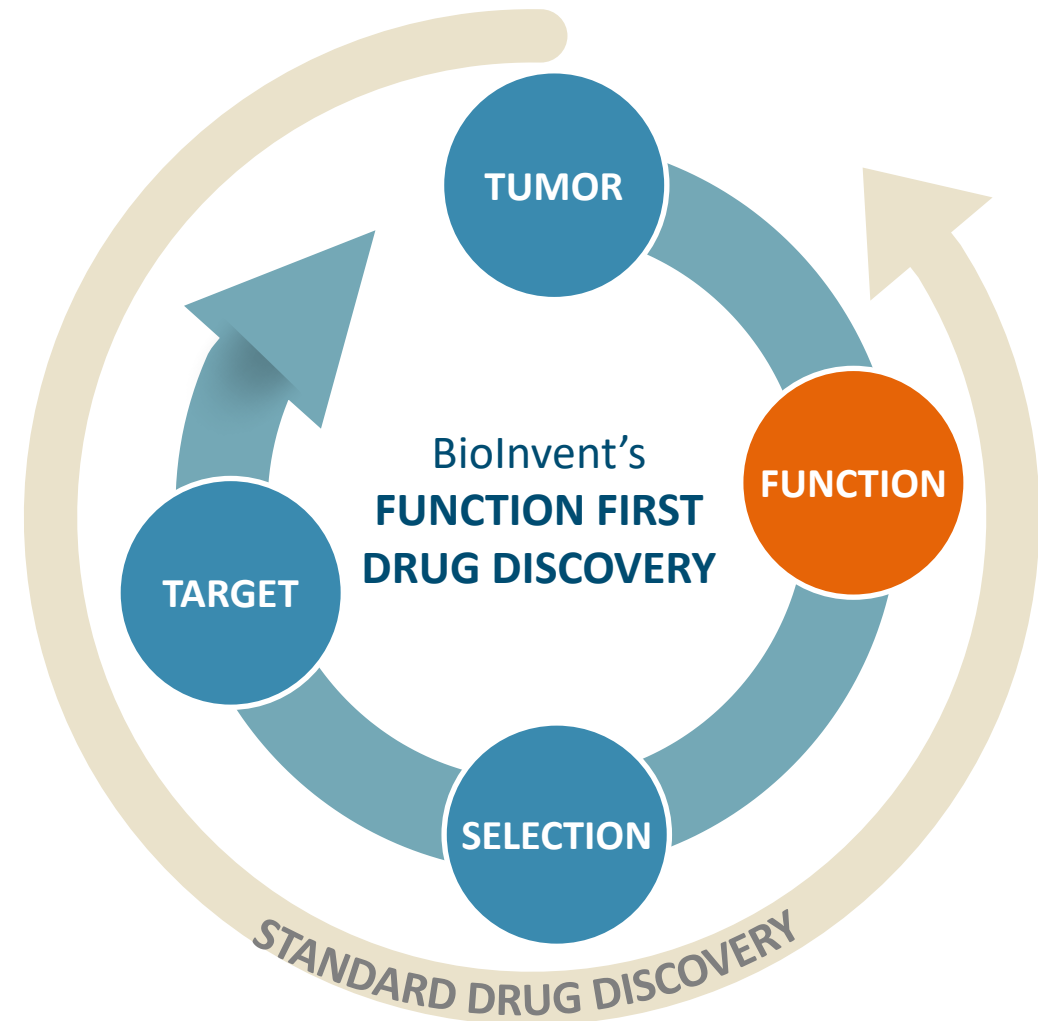
Antibody discovery partnerships using n-CoDeR® antibody library (antibodies in clinical development)



Academic/Patient organizations collaborations

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)

