



UNLEASHING IMMUNITY TO FIGHT CANCER

Function first drug discovery

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AGENDA BIOINVENT R&D DAY DECEMBER 8, 2022

Moderator Lars Frick, journalist Børsveckan

2:00 PM	Welcome & introduction	Martin Welschhof, CEO
2:10 PM	FcyRIIB clinical programs, BI-1206 and BI-1607	Björn Friendéus, CSO Andres McAllister, CMO
3:00 PM	Break	
3:15 PM	The oncolytic drug candidate BT-001 (anti-CTLA-4)	Björn Friendéus, CSO Andres McAllister, CMO
3:30 PM	BI-1808 (anti-TNFR2)	Björn Friendéus, CSO Andres McAllister, CMO
3:45 PM	<i>“ Current treatment landscape and unmet medical need in T cell lymphoma ”</i>	Dr Sean Lim
4:05 PM	Fire-side chat/ Q&A	All
4:30 PM	Networking, food & drinks	

TODAY'S PRESENTERS



Dr Sean Lim

Associate Professor and Honorary Consultant in Hematological Oncology at University Hospital Southampton

Practicing clinician specializing in lymph node cancers

Leads a scientific research group focusing on the development of new anti-cancer drugs, in particular novel therapeutic monoclonal antibodies



Andres McAllister, CMO

CMO BioInvent since 2017

Previously CSO at Debiopharm; senior roles at IDM and BioMerieux/Pierre Fabre

PhD from Pasteur Institut, Paris

MD from Universidad del Rosario, Bogotá



Björn Frendéus, CSO

CSO BioInvent since 2014

Graduated from the Swedish Foundation for Strategic Research funded Biomedicine programs within the Infection & Vaccinology program

Visiting Professor at University of Southampton



Martin Welschhof, CEO

CEO BioInvent since 2018

Previously Director Technology Axaron Bioscience; CEO Affitech, CEO Opsona Therapeutics

Board member: APIM Therapeutics, Nextera AS and Uni Targeting Research

Ph.D in recombinant antibody technology

nature reviews clinical oncology

The development of immune-checkpoint inhibitors has heralded **a new era in cancer treatment**, enabling the possibility of long-term survival in patients with metastatic disease, and providing new therapeutic indications in earlier-stage settings.

Nature Reviews Clinical Oncology volume 19, pages254–267 (2022)

Immune checkpoint inhibitors have become the standard of care for several types of solid cancer

Half of all patients with metastatic cancer are eligible in economically developed countries

Eight approved agents are available for 17 different malignancies

5,000+ clinical trials are ongoing for PD-1/PD-L1 antibodies alone

We are not there yet

The number of targets available for antibody therapy is still limited

And most of these targets have failed to deliver therapies that work in the clinic

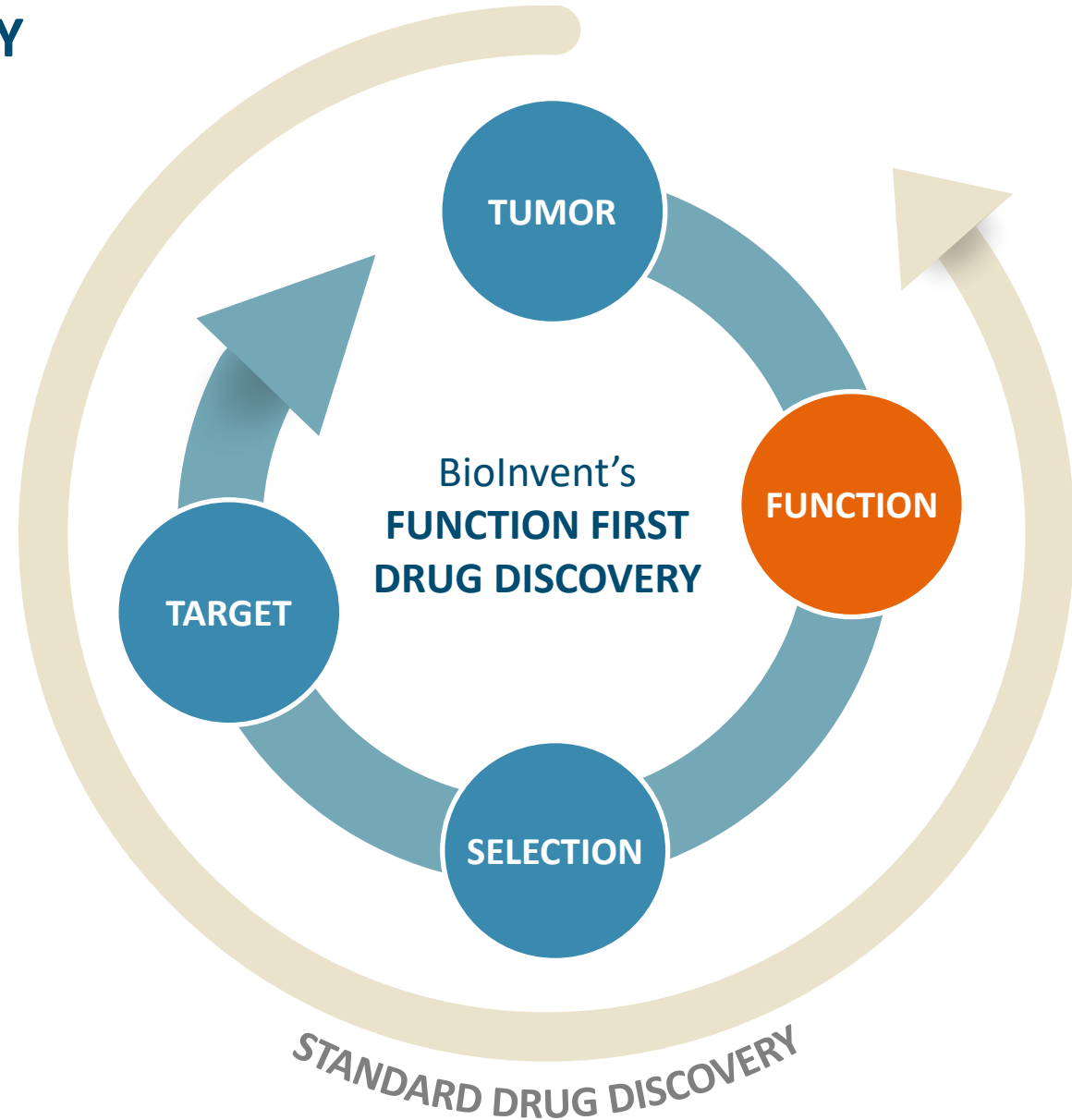
The majority of patients do not respond at all, or their response is short-lived due to rapidly evolving resistance

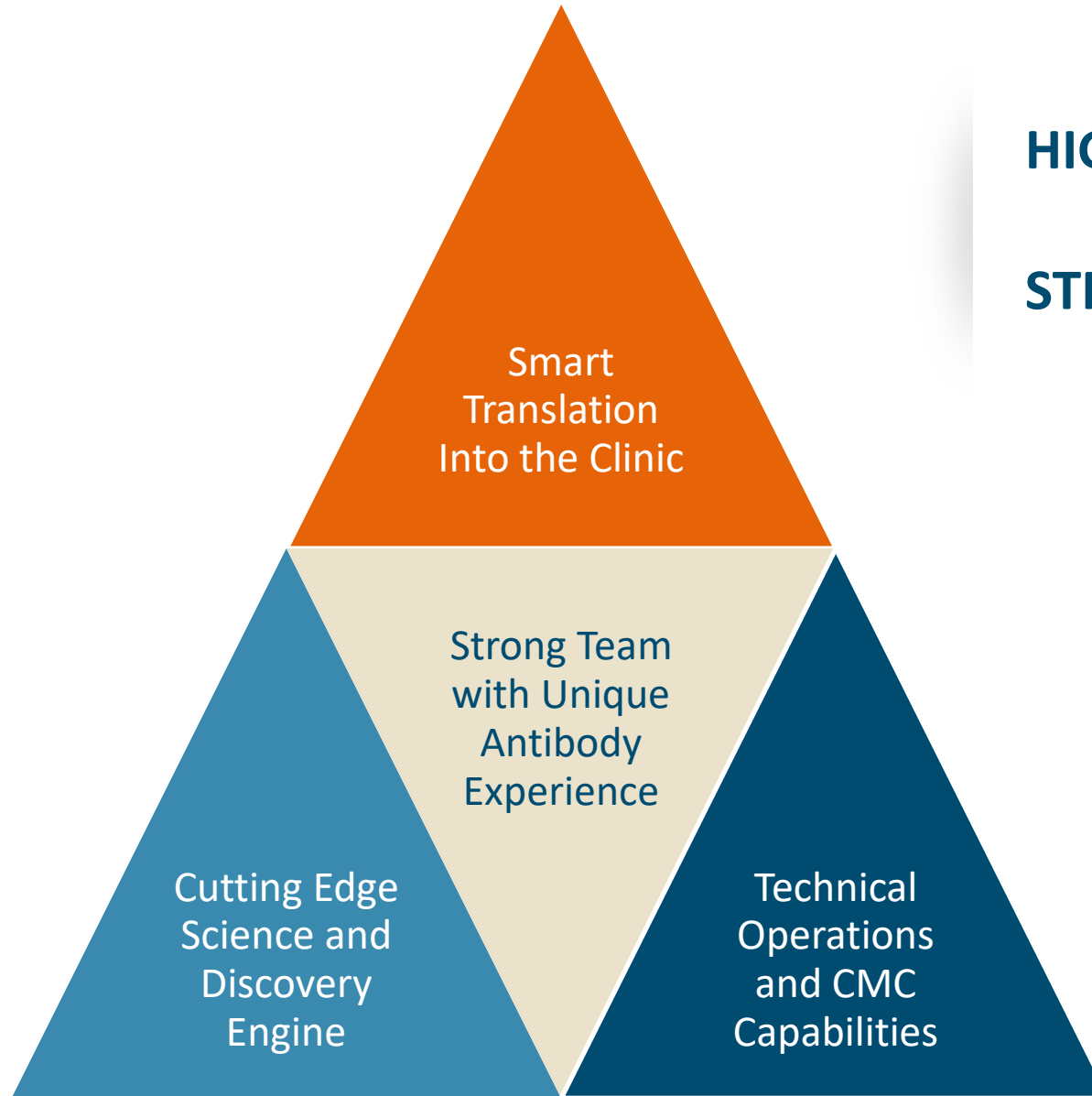
The background of the slide is a dark blue, out-of-focus image of laboratory equipment. In the foreground, a petri dish is visible, and a pipette tip is positioned above it. To the right, another petri dish is partially visible. The overall aesthetic is scientific and professional.

What if we turned the drug
discovery process around,
**to start from what matters
the most?**

FUNCTION F.I.R.S.T™ DRUG DISCOVERY

While others often focus on the targets and test function at the end, We start from the **function**

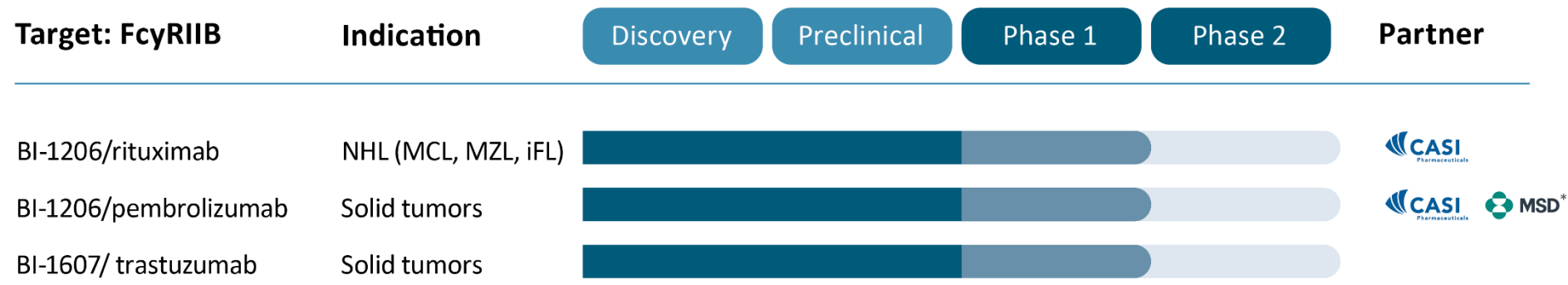




HIGHLY INTEGRATED COMPANY

STRONG COMPETITIVE ADVANTAGE

STRONG PIPELINE WITH MULTIPLE VALUE DRIVERS



Target: TNFR2 and CTLA-4



- Completed
- Ongoing
- Up-coming

* Clinical supply and collaboration agreement

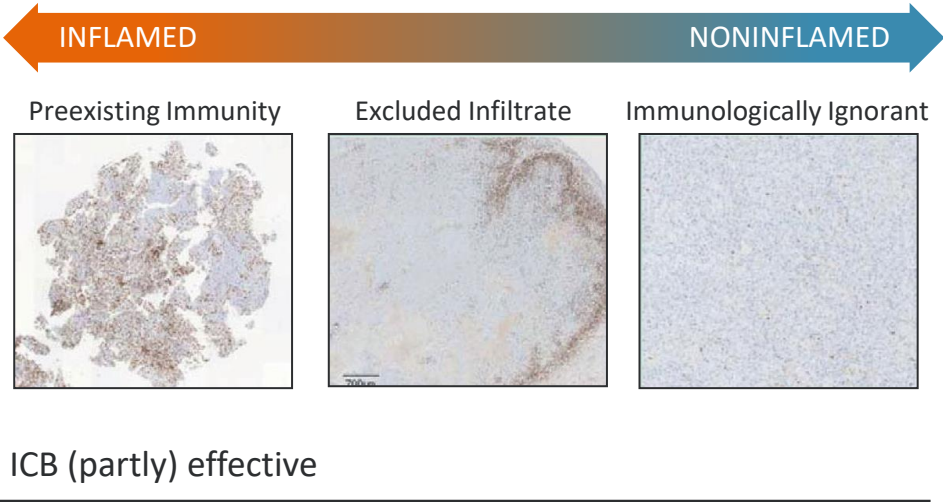
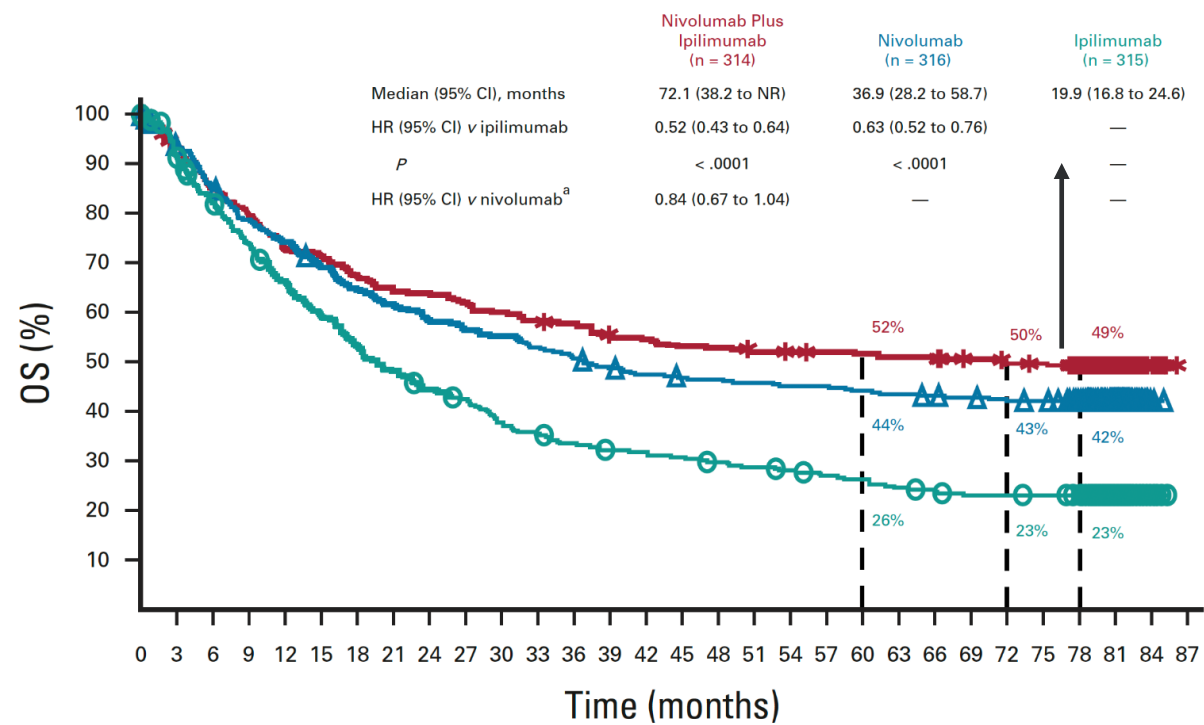


