BioInvent

UNLEASHING IMMUNITY TO FIGHT CANCER

Function first drug discovery

Martin Welschof, CEO
March 15, 2023

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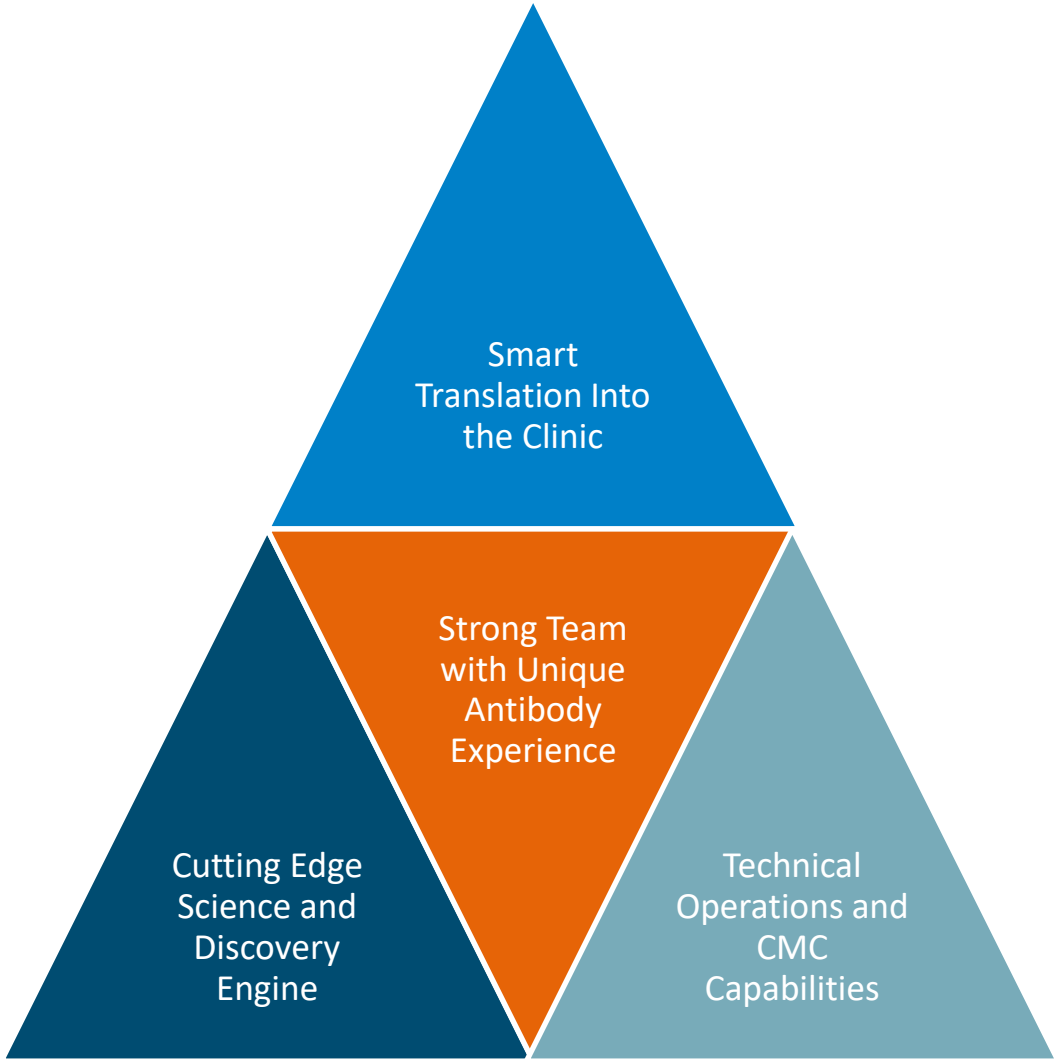
BIOINVENT IS TRANSLATING CANCER BIOLOGY INTO INNOVATIVE IMMUNO-ONCOLOGY THERAPIES