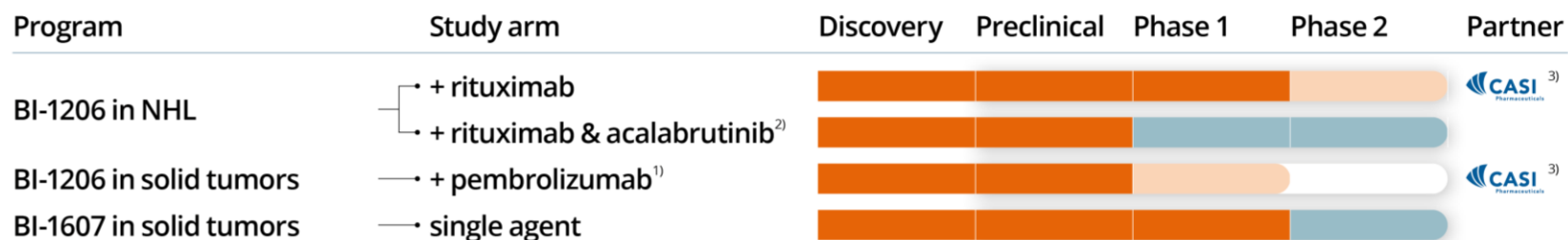


STRONG PROPRIETARY CLINICAL PIPELINE WITH MULTIPLE VALUE DRIVERS

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

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

BI-1808 is a ligand-blocking FcγR-engaging
mAb and **BI-1910** is an agonist mAb

Our focus

is to pursue both MoA's to ensure patient benefit

Competitors

are developing either agonists or antagonists

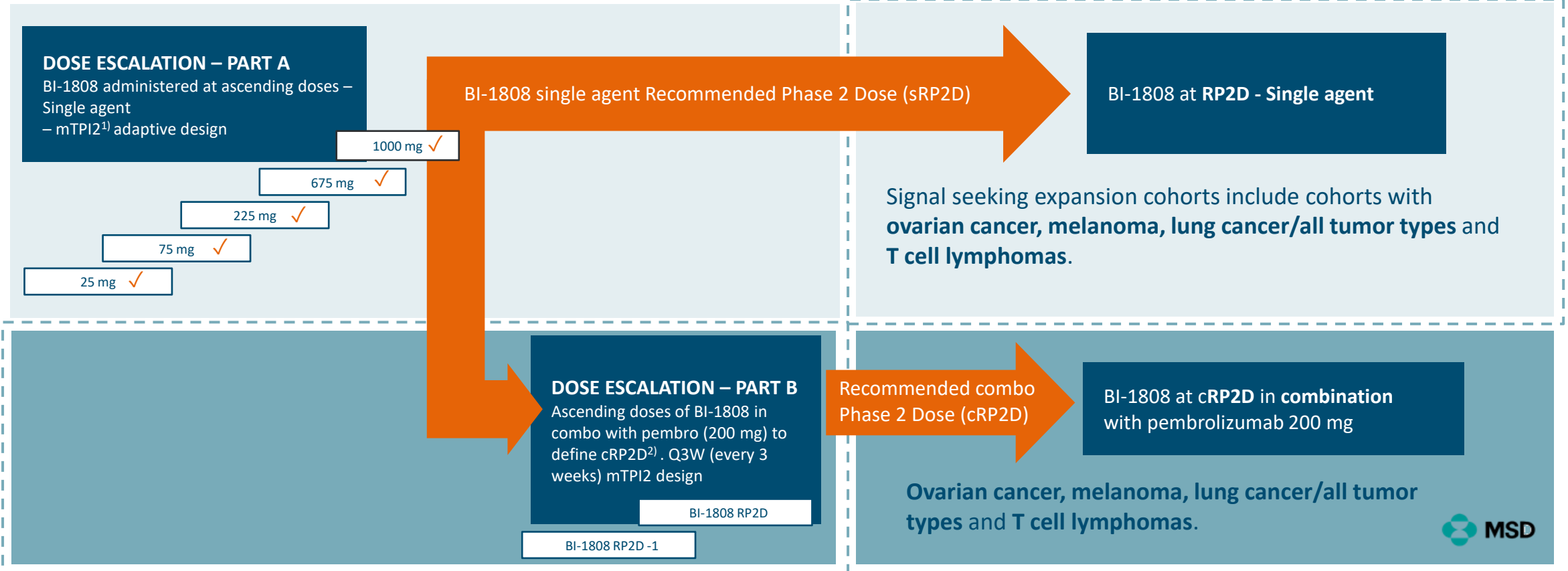
Drug Name	Company Name	Stage	Description
BI-1808	BioInvent	Phase 2	Human IgG1 Blocker
BI-1910	BioInvent	Phase 1	Human antibody Agonist
LBL-019	Nanjing Leads Biolabs	Phase 1/2	Humanized IgG1 Blocker
SIM-0235	Simcere	Phase 1	Humanized IgG1 antibody Blocker/Depleter
HFB-200301	HiFiBio	Phase 1	Humanized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

Ongoing phase

TNFR2
BI-1808

Phase 1: All Cancer Types



¹⁾ modified Toxicity Probability Interval 2

²⁾ combination recommended Phase 2 dose

BI-1808: COULD REPRESENT A **NEW CLASS** OF IMMUNOMODULATORY AGENT

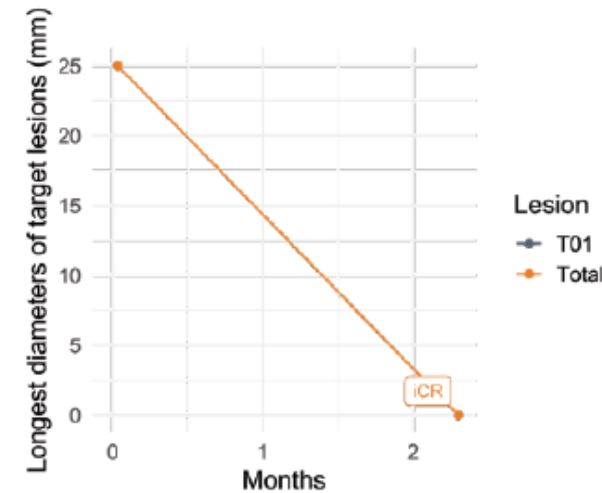
TNFR2
BI-1808

Single agent CR in ovarian cancer

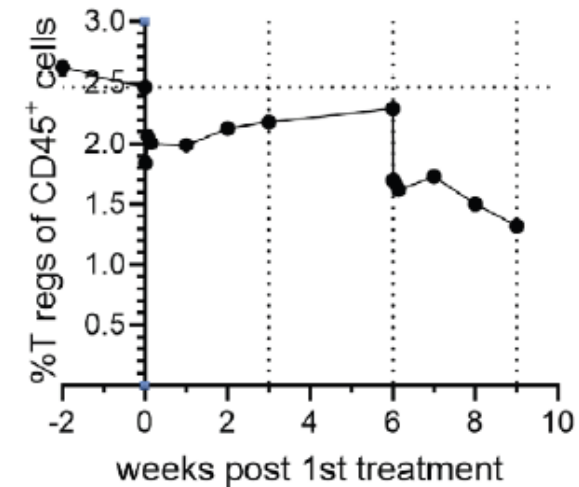
(Patient had progressed after three previous lines of therapy)

Efficacy and safety interim data (ASCO 2024) from ongoing Phase 1/2a:

- **One complete response (CR)**, **one partial response (PR)** in a GIST patient that is still improving, and **nine patients with stable disease (SD)** and **excellent safety** in **single agent arm** of BI-1808 (26 evaluable patients)
- **Heavily pretreated** patient population, tumor types known to respond poorly to checkpoint inhibitor therapy
- Promising **signs of efficacy and favorable safety profile** in the Phase 1 dose escalation part studying BI-1808 in **combination with KEYTRUDA®** (pembrolizumab)