Clinical Pipeline



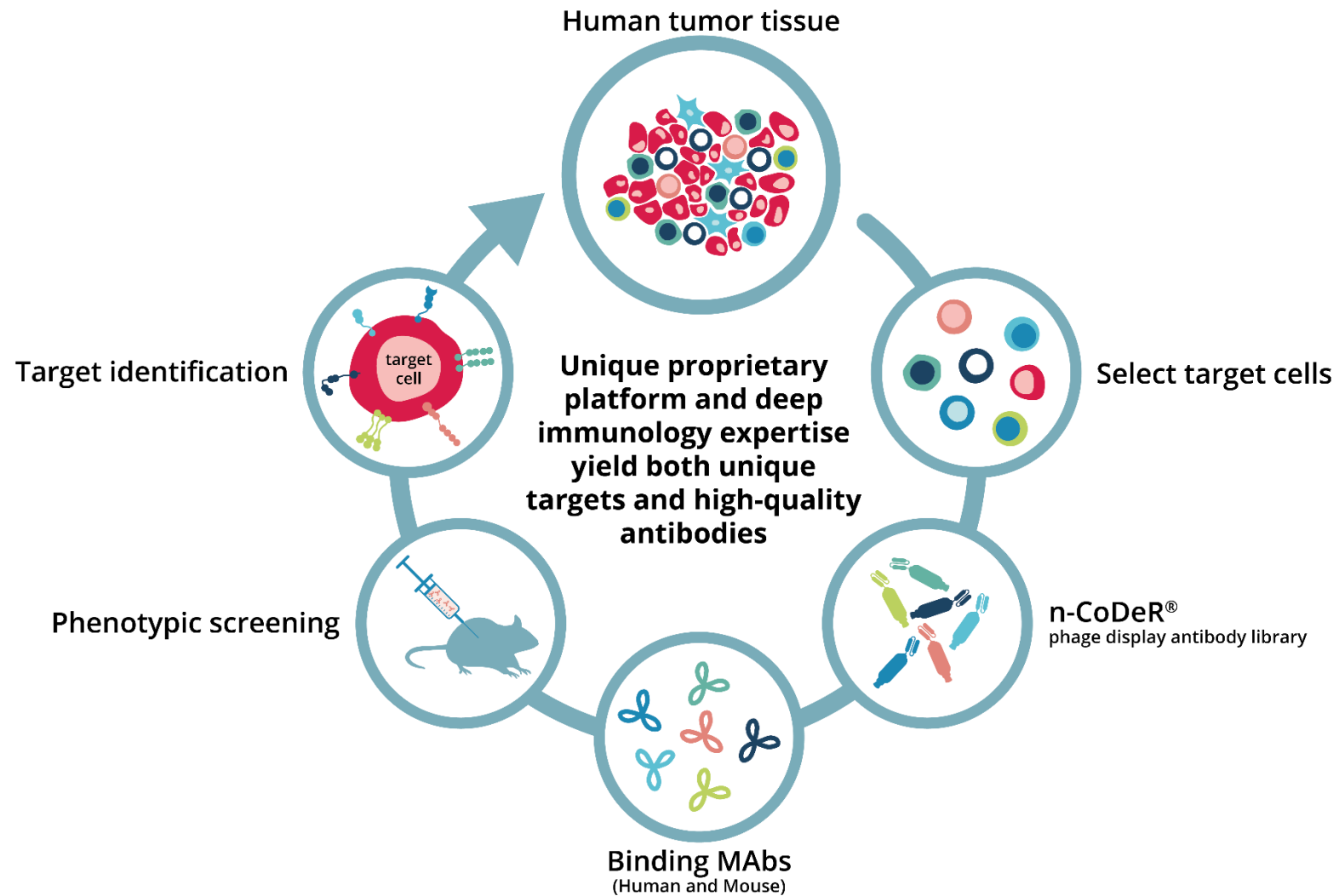
OVERCOMING THE RESISTANT TUMOR MICROENVIRONMENT

- Many cancer patients do not respond or develop resistance to immunotherapy
- New drugs and mechanisms of action that help activate robust anti-cancer immunity are needed



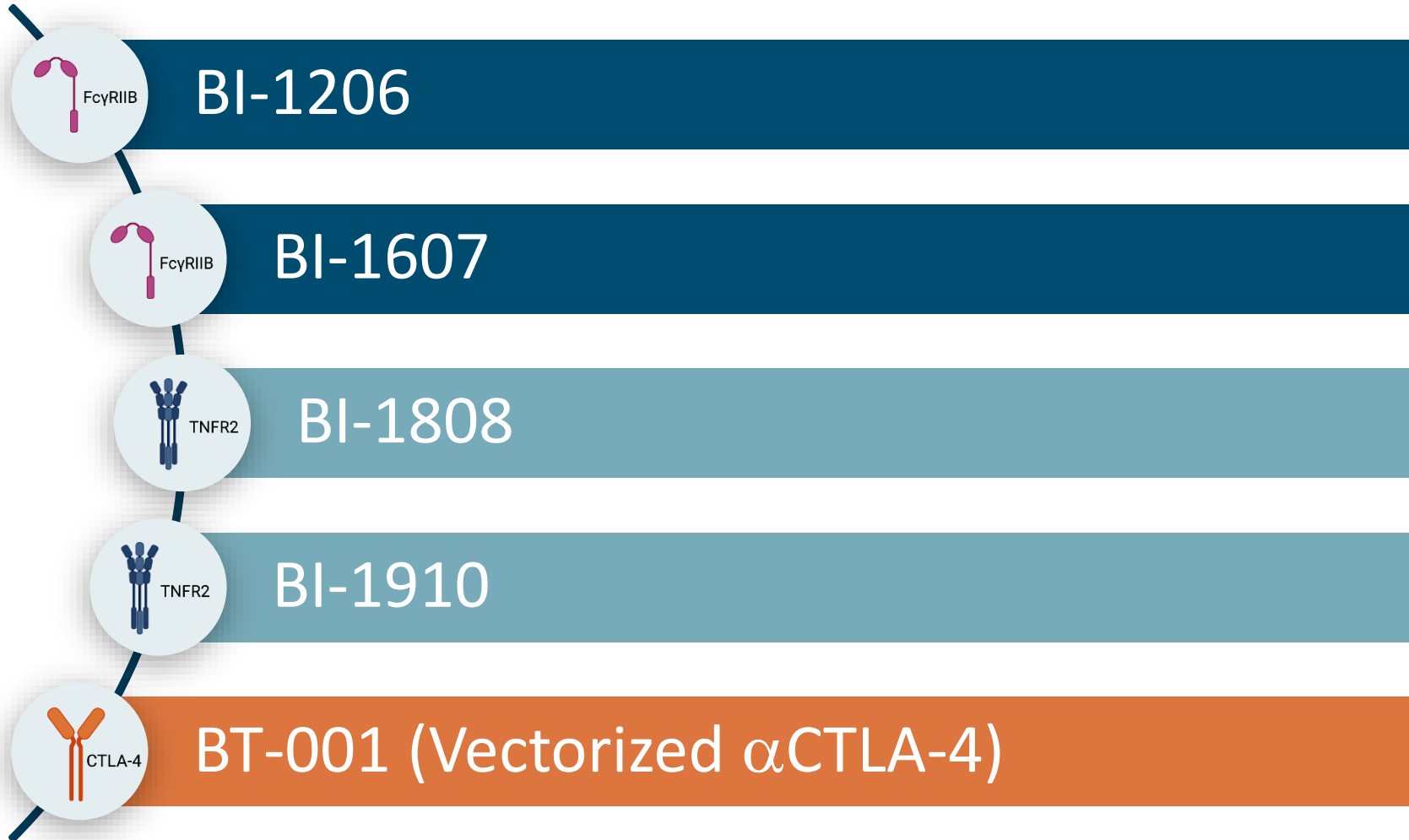
+ New MoA combinations needed

FUNCTION F.I.R.S.T™ DISCOVERY OF NEW ONCOLOGY TARGETS AND ANTIBODIES



POWERFUL TARGETS AND ANTIBODY MECHANISMS-OF-ACTION

Target





α Fc γ RIIB - BI-1206 & BI-1607

 **BioInvent**

EXECUTIVE SUMMARY – anti-FcγRIIB (BI-1206 & BI-1607)

- Fcγ receptors, “the antibody checkpoints” modulate the efficacy of IgG antibodies
 - Inhibitory receptors (CTLA-4, PD-1/PD-L1)
 - Immune agonist receptors (ox40, 4-1BB, GITR, CD40)
 - Other receptors (IL-2R)
- FcγRIIB is the sole inhibitory FcγR
- FcγRIIB is strongly upregulated and promotes resistance locally in the tumor microenvironment (TME)
- **BI-1206** is a first-in-class mAb targeting FcγRIIB with *Fc-competent* human IgG1 enhances anti-CD20 and anti-PD-1 therapeutic activity by distinct mechanisms:
 - **NHL, anti-CD20** – BI-1206 blocks rituximab internalization into tumor cells enhancing anti-CD20 efficacy and overcoming anti-CD20 resistance
 - **solid cancer, anti-PD-1** - BI-1206 blocks FcγR-dependent Macrophage removal of anti-PD-1, and anti-PD-1 induced ADCP of effector T cells, for enhanced therapeutic activity
- **BI-1607** Differentiated αFcγRIIB with *Fc-impaired* human IgG1_{N297Q} enhances therapeutic mAb target cell depletion
 - **αCTLA-4 (Treg), αHer2 (Breast tumor)**, and beyond

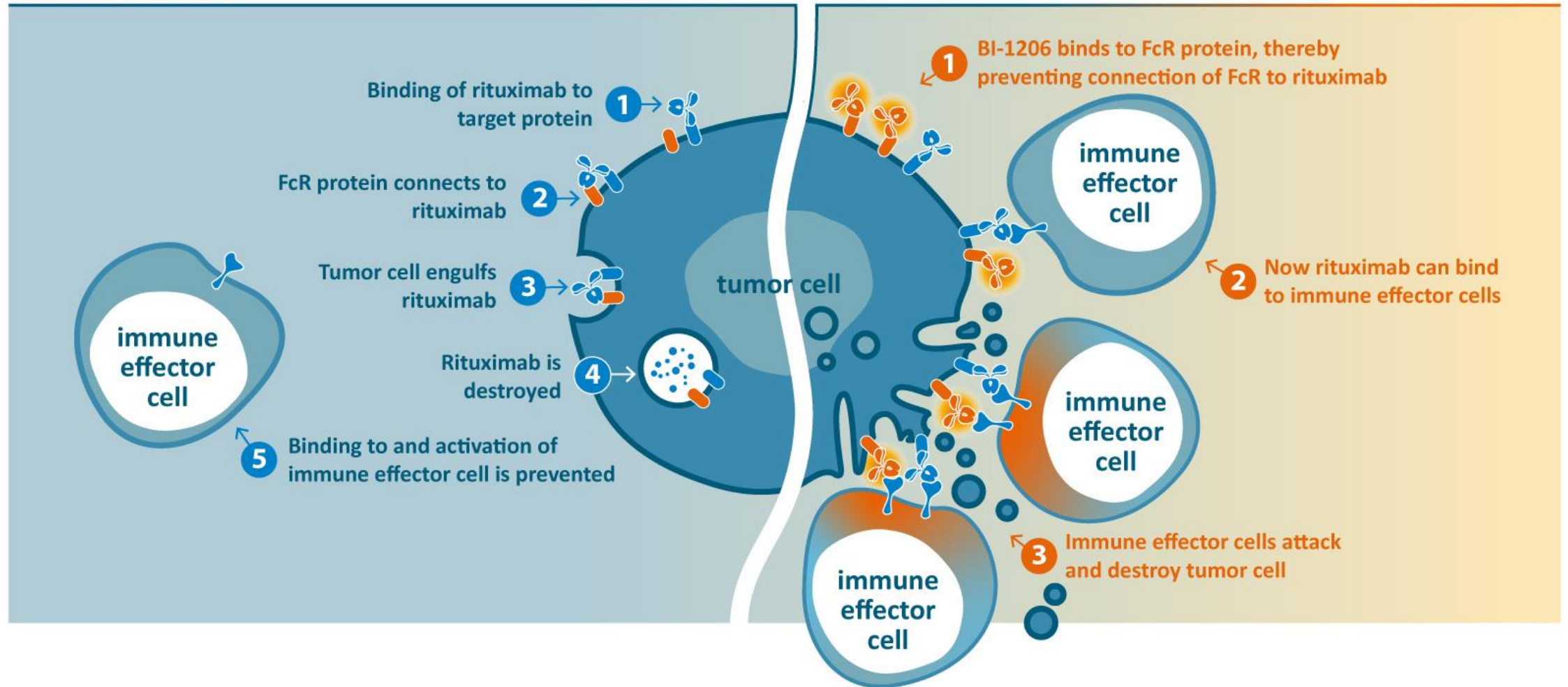


BI-1206 (α Fc γ RIIB)