BioInvent at a glance as of December 31, 2022

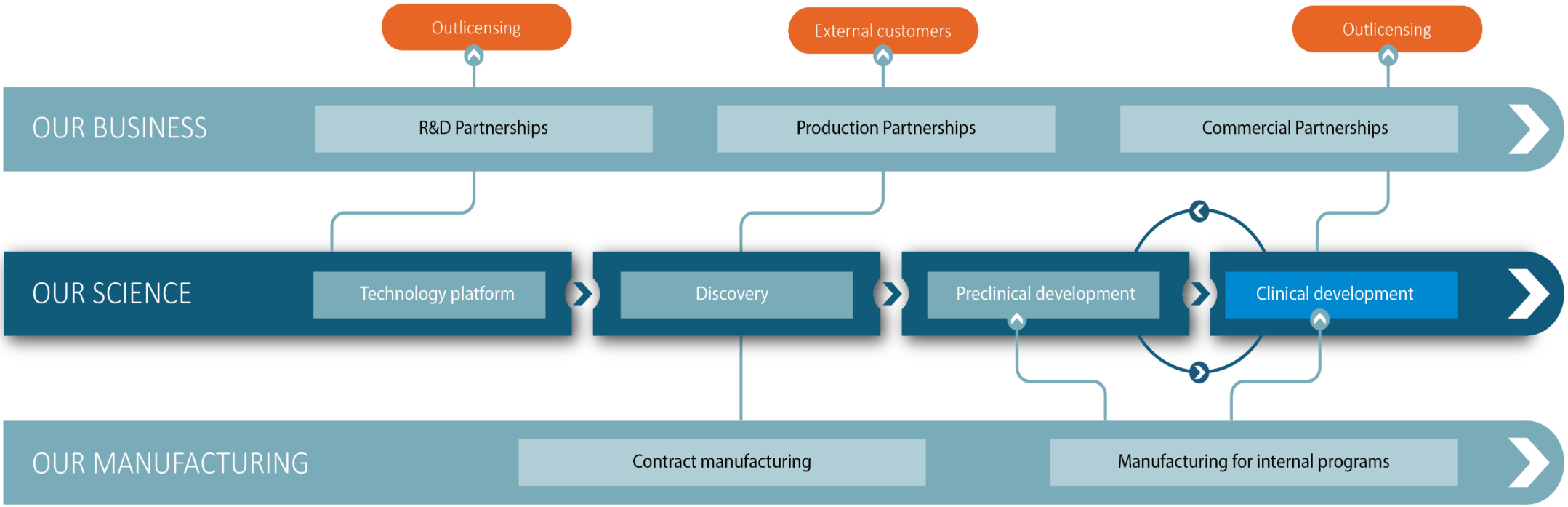
5	10+	94	1,594
projects in clinical development	Licensing, supply and collaboration agreements	employees (full time equivalent)	SEKm in liquid funds etc

- Five expanding clinical programs
  Integrated research engine, functional screening and in-house GMP manufacturing
- Technology validating deals with Exelixis, Pfizer, Daiichi Sankyo, Bayer Healthcare, Mitsubishi Tanabe, Takeda. Senior executive focus on partnering/deal making
- Strong international shareholder base - Redmile, Van Herk Investments, HBM, Forbion, Omega, AP4, Invus, Swedbank Robur, Handelsbanken, AXA
- Solid cash position, listed on NASDAQ OMX Stockholm Mid Cap (BINV)
  Global commercial strategy

HIGHLY INTEGRATED COMPANY



MULTIPLE POTENTIAL REVENUE STREAMS



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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

Nature Reviews Clinical Oncology volume 19, pages 254–267 (2022)
Nature Reviews Drug Discovery 21, 482-483 (2022)