Individual lesion sizes and total tumor burden vs time



Regulatory T cell dynamics vs time

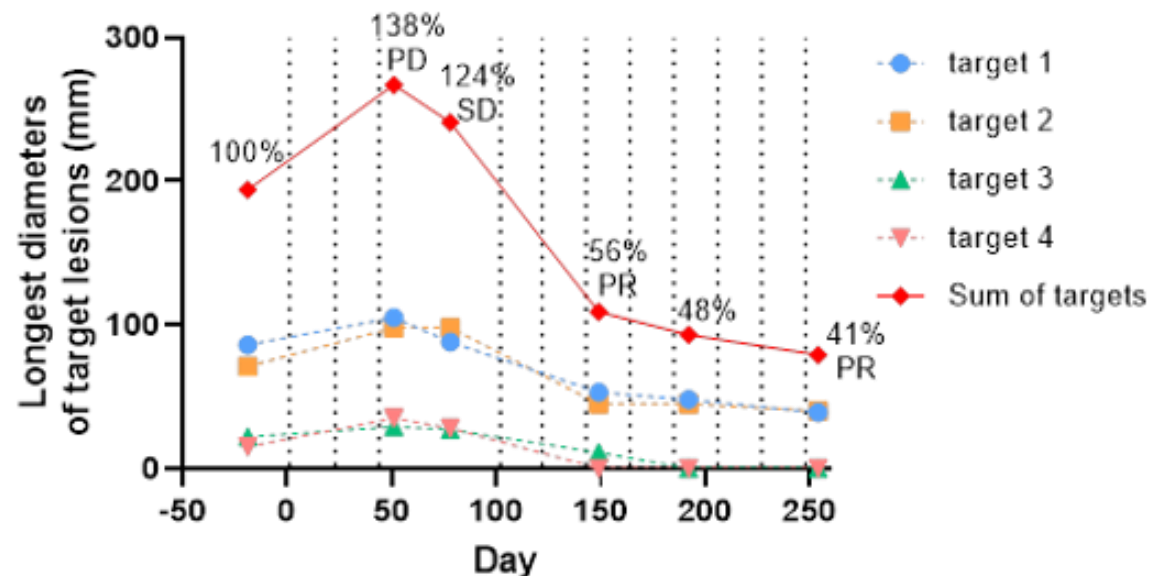
Case study (May 2024): 63-year-old ovarian cancer patient, stage IIIA at diagnosis, progressive disease after **three previous lines** of therapy. At screening, patient presented one target lesion of 25 mm and two larger non-target cystic lesions. At first post-treatment scan 9 weeks post treatment start, **no quantifiable tumor mass could be measured**.

Robust partial response (PR) observed in a patient with GIST

Phase 1 data presented at SITC Nov 2023/ASCO 2024

Patient case:

55-year-old male patient with **GIST**. Patient presented with clinically progressive disease for more than 6 months, with multiple metastatic lesions despite **12 prior lines of treatment**. Patient still on treatment.

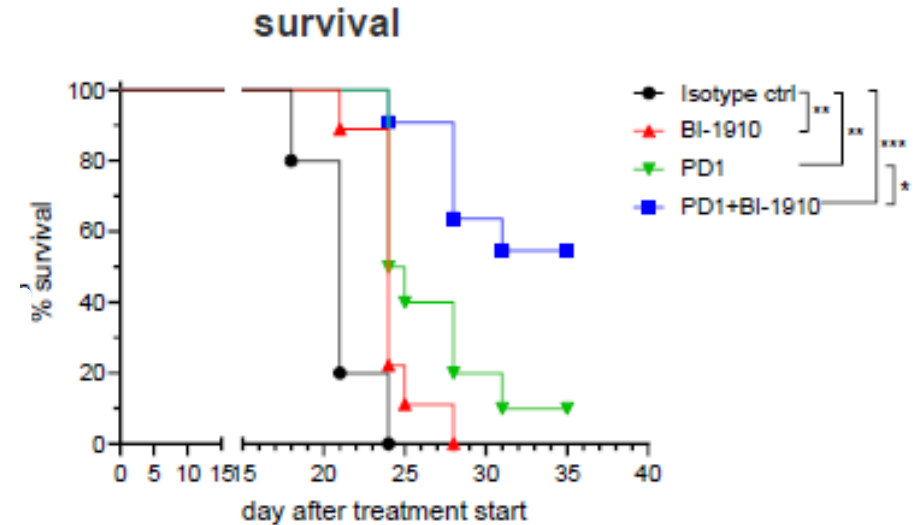


WHAT'S NEXT?

- Further Phase 2a single agent data YE 2024E

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?