 **BioInvent**

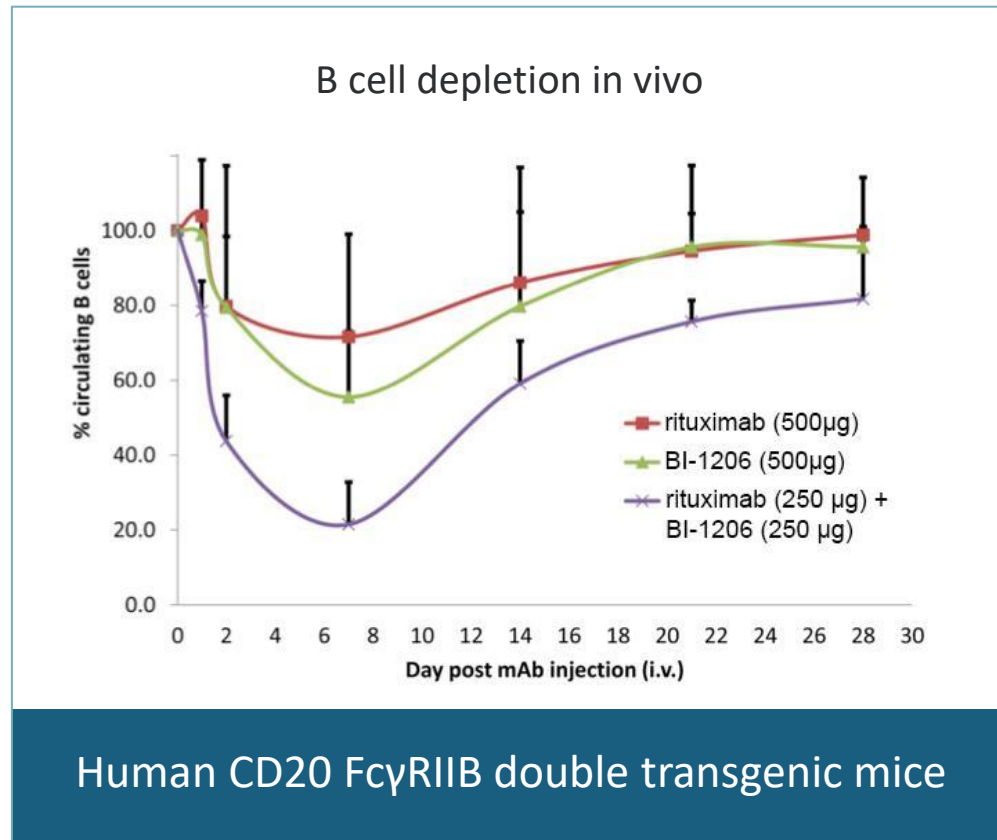
BI-1206 IN NHL – OVERCOMING RITUXIMAB RESISTANCE

without BI-1206



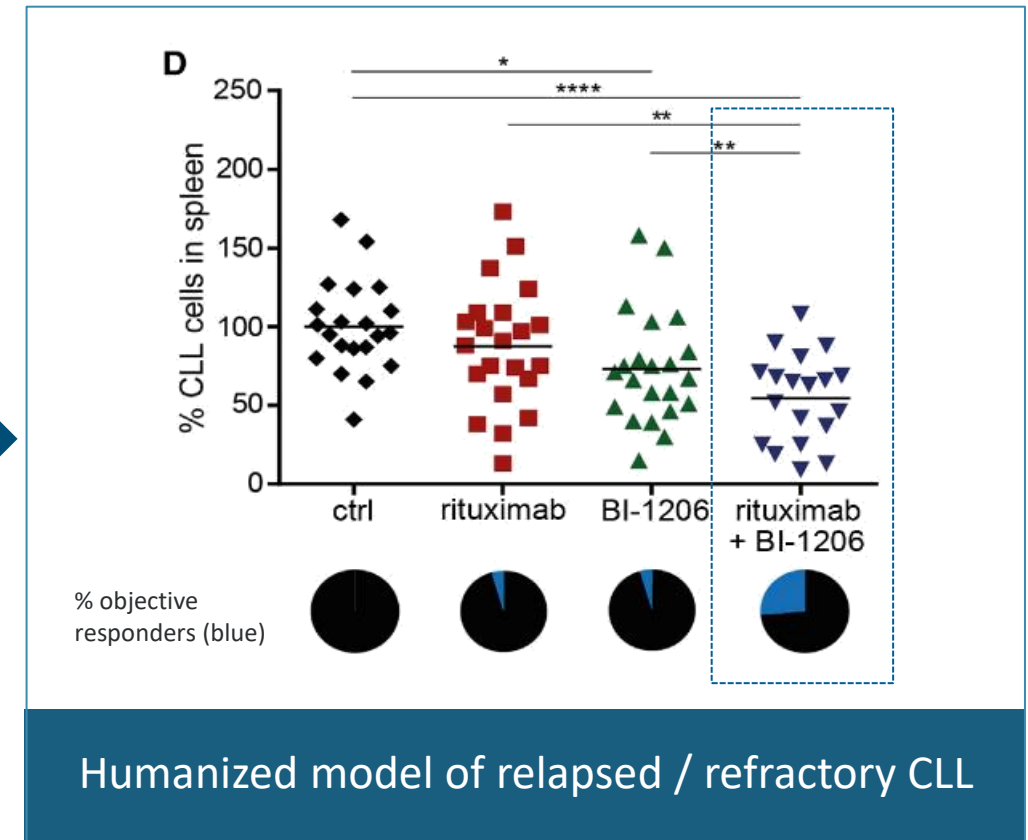
BI-1206 BOOSTS EFFICACY AND OVERCOMES RITUXIMAB RESISTANCE

BI-1206 Blocks Rituximab Internalization And Improves Its Anti-tumor Activity



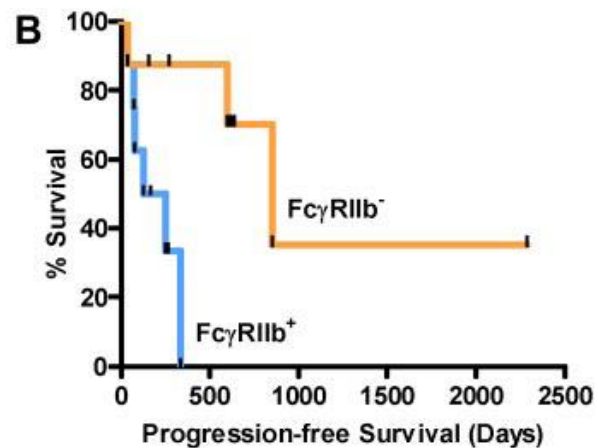
BOOSTING
RITUXIMAB'S EFFECT

OVERCOMING
RESISTANCE

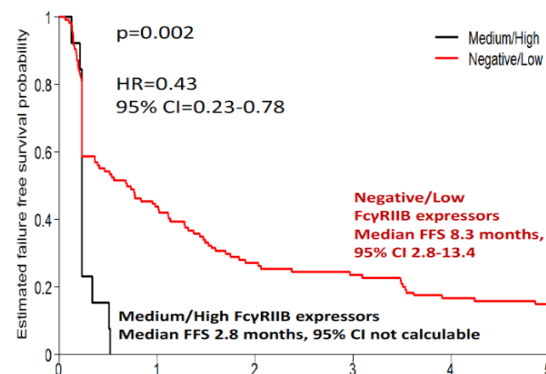


HIGH EXPRESSION OF FcγRIIB CORRELATES WITH POOR PROGNOSIS

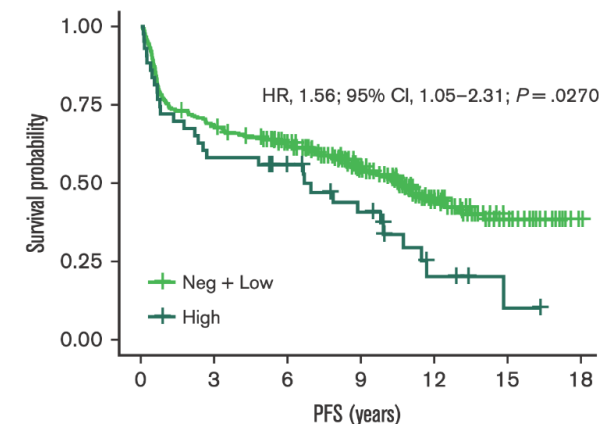
Mantle cell lymphoma



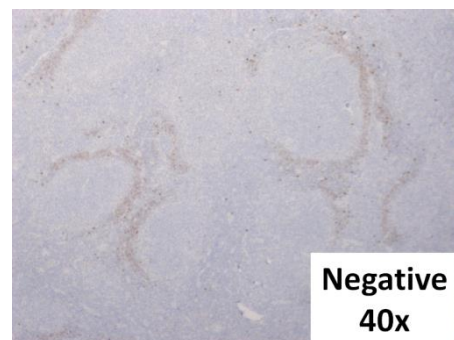
Follicular lymphoma



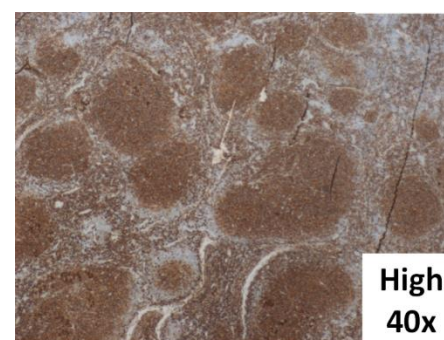
Diffuse Large B cell Lymphoma



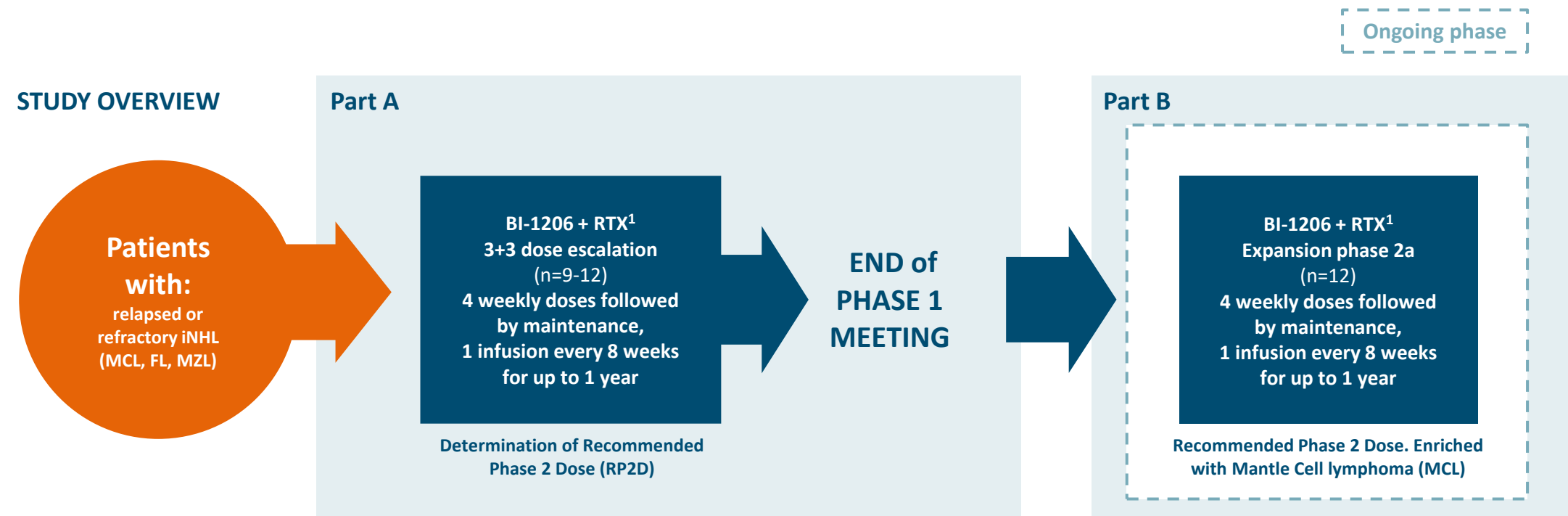
$Fc\gamma RIIB^-$



$Fc\gamma RIIB^+$



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



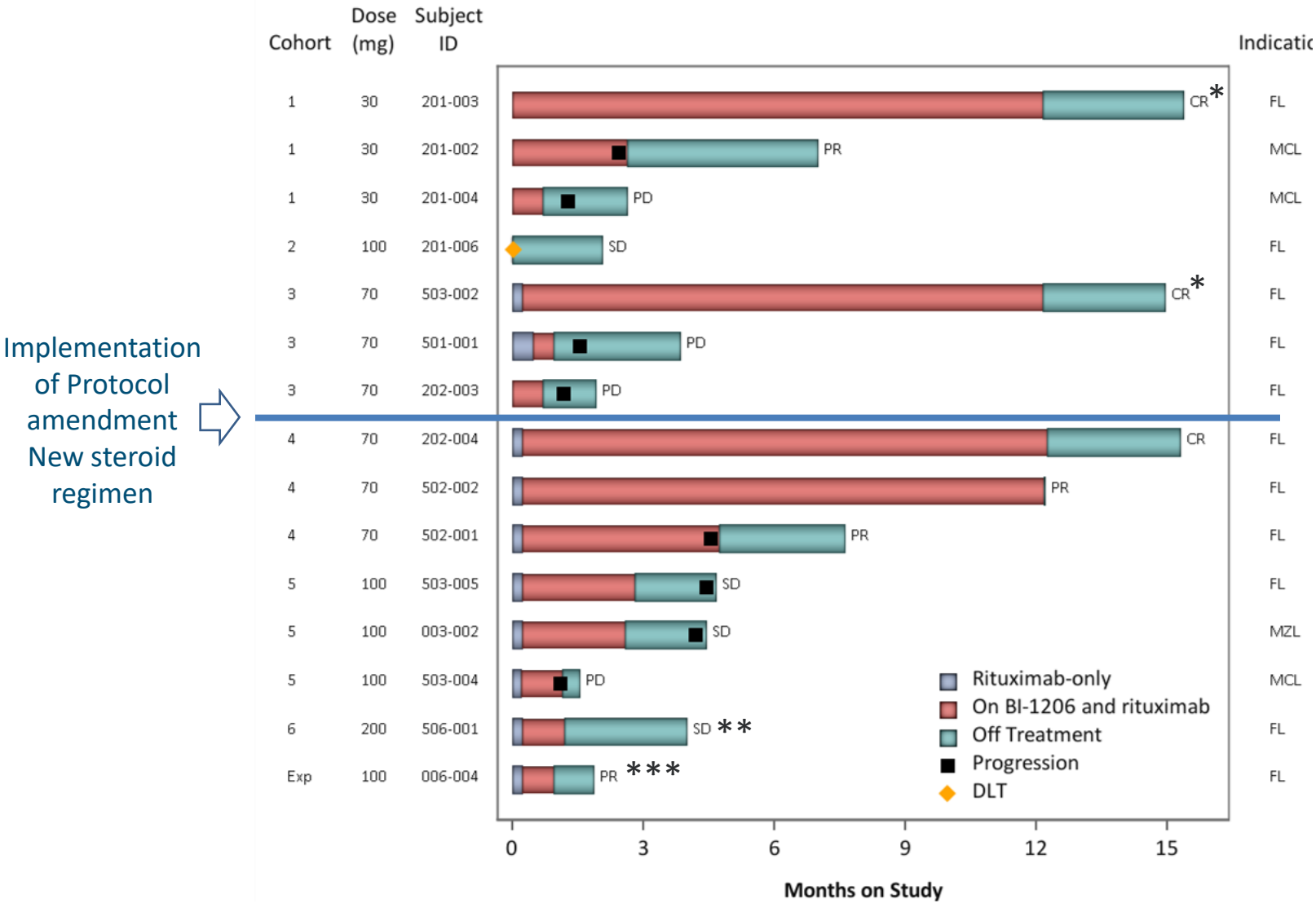
STUDY OBJECTIVES

- Explore safety & tolerability of the combination
- Select recommended phase 2 dose (RP2D)
- Determine pharmacokinetic and pharmacodynamic profile
- Observe early signs of efficacy
- Biomarker exploration (B cell depletion, depletion of circulating tumoral cells, analysis of biomarkers predictive of response)

INCLUSION CRITERIA

- Patients must have relapsed disease or disease that is refractory to conventional treatment or for which no standard therapy exists (R/R)
- Investigator judges available standard therapy as not being appropriate for the subject
- Occurrence of progressive disease after completion of a regimen of rituximab-containing therapy

Figure 1 - Swimmer Plot by Duration of Treatment and Best Overall Response
Response-Evaluable Population



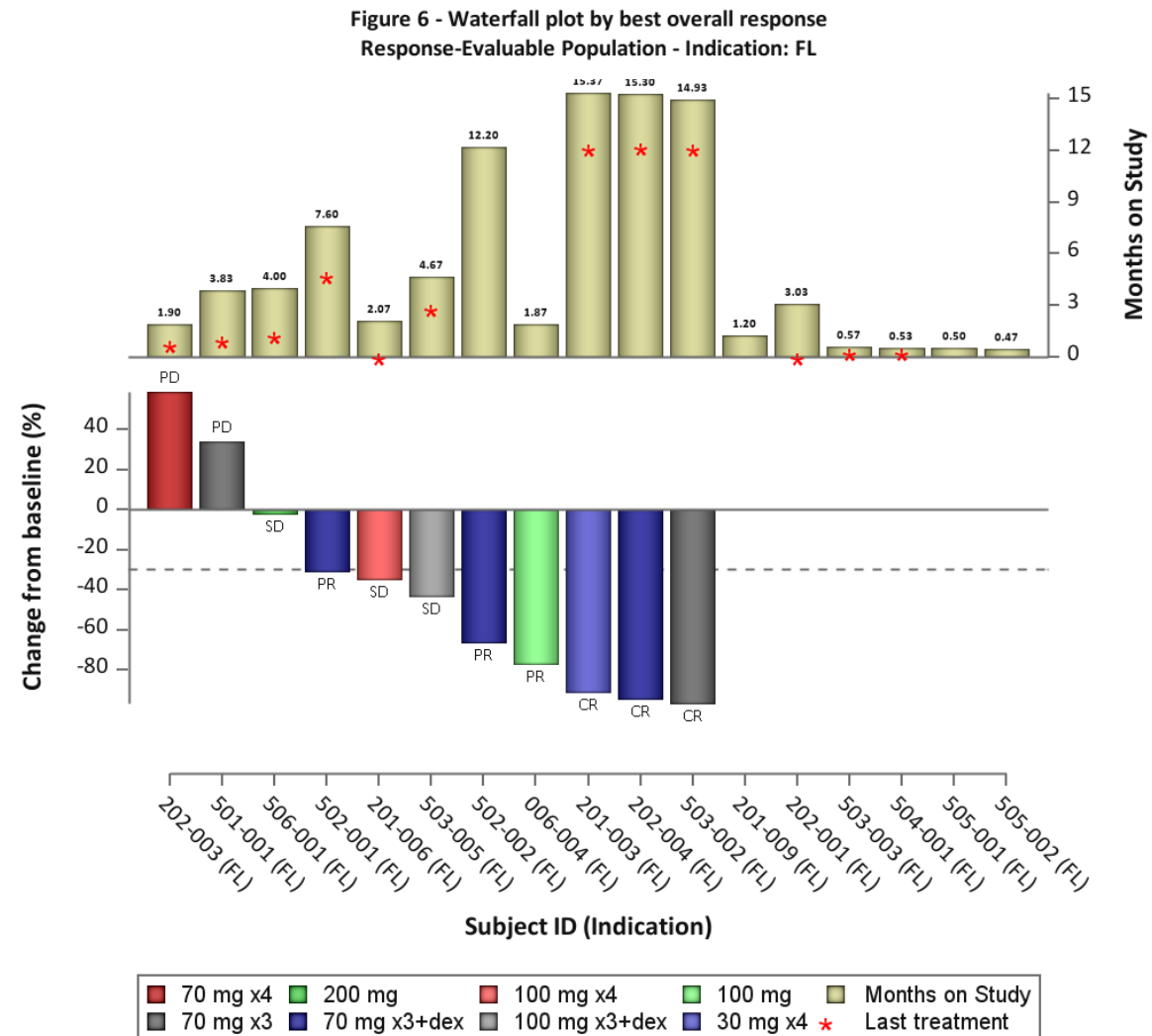
* These patients are still on CR after > 2 and 3 years after the EoT. The third patient was lost to follow up, hence we do not have the information