- Initial Phase 1 single agent data H2 2024E

ANTI-FCYRIIB

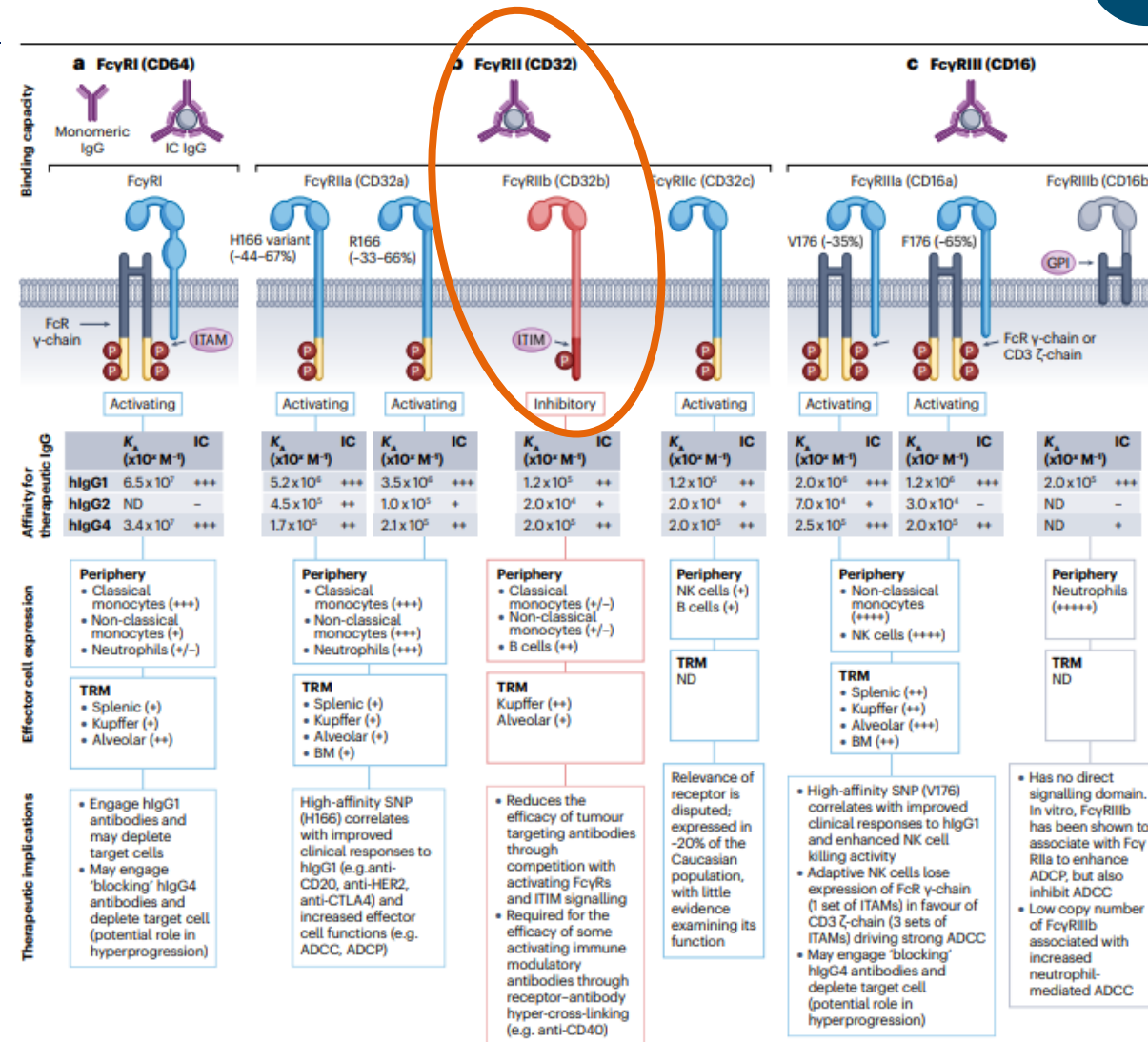
BI-1206 + RITUXIMAB

BI-1206 + PEMBROLIZUMAB

BI-1607

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

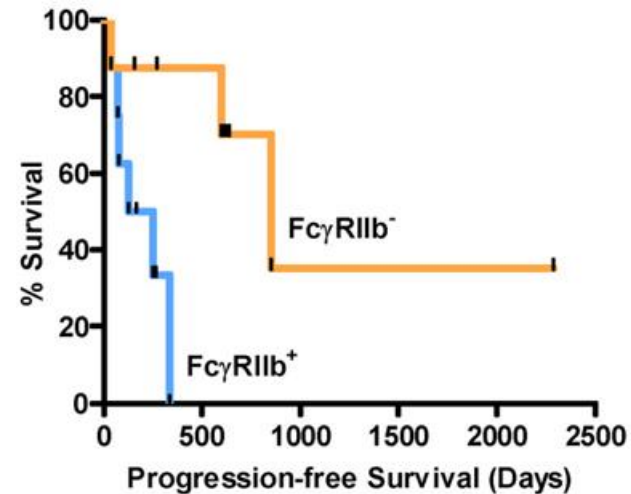
- **BI-1206** is an Fc-competent IgG1 antibody that enhances anti-CD20 and anti-PD-1 therapies. In **two separate programs** in combination with standard of care cancer treatments; **rituximab** and **pembrolizumab** (combined global annual sales of ~ USD 23 bn)
- **BI-1607** has a different MoA compared to BI-1206 having been engineered for reduced Fc-binding to FcγR



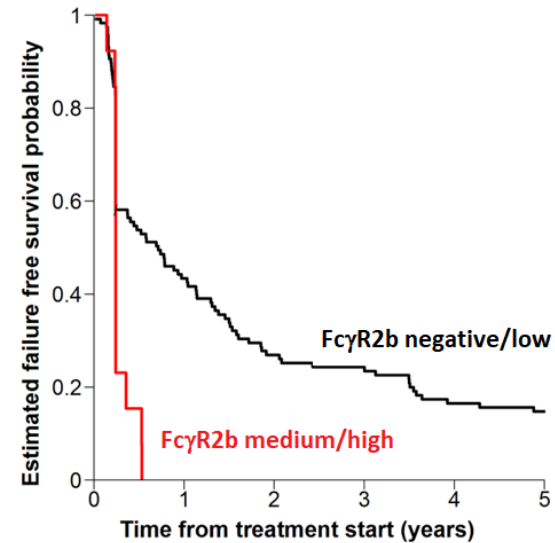
Galvez-Cancino, F., Simpson, A.P., Costoya, C. et al. Fcγ receptors and immunomodulatory antibodies in cancer. *Nat Rev Cancer* 24, 51–71 (2024). <https://doi.org/10.1038/s41568-023-00637-8>