**4 patients were dosed at 200 mg split dose

*** Patient 006-004 is entering Maintenance treatment

BI-1206-02 TIME ON STUDY & TUMOR CHANGE (%) IN FOLLICULAR LYMPHOMA SUBSET

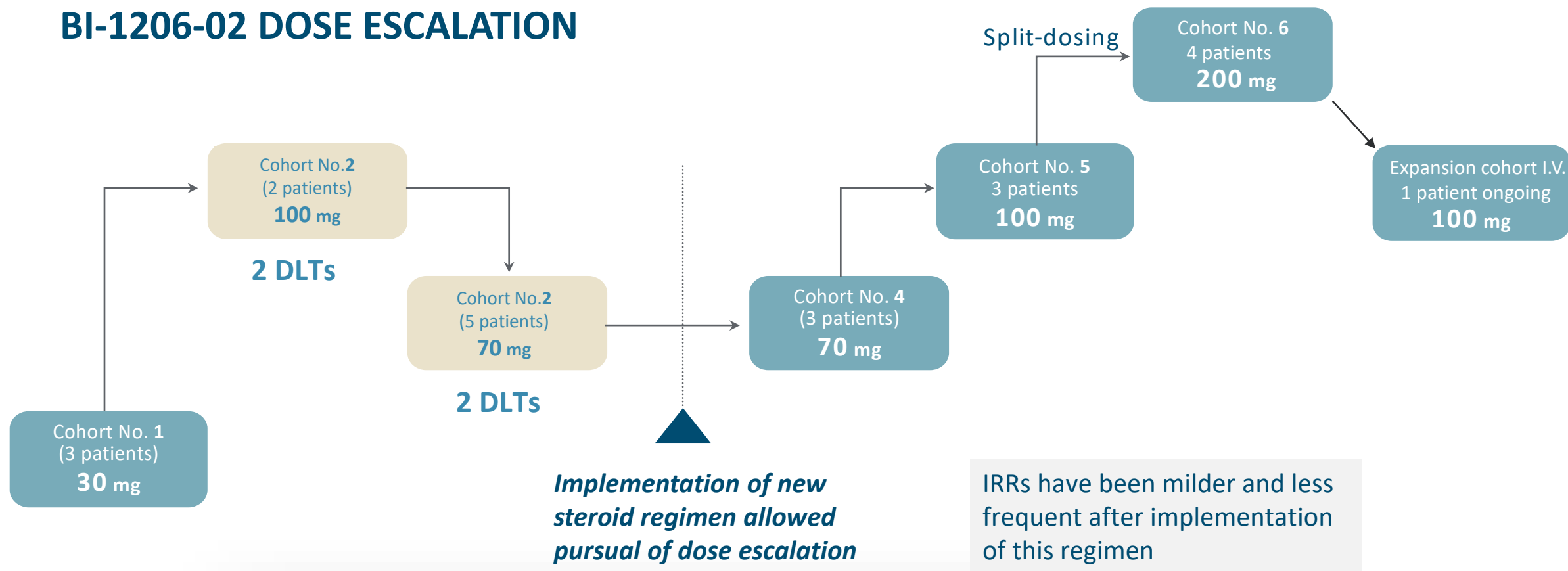
BioInvent BI-1206-02
Data cut-off 28 NOV 2022



BI_1206_waterfall_01DEC2022.sas

Run Date/Time: 01DEC2022 10:59

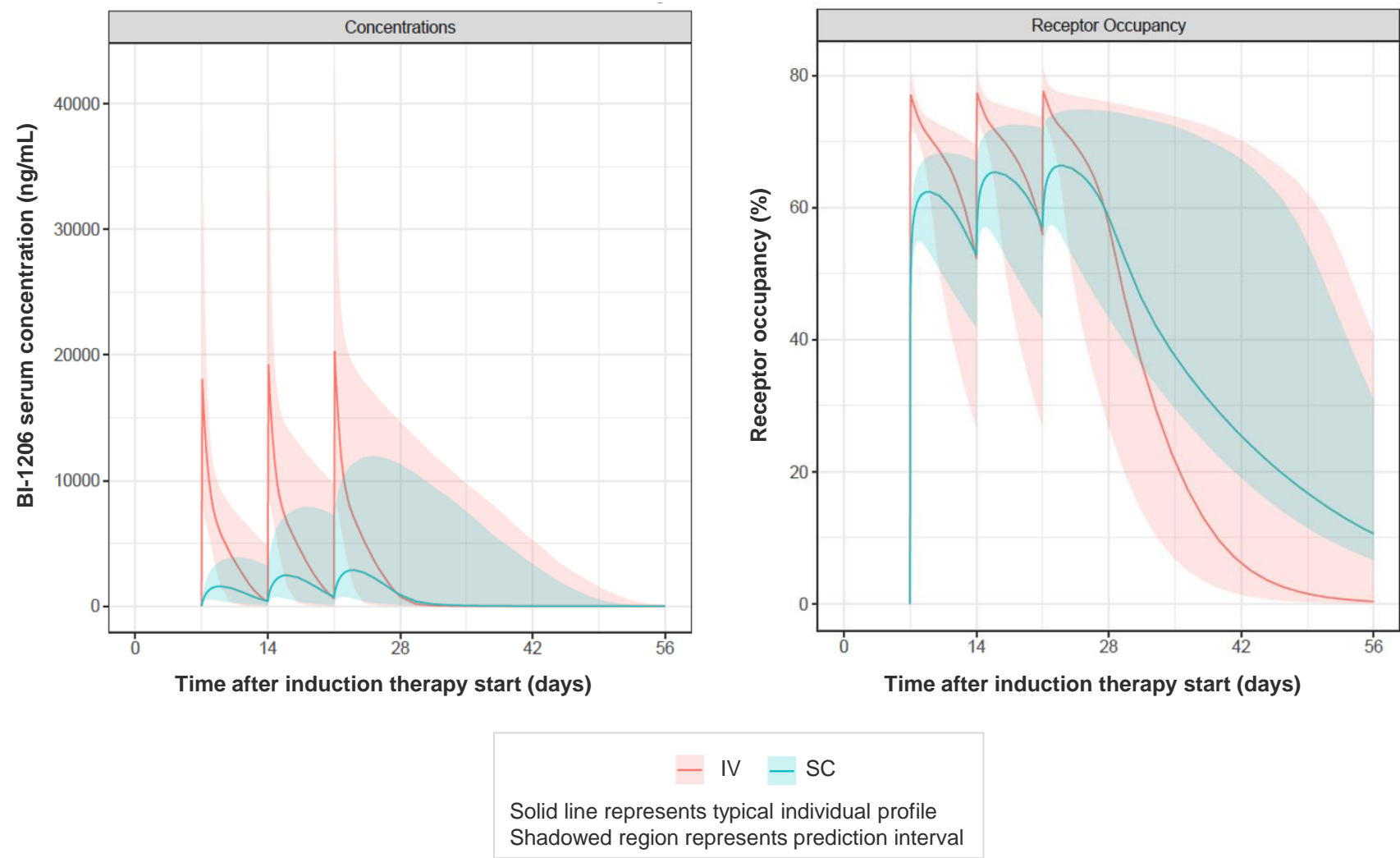
BI-1206-02 DOSE ESCALATION



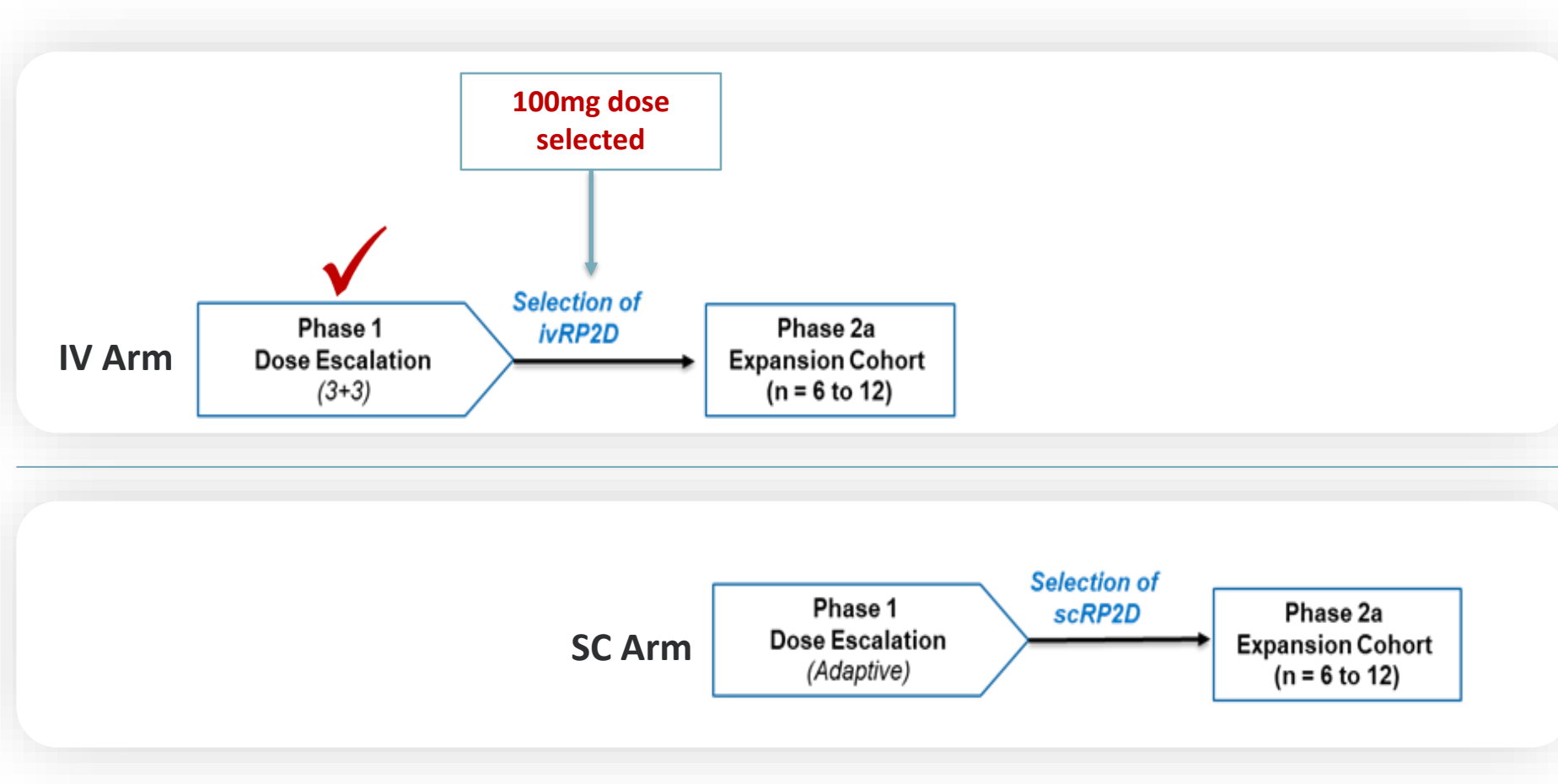
The 4 DLTs were associated with infusion-related reactions (IRRs):

- Only lab values, no clinical signs or symptoms
- All patients recovered rapidly, and lab values returned to normal within days