FCγRIIB EXPRESSION CORRELATES INVERSELY WITH SURVIVAL

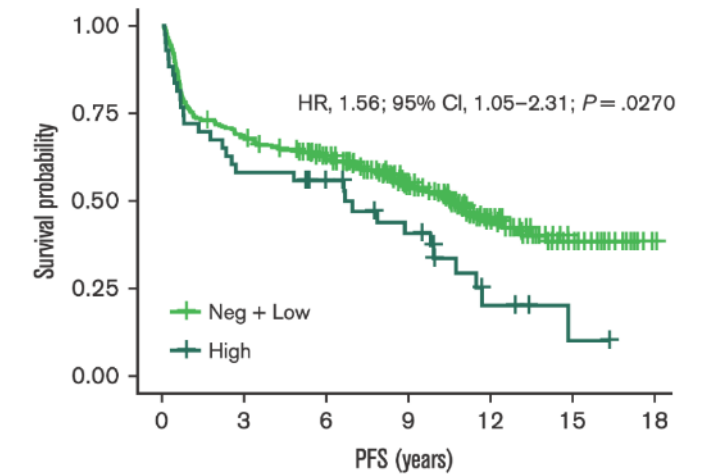
Mantle Cell Lymphoma



Follicular Lymphoma



Diffuse Large B Cell Lymphoma



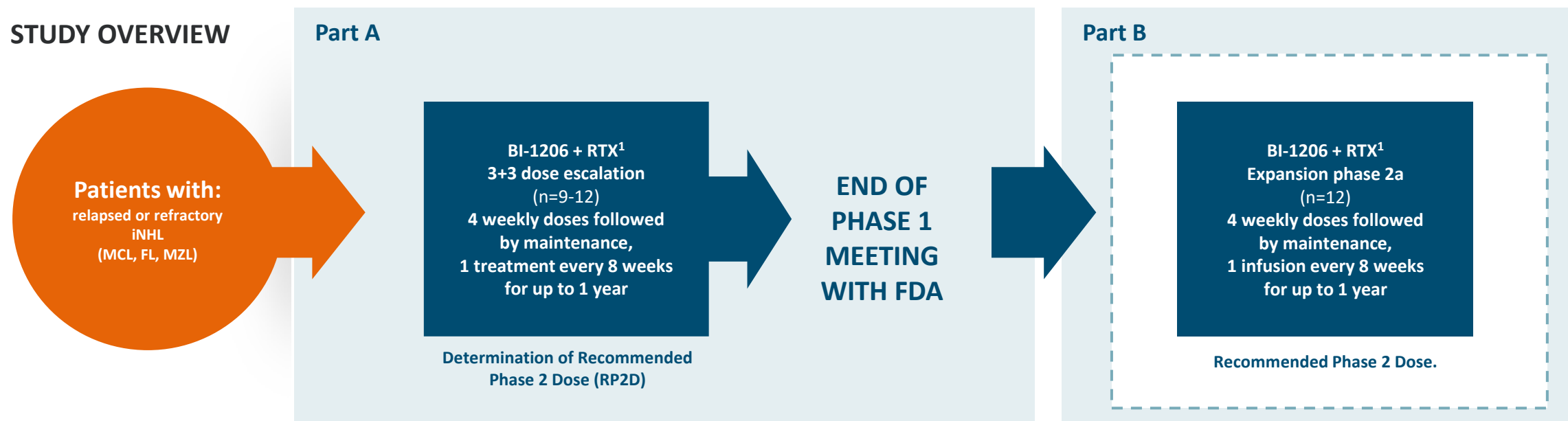
High FcγRIIB expression is associated with shorter survival in patients receiving rituximab therapy

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

Ongoing phase

FcγRIIIB
BI-1206 +
ritux

STUDY OVERVIEW



- **Phase 2a** dose expansion **ongoing** with intravenous (IV) administration of BI-1206
- A subcutaneous (SC) formulation in development **in parallel** to IV, first data presented at EHA 2024

Quality of responses particularly impressive

(May 2024):

- First data for the **SC** arm: **1 complete response (CR)**, **2 partial responses (PR)**, **1 stable disease (SD)** out of 4 evaluable patients.
- Further updates from the **IV** arm; a fifth CR has been observed, adding to a **total of 5 CR, 1 PR** and **6 SD** out of 17 evaluable patients.
- **CR:s** have been **long-lasting**, three of them **lasting years** after end of treatment
- **No safety or tolerability concerns**

- **6 Complete responses**
- **3 Partial responses**
- **7 Stable disease**

▶ **IV + SC : 17 + 4
evaluable patients)**

WHAT'S NEXT?

- **Data to be presented at the European Hematology Association (EHA) June 14, 2024.**

CASI Phase 1 dose-escalation data re-inforce 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 combination with rituximab and Calquence

- AstraZeneca to provide **Calquence** (BTK inhibitor) for combination with BI-1206 and rituximab in the ongoing Phase 1/2a clinical study for the treatment of patients with follicular lymphoma/mantle cell lymphoma who have progressed or are refractory to rituximab.
- The **Phase 2a IV dose expansion cohort** in combination with rituximab is currently enrolling patients, and it 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.

WHAT'S NEXT?

- Initial Phase 2a triplet data YE 2024E



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 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 develop 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 subcutaneous (SC) formulation of BI-1206 is also being 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.

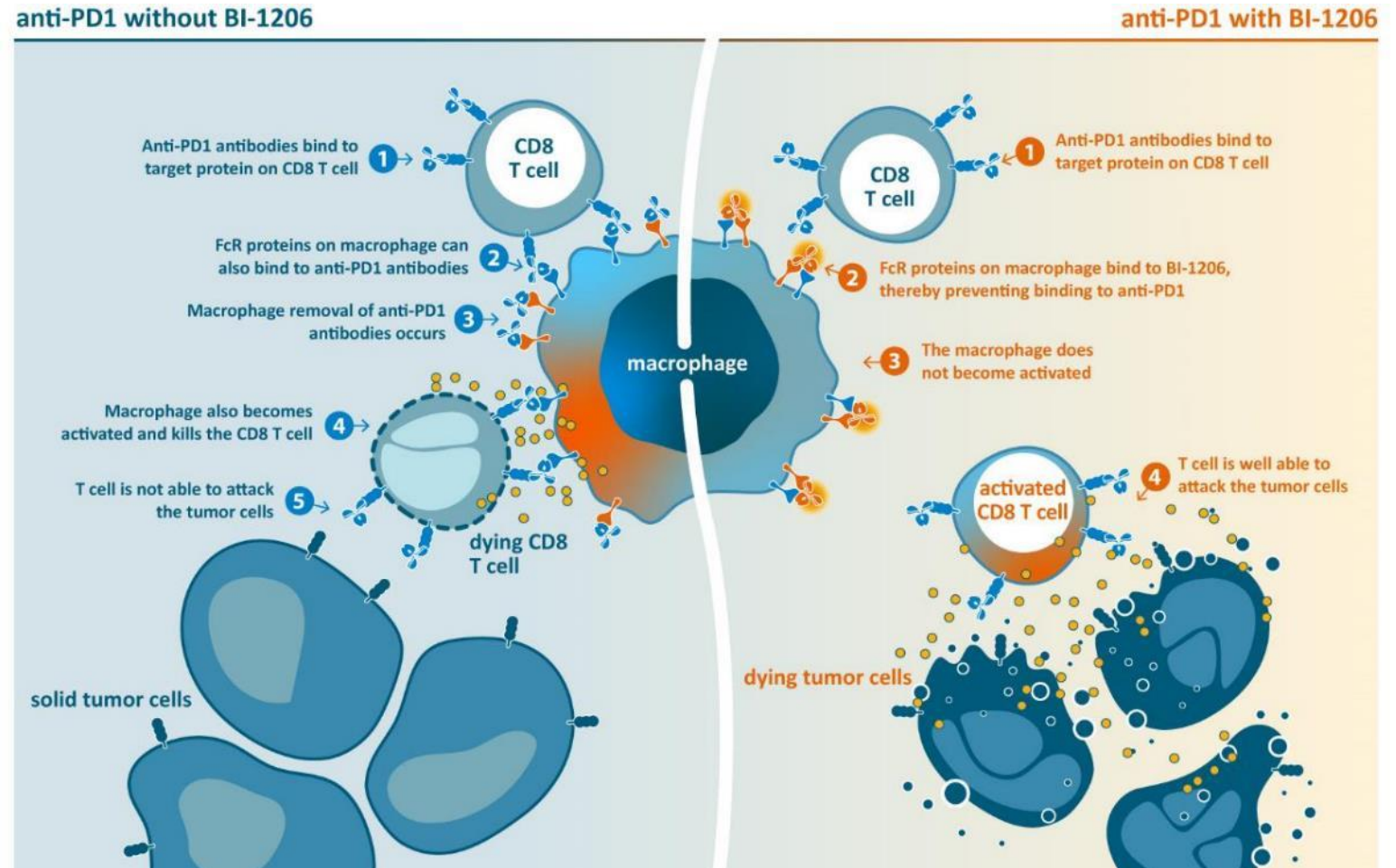
FCYR2B BLOCKERS MAY ENHANCE RESPONSE TO PD-1 INHIBITION

FcγRIIb
BI-1206 +
pembro

Strong rationale to combine BI-1206 with anti-PD-1

FcγRs have been shown to modulate the activity of immune checkpoint inhibitors

- **Overexpression** of FcγRIIb may determine **resistance to anti-PD-1** therapy in metastatic melanoma, NSCLC and others



BI-1206 IN COMBINATION WITH PEMBROLIZUMAB

KEYNOTE-A04: PHASE 1/2A CLINICAL STUDY DESIGN

Ongoing phase

Phase 1 All Tumor Types

IV

BI-1206 IV + Pembro IV
Advanced solid tumors
1mg/kg, mTPI2 dose escalation
Q3W (2 years)

ONGOING

Phase 2a Tissue-Specific Cohorts

Signal Seeking

BI-1206 IV + Pembro (N = 12)
1st Line Melanoma

BI-1206 IV + Pembro (N = 12)
Non-Small Cell Lung Cancer

BI-1206 IV + Pembro (N = 12)
Other Solid tumor

Dose Optimization

BI-1206 IV + Pembro (N = 20)
Selected Indication
Dose A

BI-1206 IV + Pembro (N = 20)
Selected Indication
Dose B

Key objectives:

- Confirm strong rationale for combination, as FcγRs have been shown to modulate the activity of immune checkpoint inhibitors.
- Explore overexpression of FcγRIIb that may determine resistance to anti-PD-1 therapy in metastatic melanoma, NSCLC and others.
- Explore safety & tolerability and illustrate pharmacokinetic and pharmacodynamic profile of combination.
- Determine recommended Phase 2 dose (RP2D).
- Observe early signs of efficacy.
- Biomarker exploration (B cell depletion, analysis of biomarkers predictive of response).