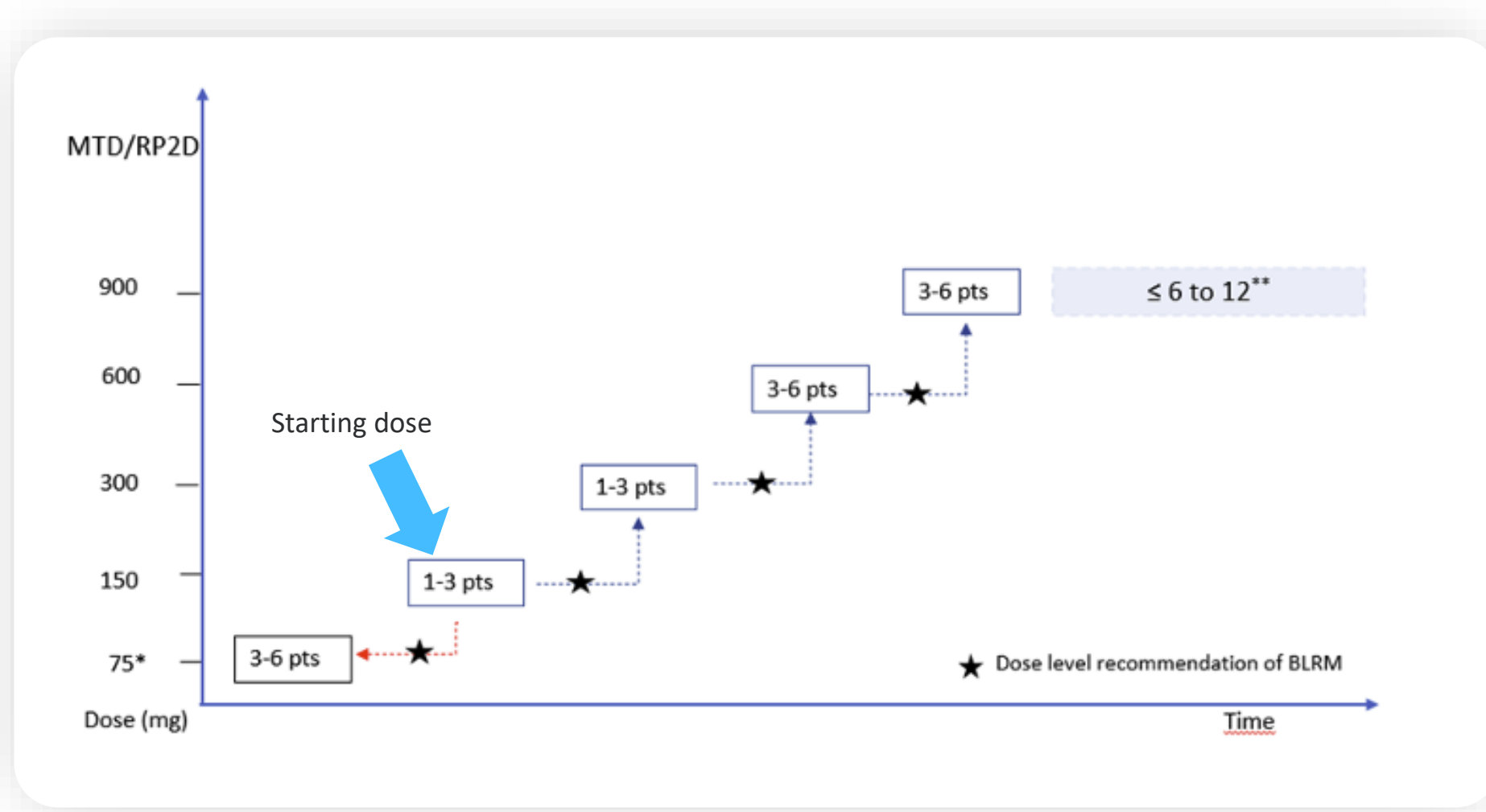
RECEPTOR OCCUPANCY OF SC STARTING DOSE COMPARED TO AN IV DOSE



BI-1206-02 TRIAL: IV & SC OVERALL DESIGN

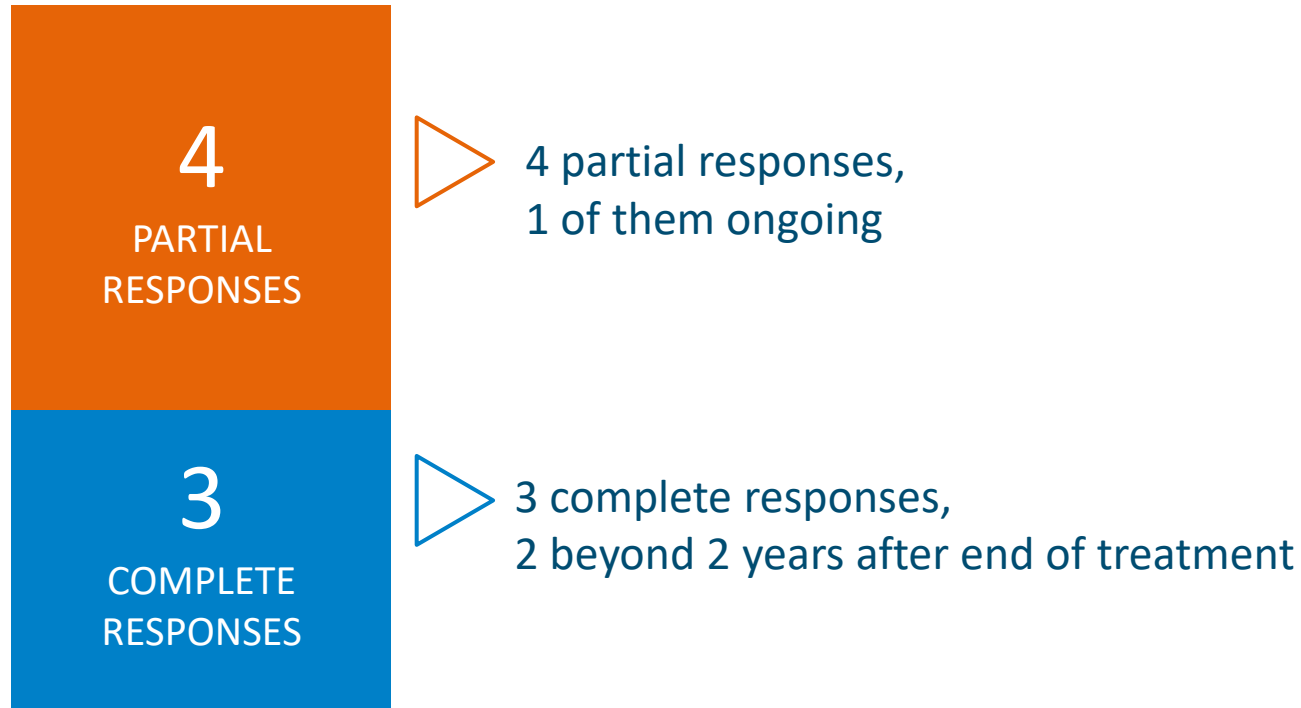


BI-1206-02 TRIAL: SC DOSE ESCALATION ADAPTIVE DESIGN BLRM



BI-1206-02 TRIAL: IMPRESSIVE EARLY EFFICACY DATA

Responses From Seven Patients Completing Induction Cycle



Patients Completed Induction Cycle


SC formulation approved by all regulatory authorities in EU and US

- Adaptive design, with 1 patient cohort dose-escalation design
- FPI any day

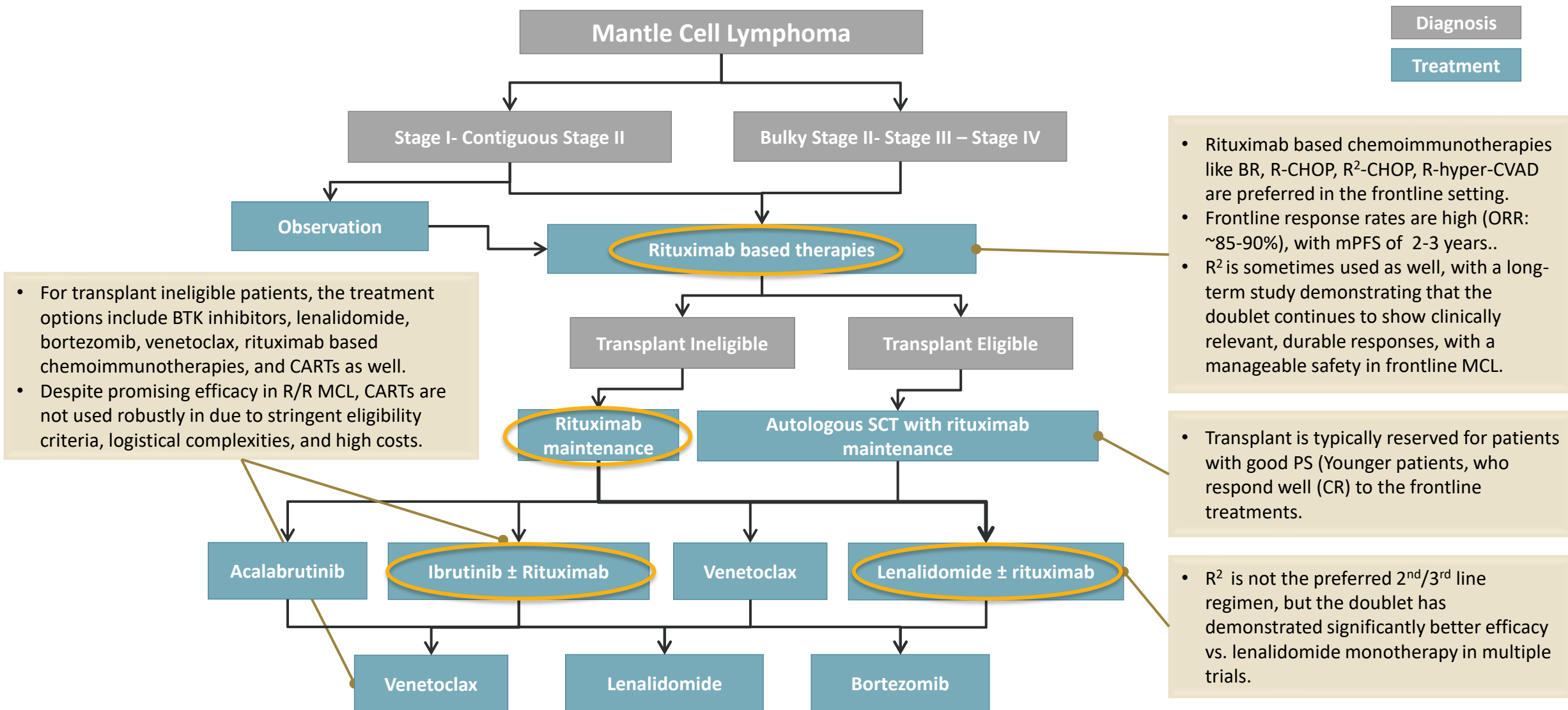
Aside the initial IRRs, no overlapping or enhanced toxicity of rituximab and no long-term safety concerns observed

How is BI-1206 Positioned in the Competitive Landscape?

Bispecific Mabs (CD3 retargeting)	First approval in FL of monetuzumab (CD20/CD3); class has some safety and tolerability issues
Fc-engineered anti-CD20 MAbs	Approved drugs (Gazyva) have low market uptake and do not seem to be displacing rituximab as global treatment of choice. Combination potential with BI-1206.
Anti-CD47	Efficacy not yet clearly established. Class has potential safety issues associated with target expression on RBC
Antibody-Drug Conjugates	Toxicity of the linked chemotherapeutic agent is an issue
CAR-T Treatments	Cost of treatment, toxicities, and supply chain are major issues that are likely to relegate these treatments to a small number of patients


- 
- Many drugs in development but few distinct MoA
 - Rituximab will remain the backbone
 - New treatments have cost or safety challenges
 - Enhancing/recovering rituximab's efficacy will further consolidate rituximab's position
 - BI-1206 can be used in several lines of Tx

RITUXIMAB BASED REGIMENS - MCL



Rituximab Will Remain a Mainstay of Therapy for Many Years

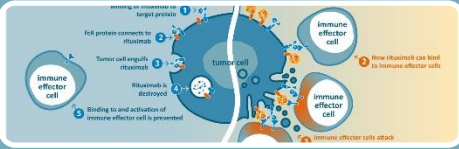
- Decline of Roche's sales of Rituxan \$7 billion masks a **significant expected growth** of the overall rituximab market, driven by:
 - Availability of biosimilar rituximab (8 approved in EU/US, 70% market share in Europe by treatment days)
 - **More patients** have access to rituximab as biosimilars drive down price
 - **Increase in prevalence of NHL**
 - Significant rituximab **growth** expected in **Asia**
- Predicted **expansion of rituximab market** in terms of treatment days
- Many NHL recommended treatment regimens include rituximab



Rituximab market dynamics are **favorable** for the market potential of BI-1206:

- Expanded use of biosimilars
- Triplet combinations will be more affordable
- Biosimilar already included in our clinical studies

BI-1206 in Non-Hodgkin's Lymphoma: Unique Value Proposition



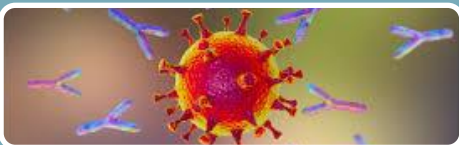
Compelling scientific rationale in anti-CD20 refractory B-cell lymphoma



First-in-class in hematology with no direct competitors



High unmet need for safer -chemo-free- options in 2nd and 3rd lines



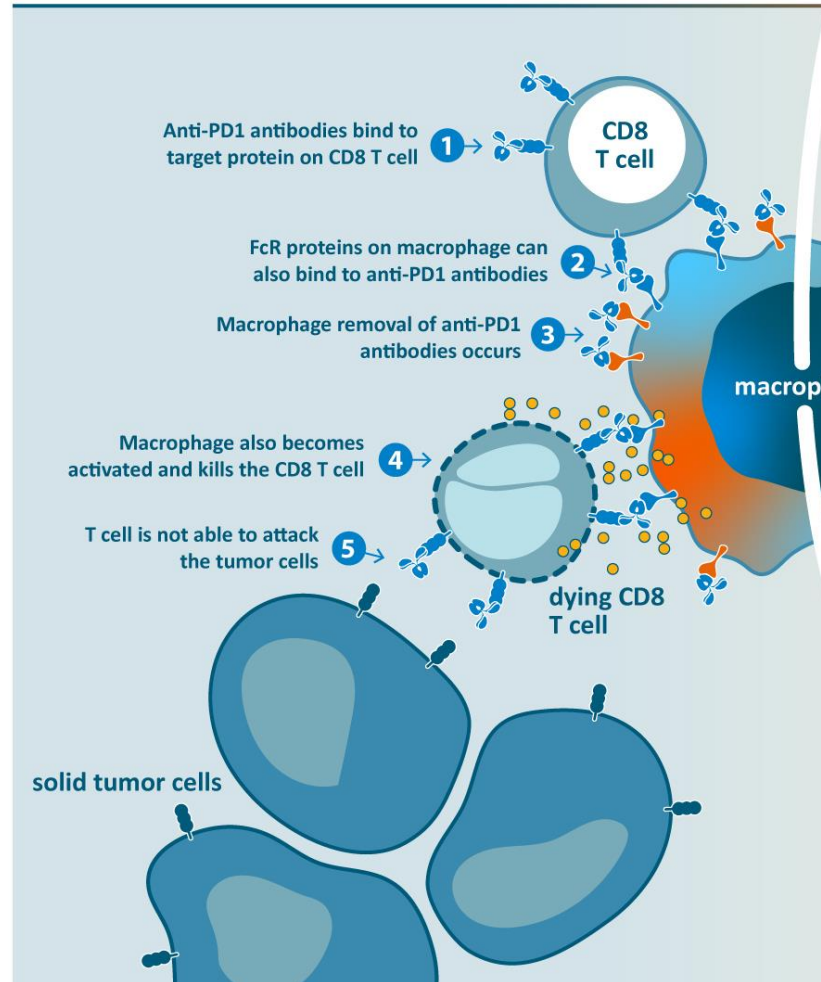
Can be combined with anti-CD20s, including non-oncology indications



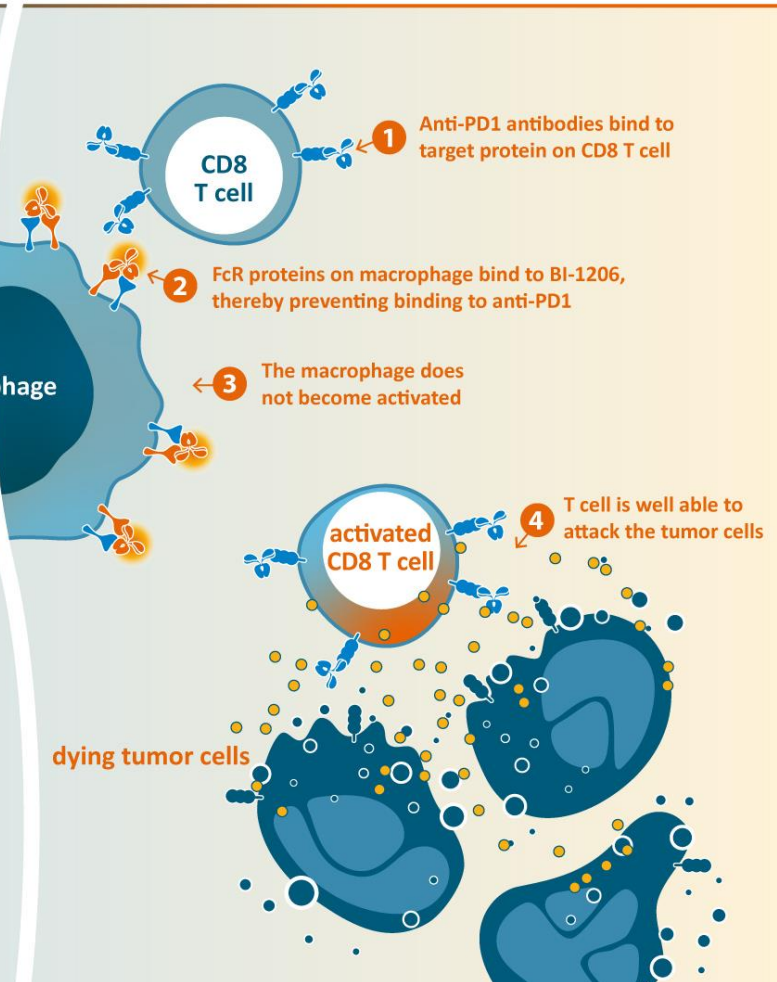
Long-lasting complete responses after treatment is discontinued

BI-1206 IN SOLID CANCER – ENHANCING ANTI-PD-1 ACTIVITY

anti-PD1 without BI-1206

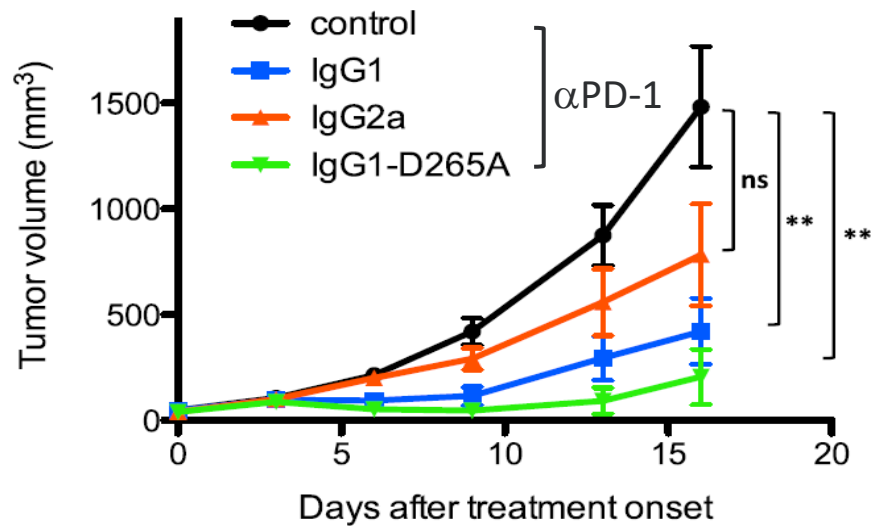


anti-PD1 with BI-1206

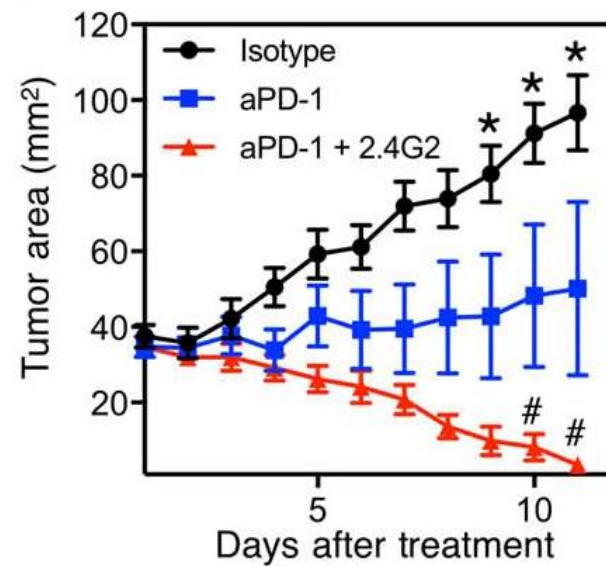


BI-1206 UNLEASHES FULL THERAPEUTIC POTENTIAL OF ANTI-PD-1 ANTIBODIES

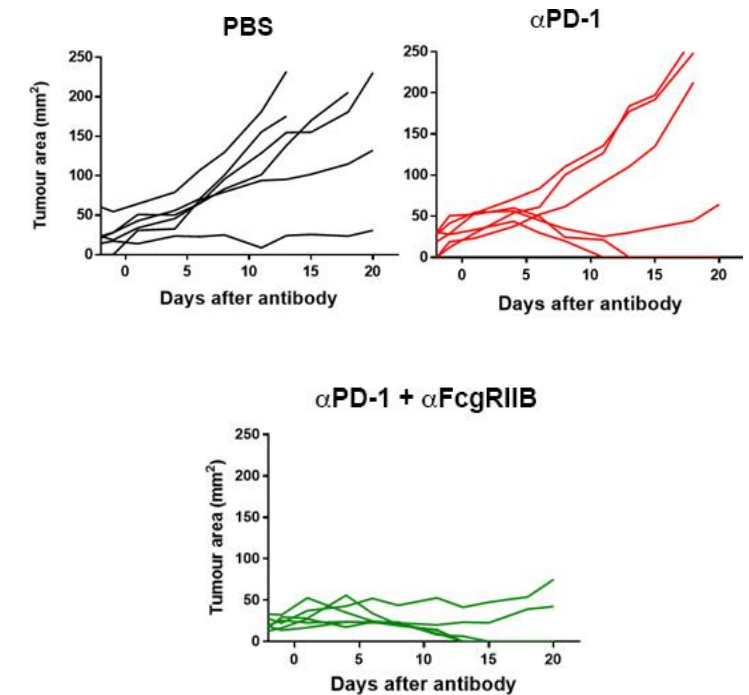
α PD-1 Fc-dependence



Fc γ R-block



α Fc γ RIIB

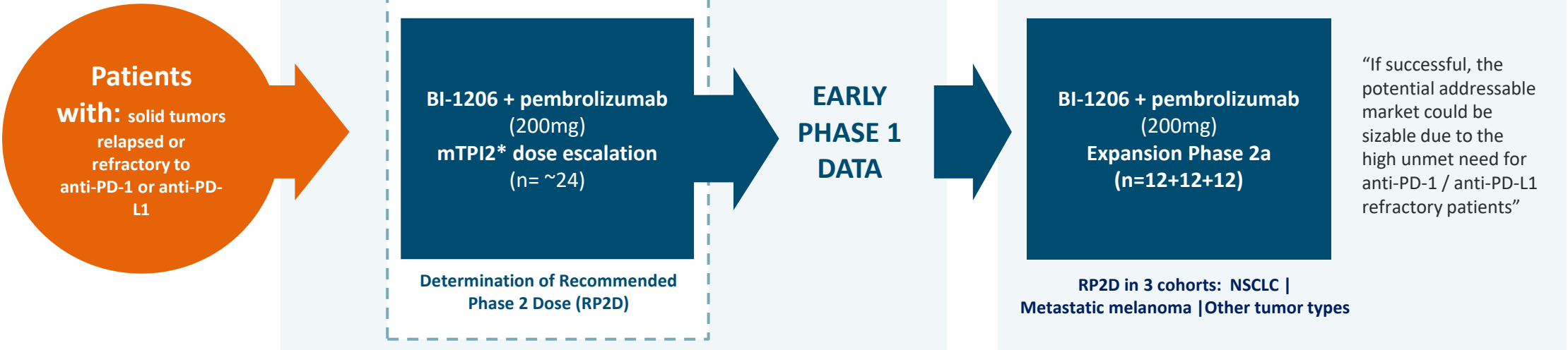


BI-1206 IN COMBINATION WITH PEMBROLIZUMAB (SOLID TUMORS): PHASE 1/2a STUDY WITH MERCK - KEYNOTE-A04



Ongoing phase

STUDY OVERVIEW



STUDY 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)