BI-1206 IN SOLID TUMORS: POSITIVE CLINICAL PHASE 1 RESULTS

FcγRIIB
BI-1206 +
pembro

Responses in melanoma patients who previously failed on anti-PD1 therapy

(ASCO 2024):

- **One complete response (CR), one partial response (PR) and seven patients with stable disease (SD)** including one long-lasting, out of 24 evaluable patients
- BI-1206 evaluated both as IV and SC administration
- Potential to **overcome resistance** to immune checkpoint inhibition (CPI)
- All patients enrolled had received **at least one prior line of anti-PD1/PDL1** therapy
- Combination **well-tolerated** in this **heavily pre-treated** population of patients



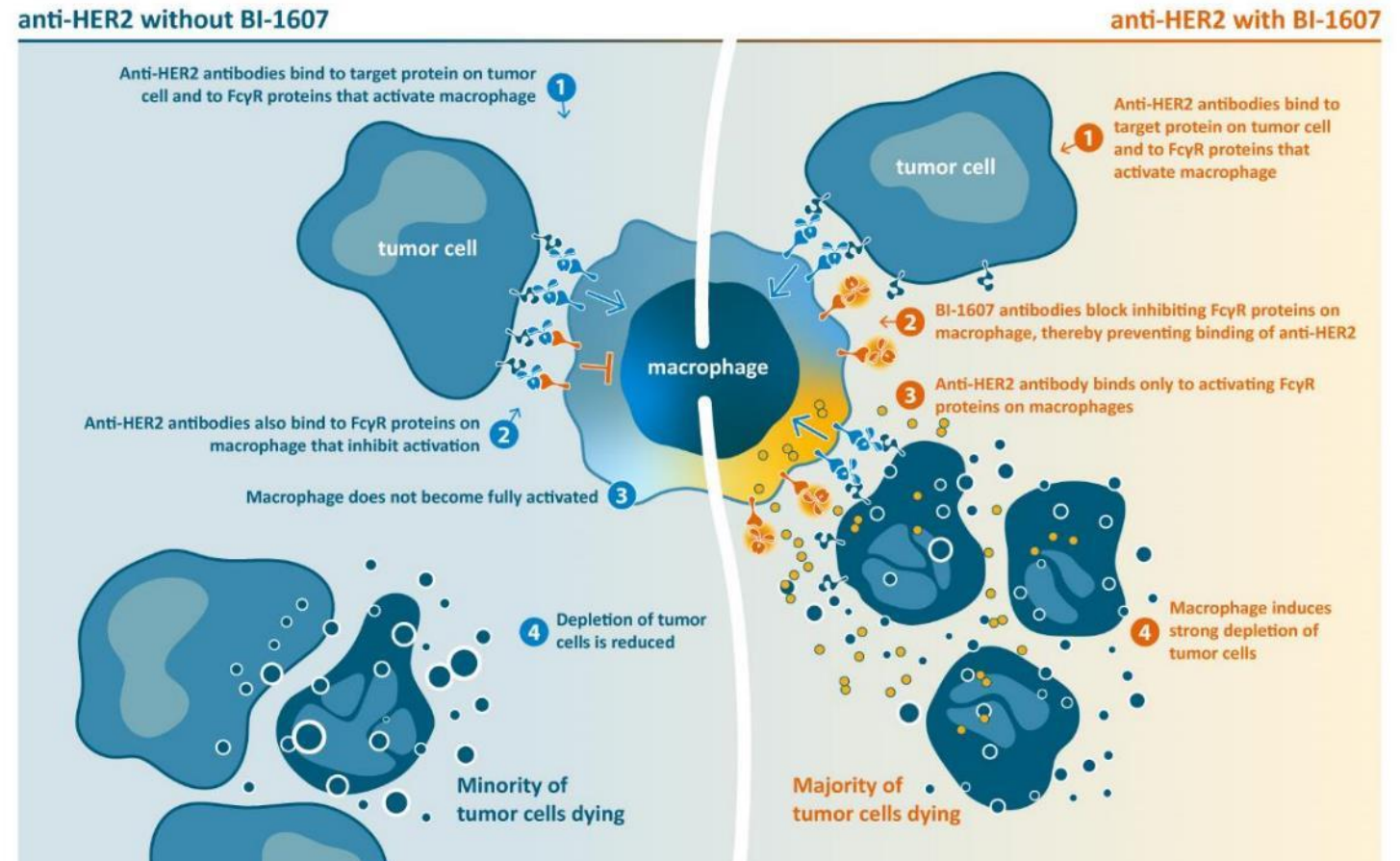
BI-1607 HAS THE POTENTIAL TO INCREASE EFFICACY OF OTHER ANTIBODY DRUGS

FcγRIIB
BI-1607

BI-1607 has an antagonistic function

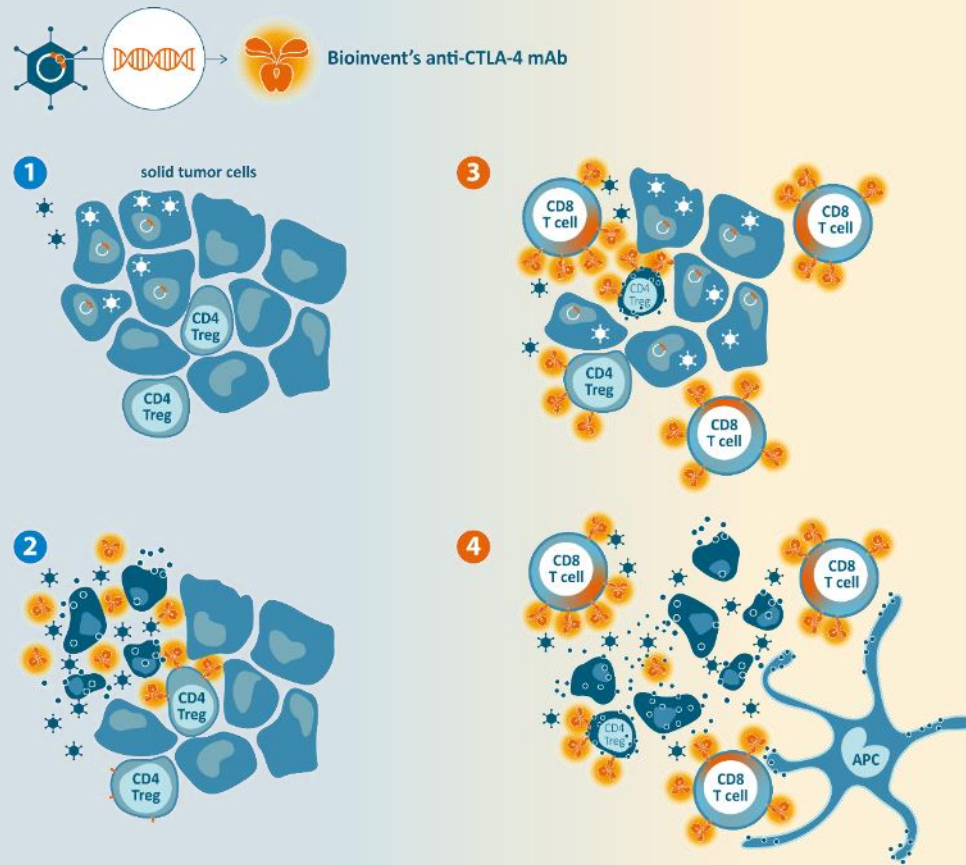
Blocking the inhibitory function of immune effector cells

- 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



ANTI-CTLA-4
BT-001

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 Frendéus^{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_Δ- 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

CTLA-4
BT-001

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

CTLA-4
BT-001

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 H2 2024**



OUT-LICENSED PROGRAMS KEY CATALYSTS

OUT-LICENSED PROGRAMS A SEAL OF EXCELLENCE

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

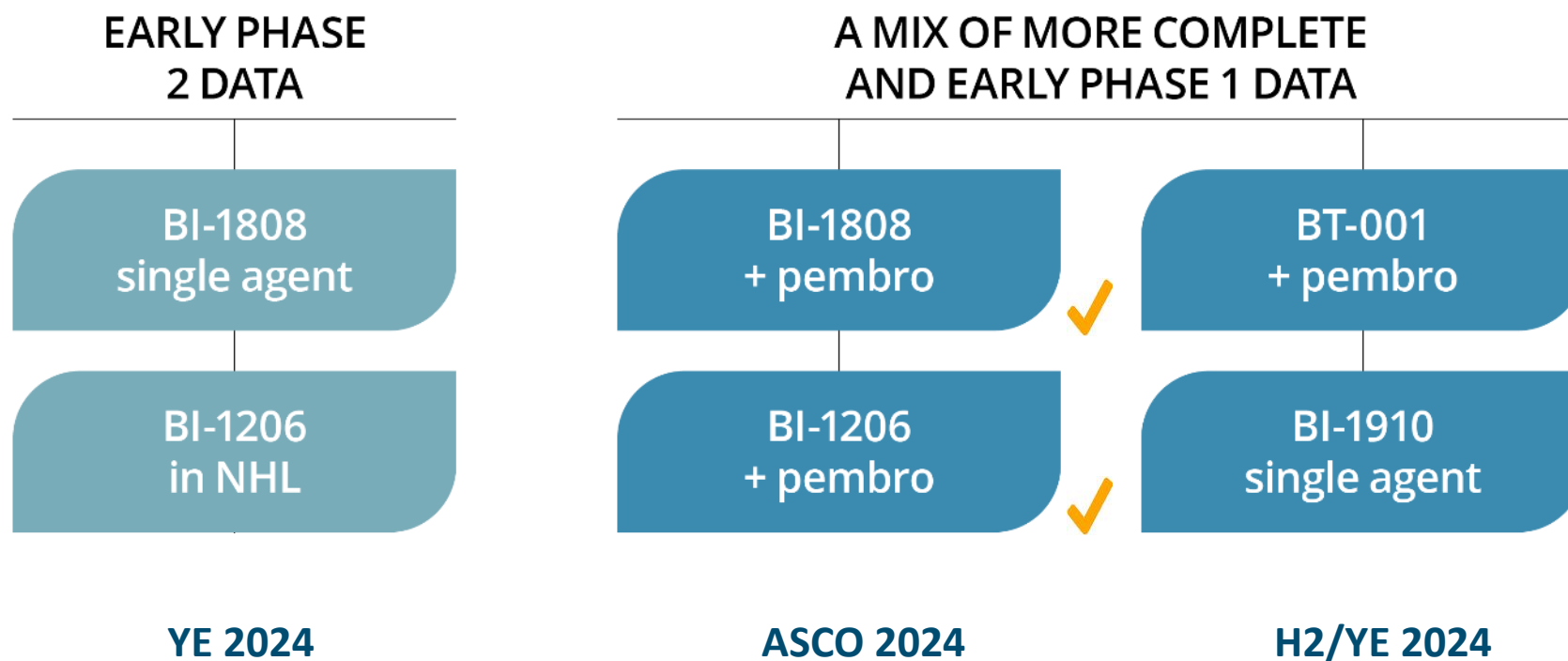
- Funded and fully run by external partners, no costs involved for BioInvent
- Include development milestones and potential royalties on future sales

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.

EXPECTED KEY CLINICAL MILESTONES 2024





Virtual KOL Event to highlight recently presented efficacy data from BioInvent's lead candidates BI-1808 and BI-1206; Discussion on TNFR2 and FcγRIIB as promising targets in immuno-oncology

Featuring Alexander Eggermont, MD, PhD (University Medical Center Utrecht)

Tuesday, June 18, 2024 | 9:00 AM ET/3:00 PM CEST

CLICK HERE TO REGISTER & ATTEND



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