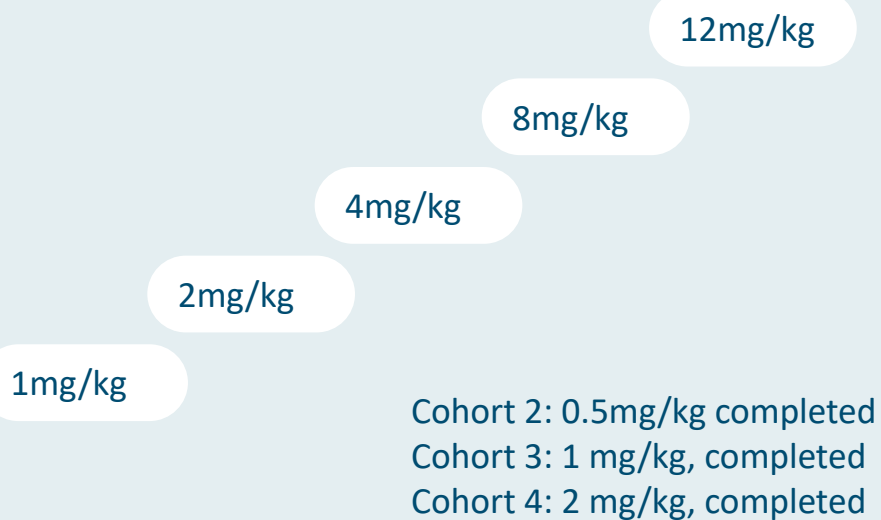
KEYNOTE-A04: BI-1206 AND PEMBROLIZUMAB

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

Design:

Phase 1: Dose Escalation

BI-1206 in combination with pembrolizumab 200mg
dose-escalation BI-1206 dose levels



Phase 2a: Expansion

3 cohorts, 12 subjects/cohort. 36 subjects total;
BI-1206 in combination with pembrolizumab 200mg

Cohort 1: Non-Small Cell Lung Cancer

Cohort 2: Metastatic melanoma

Cohort 3: Other tumor types

KEYNOTE-A04: BI-1206 AND PEMBROLIZUMAB

Efficacy:

- 1 PR still ongoing (uveal melanoma) > 70 weeks; >50% reduction in lesions
- One pseudo-progression: sarcoma patient; enrolled June 2021, PD in Jan 2022 but with clear clinical improvement
 - Disappearance of metastasis and radiological improvement. No other treatment has been administered
- “Compassionate patient protocol” started treatment on Feb 2022. Disease still under control

Safety:

No safety concerns identified

Next steps:

Implementation of SC administration

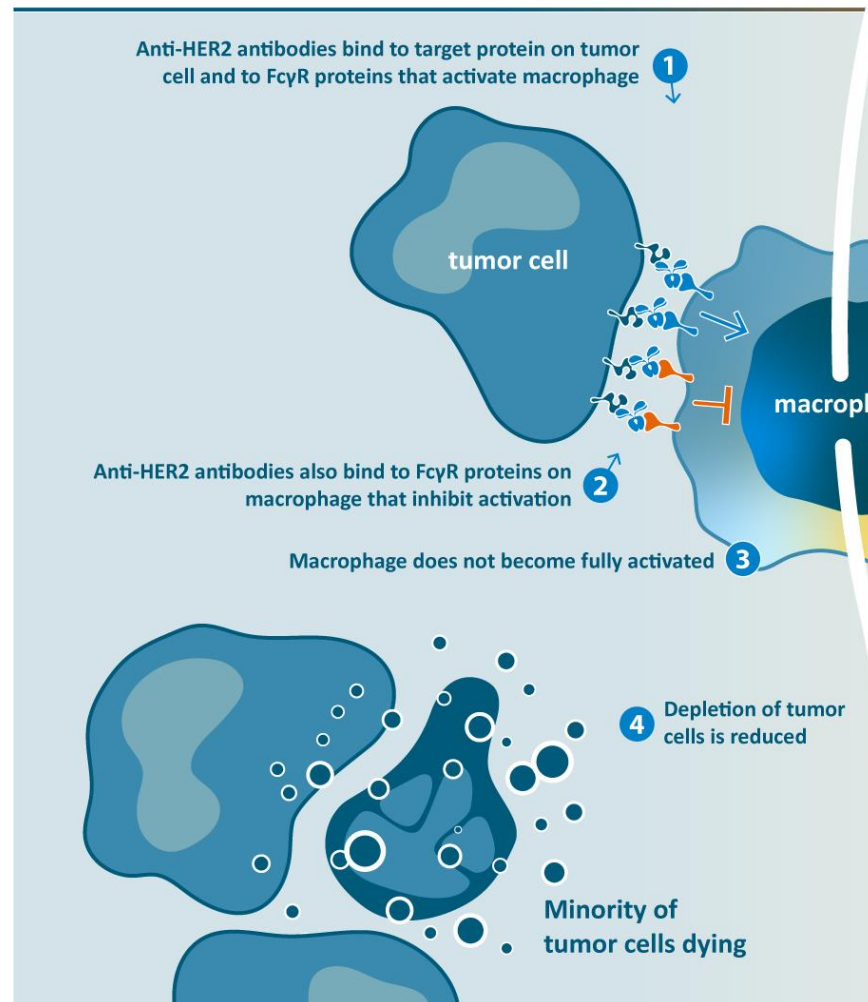


BI-1607 (α Fc γ RIIB)

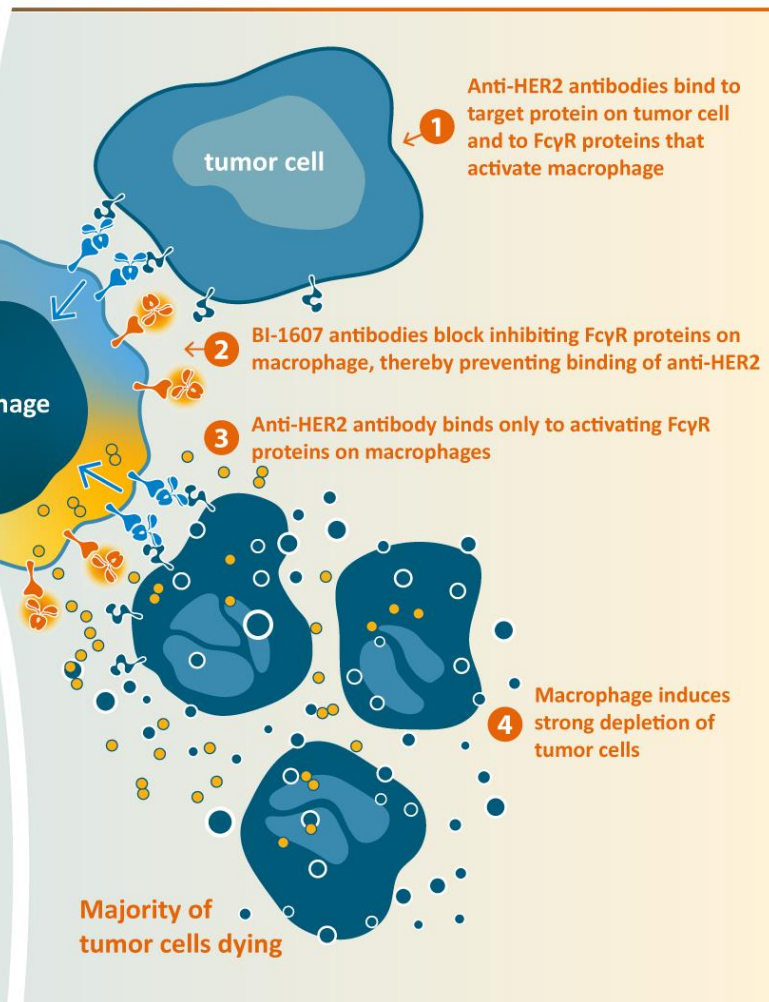


BI-1607 – A NOVEL FcγRIIB-BLOCKING ANTIBODY TO ENHANCE FcγR-DEPENDENT ANTITUMOR IMMUNITY

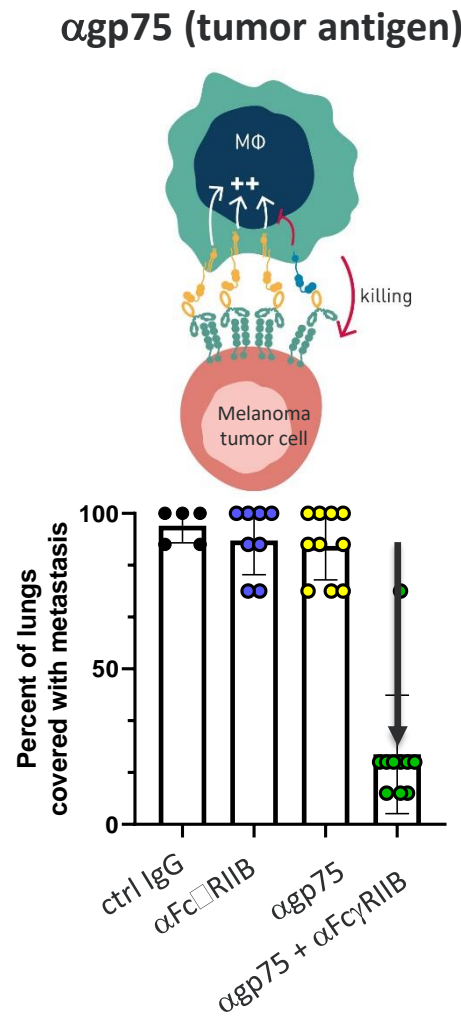
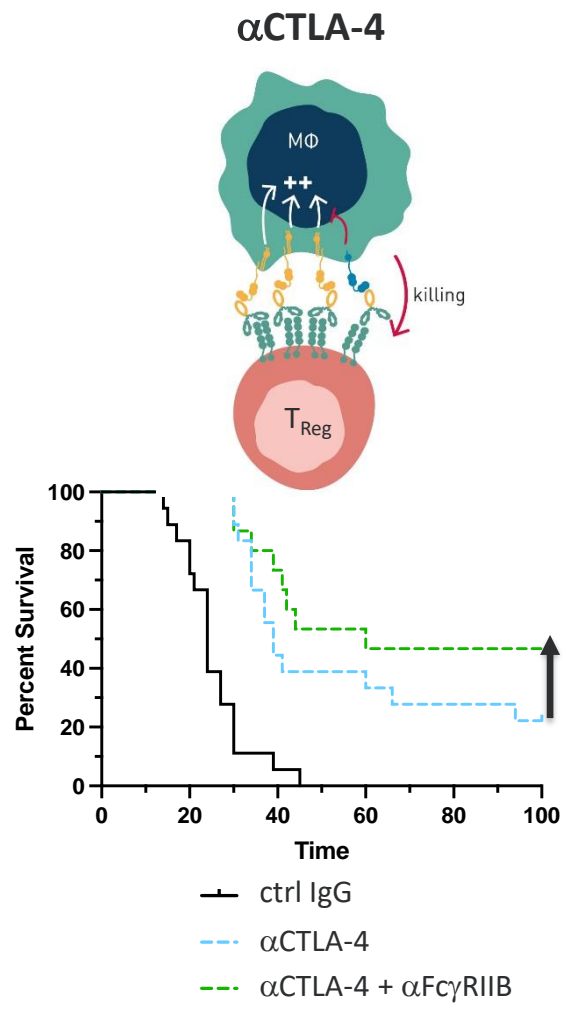
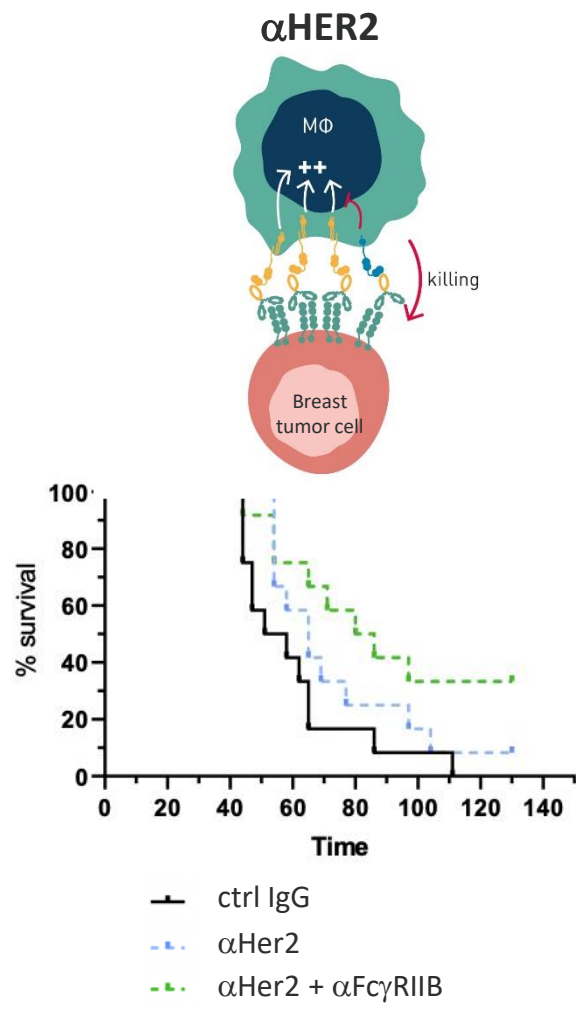
anti-HER2 without BI-1607



anti-HER2 with BI-1607



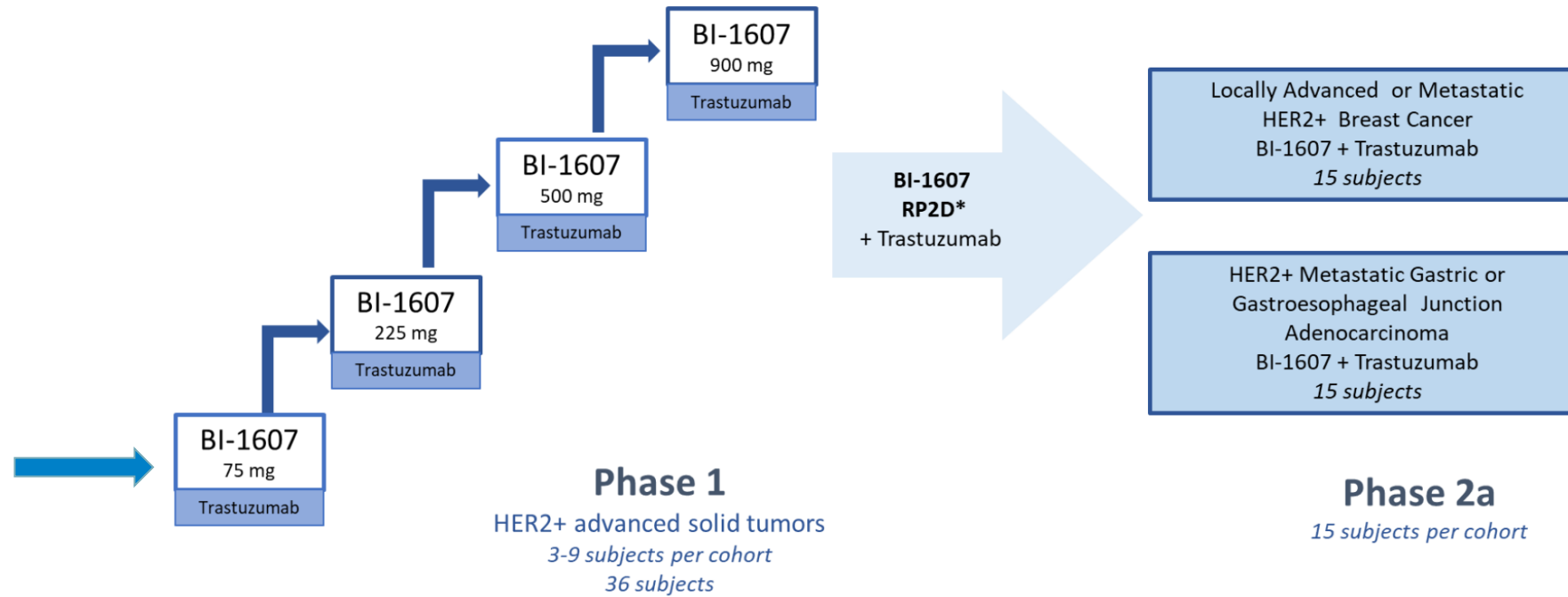
BI-1607 ENHANCES ON α HER2, α CTLA-4, AND BEYOND



BI-1607 CONTRAST TRIAL - MODIFIED ANTI-FcγRIIB

Study: Phase 1/2a Open-label Clinical Trial of BI-1607, an Fc-Engineered Monoclonal Antibody to CD32b (FcγRIIB), in Combination with Trastuzumab in Subjects with HER2-positive Advanced Solid Tumors – CONTRAST

Design:



Countries:

- Currently enrolling patients in Europe
- Recent FDA IND approval

CONTRAST TRIAL: BI-1607 AND TRASTUZUMAB

1st in class anti-FcγRIIB mAb

Enhances efficacy of several other marketed antibodies (trastuzumab, ipilimumab)

May allow dose-reduction of anti-CTLA4

FIM study in combination with trastuzumab currently in dose-escalation

Our previous knowledge of the target allowed starting at an adequate dose

No safety or tolerability concerns and no IRRs to date



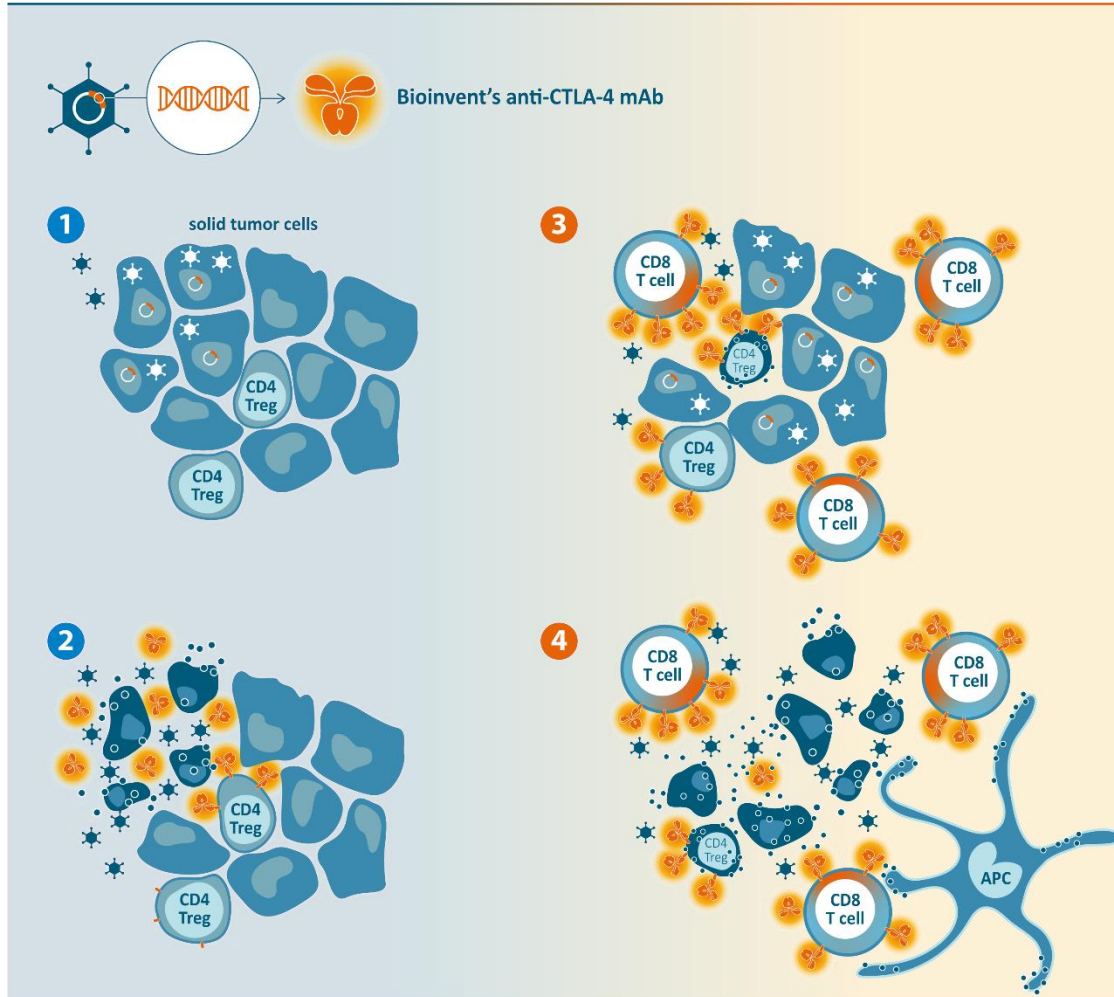
BT-001

(Vectorized T_{reg}-depleting αCTLA-4)



BT-001 - VECTORIZED TREG-DEPLETING α CTLA-4 FOR CANCER IMMUNOTHERAPY

BT-001

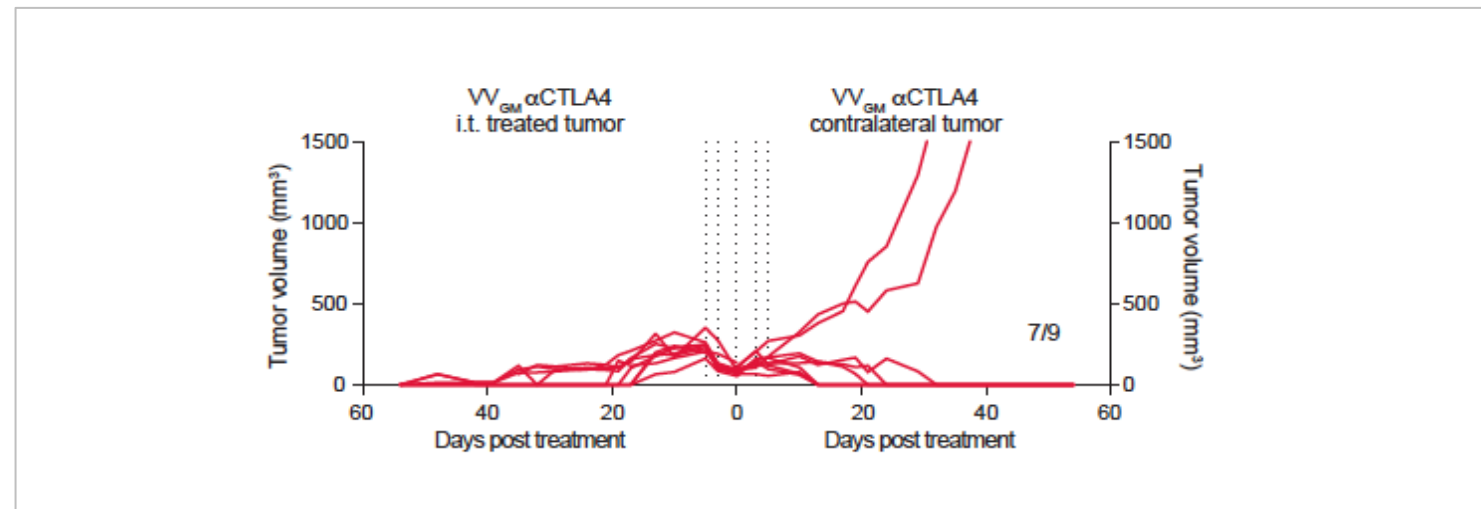
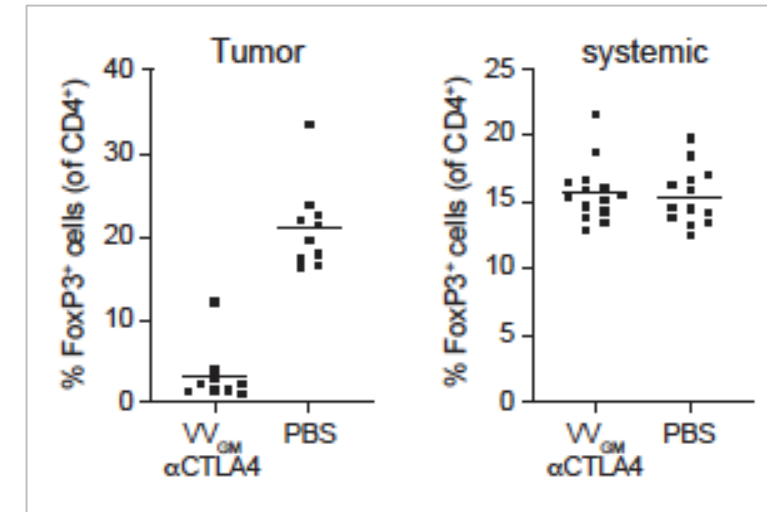
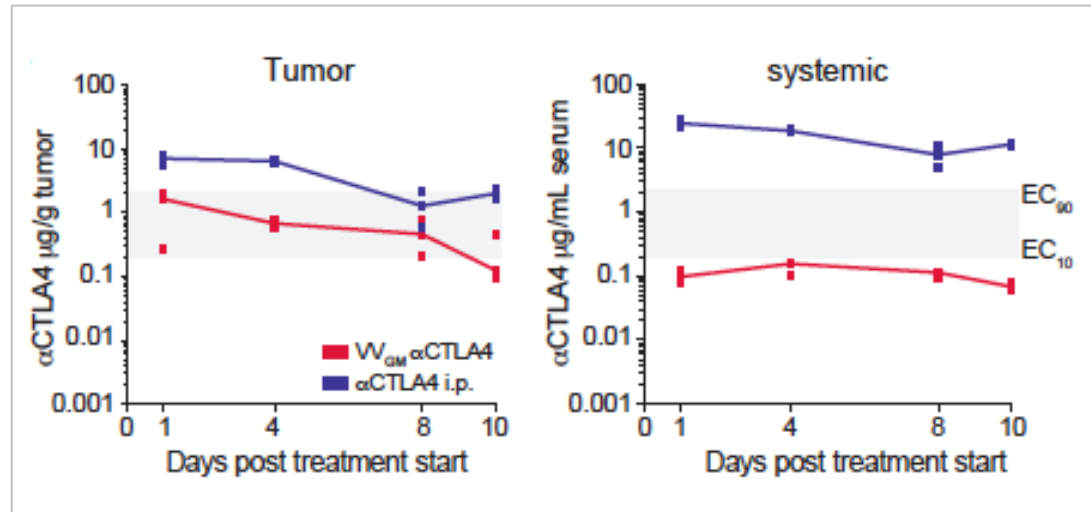


1. Intratumoral injection of oncolytic virus encoding aCTLA-4 mAb
2. Infection, replication, aCTLA-4 mAb production and lysis of tumor cells
3. Antibody binding and saturation of tumor-associated CTLA-4 receptors
 1. Treg-depletion
 2. Tumor antigen cross-presentation
 3. Priming of systemic CD8 T cell antitumor immunity
4. Rejection of injected and non-injected (disseminated) tumors

Full therapeutic targeting of (only) tumor-associated CTLA-4 →

- Improved tolerability
- Enhanced efficacy
- Powerful combination therapy with systemic aPD-1

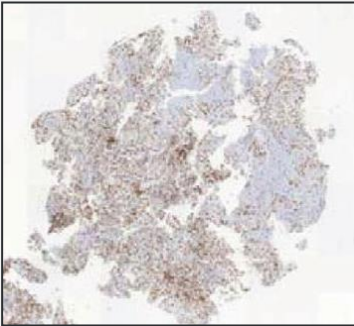
BT-001: TUMOR-RESTRICTED mAb EXPOSURE AND T_{REG}-DEPLETION



BT-001: HAS BROAD ANTI-TUMOR ACTIVITY



Preexisting Immunity



Excluded Infiltrate

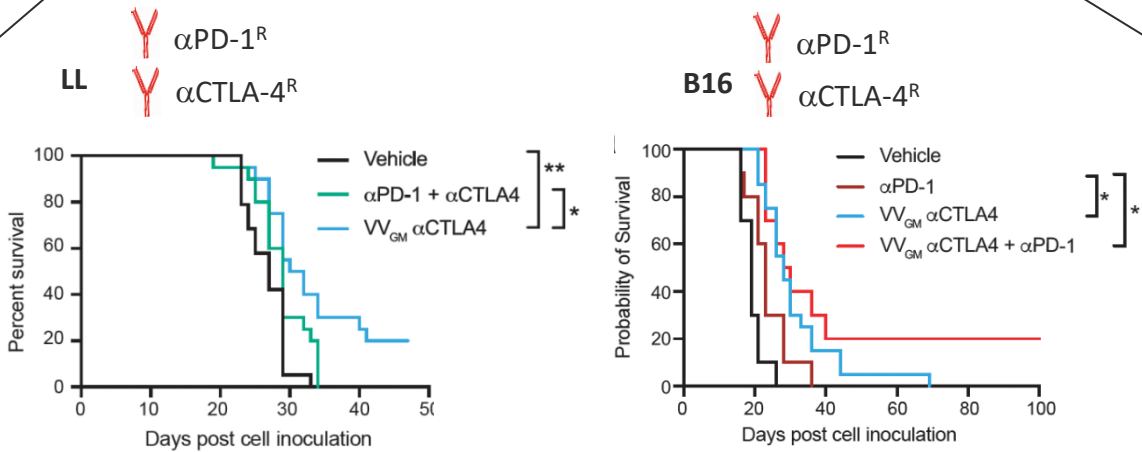
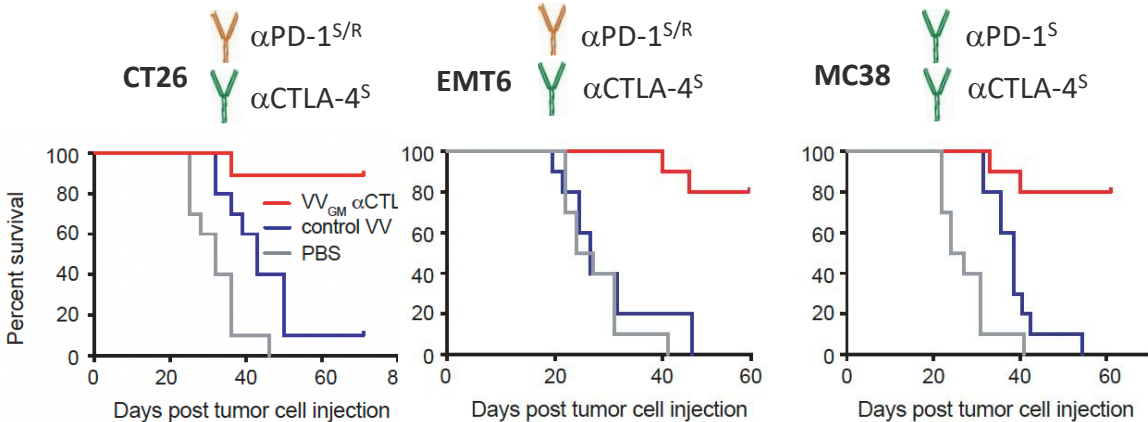


Immunologically Ignorant



“hot”

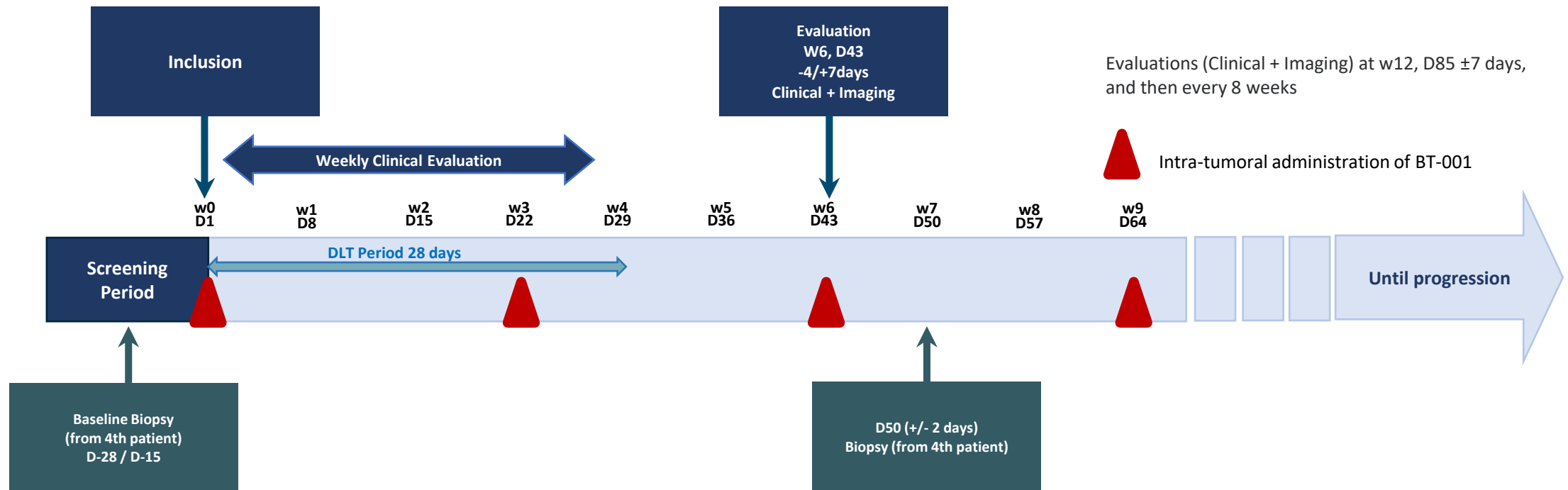
“cold”



BT-001.01 TRIAL: VECTORIZED-ANTI-CTLA4

Study: A Phase 1/2a study of intra-tumoral BT-001 (TG6030) administered alone and in combination with pembrolizumab in patients with cutaneous or subcutaneous lesions or easily injectable lymph nodes of metastatic/advanced solid tumors.

Design:

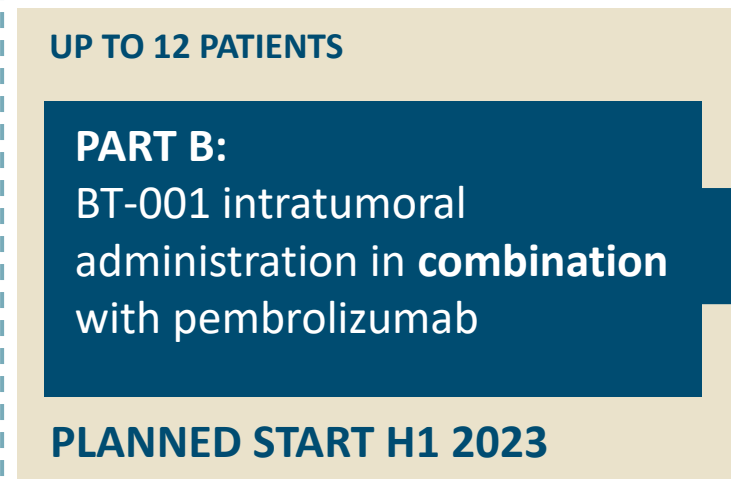
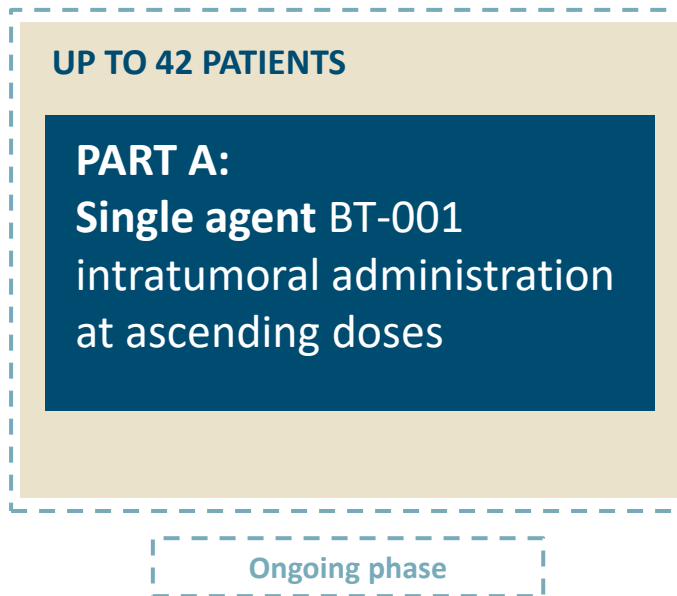


Countries and number of sites:

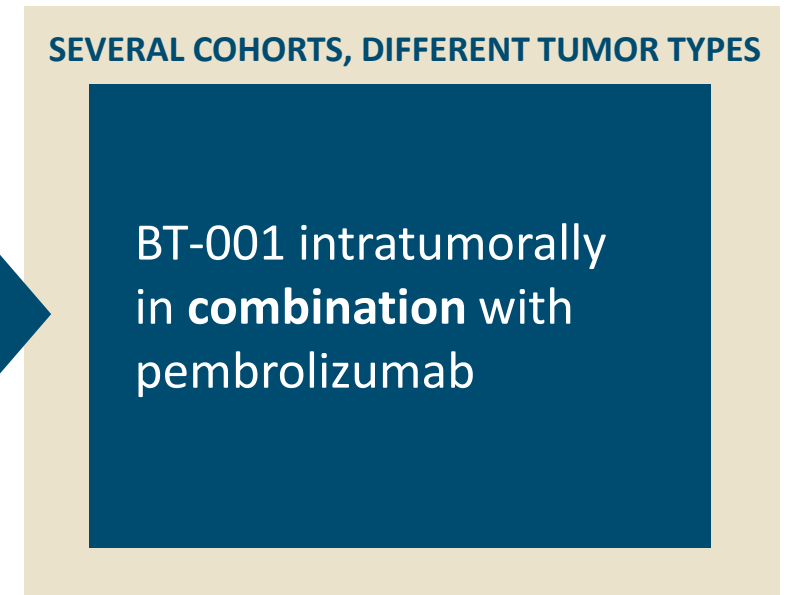
2 countries (France, Belgium); a total number of 5 sites

ONGOING PHASE 1/2a OPEN-LABEL, MULTICENTER, DOSE-ESCALATION STUDY

PHASE 1 - PART A & B



PHASE 2a



BT-001.01 TRIAL: VECTORIZED-ANTI-CTLA4

Third cohort of phase 1A (single agent, highest dose), 10^8 pfu currently ongoing

Expression of the mAb in the tumor has been detected

Viral replication in the tumor

No systemic exposure to anti-CTLA4

Key upcoming milestones: End single agent cohort and FPI in combination cohort H1 2023

No safety or tolerability concerns



BI-1808 (α TNFR2)

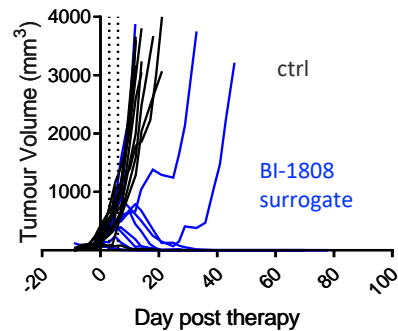
 **BioInvent**

BI-1808: LIGAND-BLOCKING FcγR-ENGAGING ANTI-TNFR2

- 1st in class anti-TNFR2 mAb (BI-1808)
- Compelling efficacy as single agent and in combination, across inflamed and “cold” tumor microenvironments
- Differentiated mechanism-of-actions compared to other mAbs to TNFRs
 - Regresses pre-existing large tumors and synergizes with PD-1 blockade
 - Depletes/reduces TNFR2^{High} intratumoral Treg
 - Expands intratumoral CD8+ effector T cells
 - Reprograms tumor-associated myeloid cells
- MoA-matched surrogate enables hypothesis-driven biomarker identification
- Phase 1/2 study in solid cancer with BI-1808 as a single agent and in combination (anti-PD-1) is ongoing

α TNFR2 HAS BROAD ANTITUMOR ACTIVITY AND SYNERGIZES WITH α PD-1

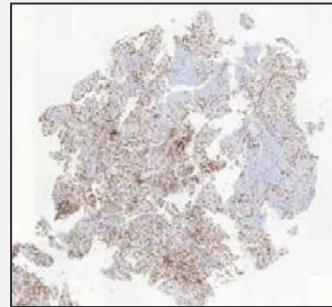
Representative tumor growth experiment, CT26



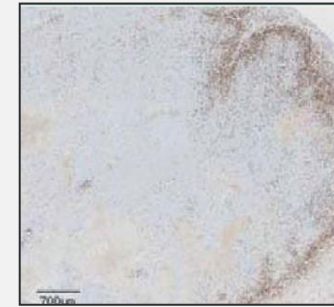
INFLAMED

NONINFLAMED

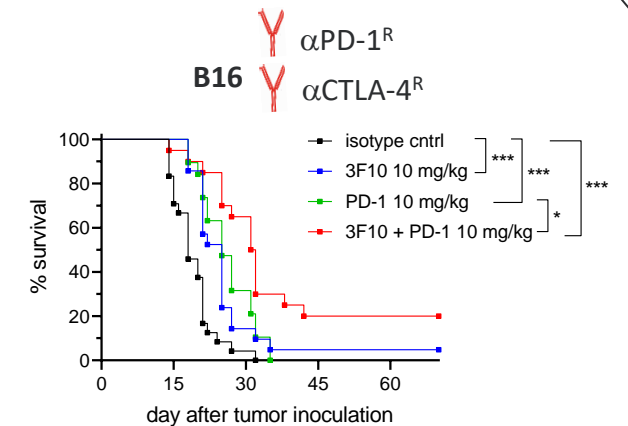
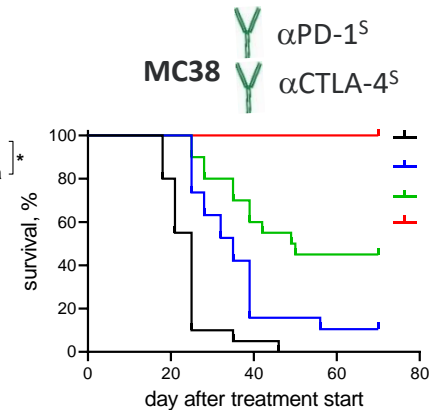
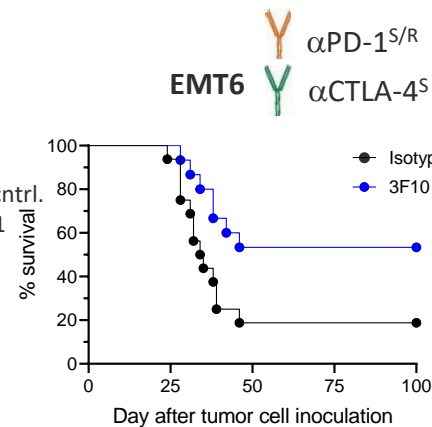
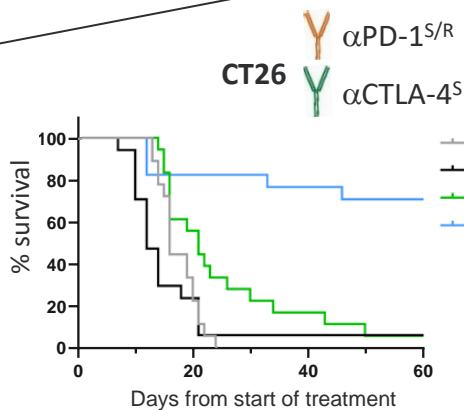
Preexisting Immunity



Excluded Infiltrate



Immunologically Ignorant

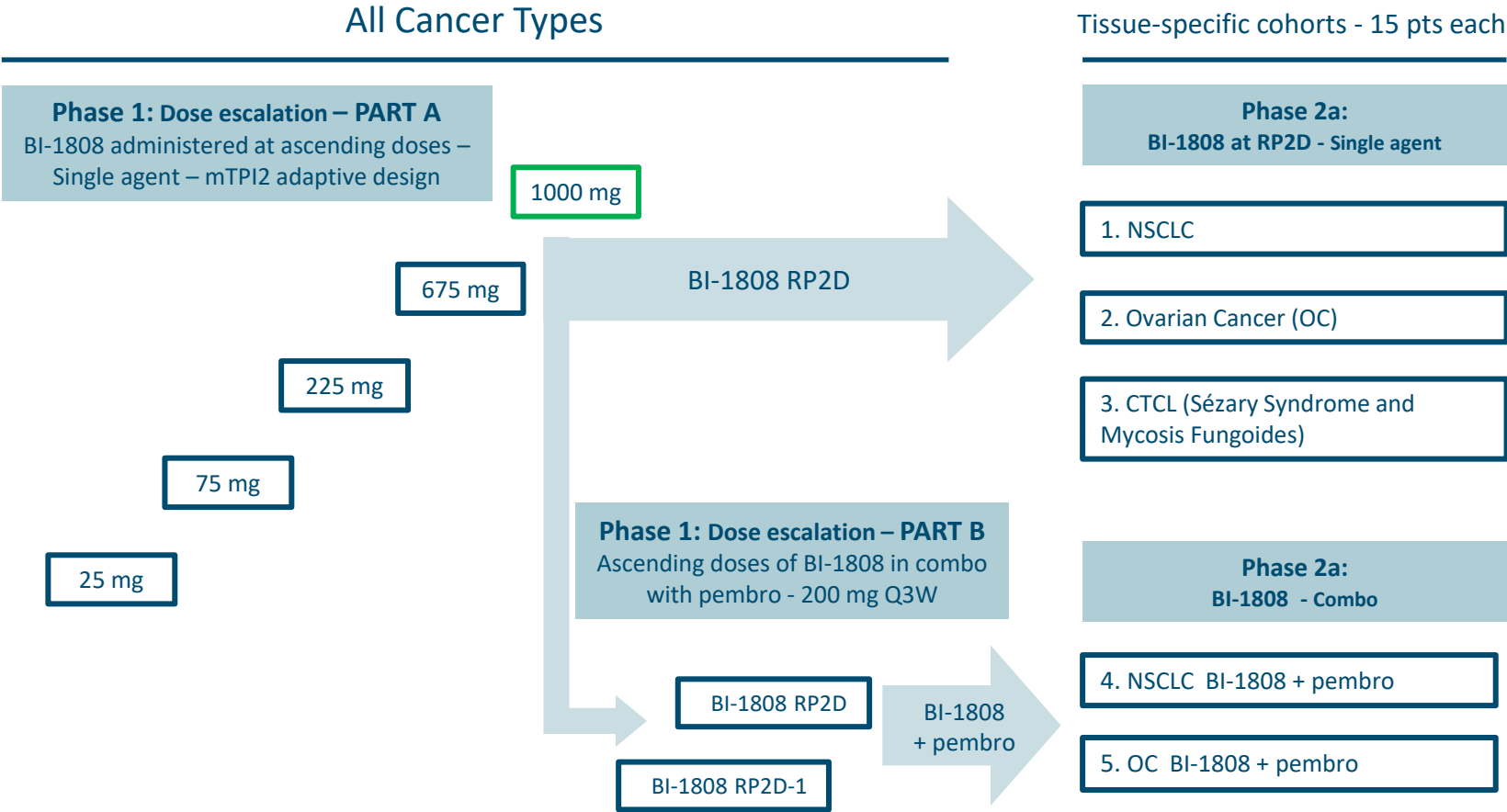


CT26: Tumor 220mm³= ca 8x8 mm at therapy start, 3 expts combined
 EMT6: Tumor 15 mm³= ca 3x3 mm at therapy start, 2 expts combined
 MC38: Tumor 100 mm³= ca 6x6 mm at therapy start, 2 expts combined
 B16: Tumor 15 mm³= ca 3x3 mm at therapy start, 3 expts combined

KEYNOTE-D20: BI-1808 +/- PEMBROLIZUMAB

Study: Phase 1/2a Open-Label, Dose-Escalation, Multicenter, First-in-Human, Consecutive-Cohort, Clinical Trial of BI-1808, a Monoclonal Antibody to Tumor Necrosis Factor Receptor 2 (TNFR2), as a Single Agent and in Combination with Pembrolizumab in Subjects with Advanced Malignancies.

Design:



Countries:

- Europe and the US

KEYNOTE-D20: BI-1808 +/- PEMBROLIZUMAB

Currently enrolling. Approved in all countries: Europe, UK, and the USA

Phase 1 Part A:

- **Cohort No. 5** New dose cohort **ongoing** (1000mg)

Phase 1 Part B combination open (225 mg BI-1808/200mg pembrolizumab):

- Cohort filled and patients are in observation period
- First CTCL patient treated

Phase 2 Part A planned to start H2 2023

Responses observed:

- 3 SDs that have subsequently progressed;
- 1 Interesting SD -NSCLC patient with 20% tumor reduction
- No safety and tolerability concerns

Post-IND Competitive Landscape for TNFR2: BioInvent Leading

Drug Name	Company Name	Stage	Description
LBL-019	Nanjing Leads Biolabs	Phase I/II (China)	Agonist
SIM-0235	Simcere	Phase I (China / US)	humanized IgG1 antibody Blocker/Depleter
HFB-200301	HiFiBiO	Phase I (US)	humanized murine (IgG1?) Agonist
APX-601	Apexigen	IND-enabling	Humanized rabbit IgG1 Blocker/Depleter
BITR-2101	BITT / BeiGene	IND-enabling	humanized IgG2 (variant) Antagonist

- Competitors are developing agonists **or** antagonists (but no other company has both)
- BioInvent leads the way on TNFR2 biology
- Competition early stage but increasing



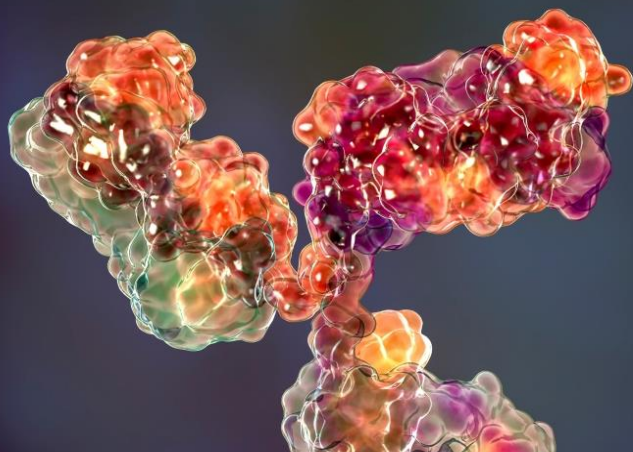
THANK YOU!

EXPECTED KEY CATALYSTS 2023

BI-1206 + ritux	Preliminary results Phase 1 s.c	H1 2023
BI-1206 + pembro	Start of Phase 1 s.c.	H1 2023
BI-1808 single agent	Preliminary results Phase 1	H1 2023
BT-001	Start combination study with Keytruda	H1 2023
BI-1808 + pembro	Preliminary results Phase 1	H2 2023
BI-1607 + trastuzumab	Preliminary results Phase 1	H2 2023
BI-1910	Start Phase 1/2a	H2 2023

Our Success Factors

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



TECHNOLOGY

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



EXPERTISE

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



INTEGRATION

We can go fast to development because we can take care of all the steps from early discovery to manufacturing.