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We are not there yet

The number of targets available for antibody therapy is still limited

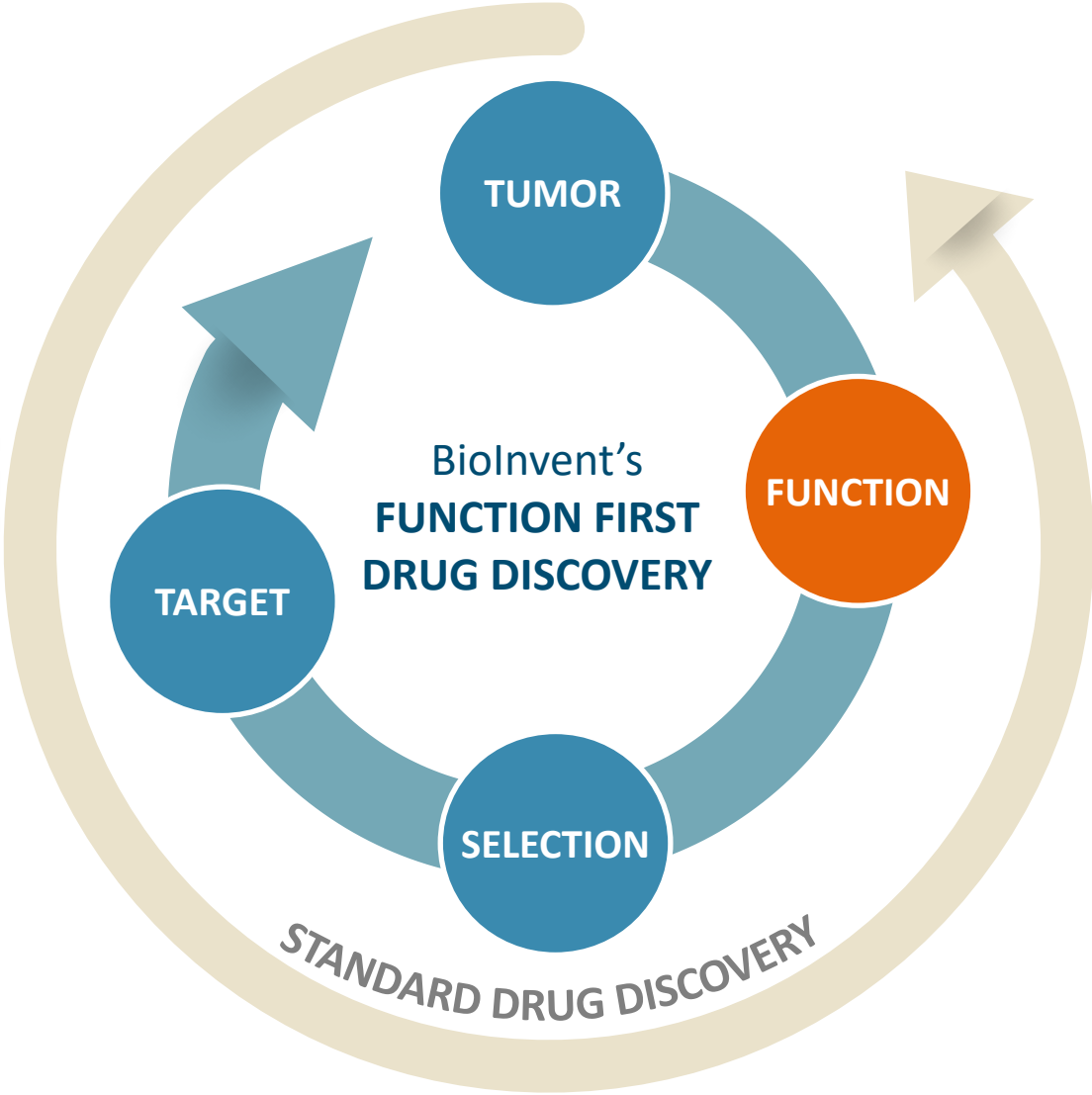
And most of these targets have failed to deliver therapies that work in the clinic

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

BIOINVENT IS TRANSLATING CANCER BIOLOGY INTO INNOVATIVE IMMUNO-ONCOLOGY THERAPIES

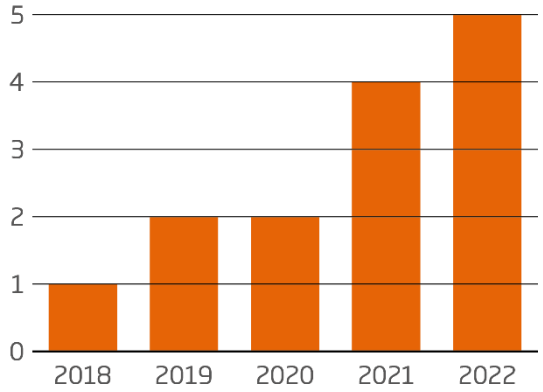
FUNCTION F.I.R.S.T™ DRUG DISCOVERY

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



STRONG PIPELINE WITH MULTIPLE VALUE DRIVERS

The number of projects in clinical phase has grown from one to five over the past five years.



Target: FcyRIIB	Indication	Partner
BI-1206/rituximab	NHL (MCL, MZL, iFL)	CASI
BI-1206/pembrolizumab	Solid tumors	CASI, MSD*
BI-1607/ trastuzumab	Solid tumors	

Target: TNFR2 and CTLA-4		
BI-1808 (TNFR2)	Solid tumors	MSD*
BT-001 (CTLA-4, GM-CSF)	Solid tumors	transgene, MSD*
BI-1910 (TNFR2)	Solid tumors	

Discovery | Preclinical | Phase 1 | Phase 2

Completed
Ongoing
Up-coming

* Clinical supply and collaboration agreement

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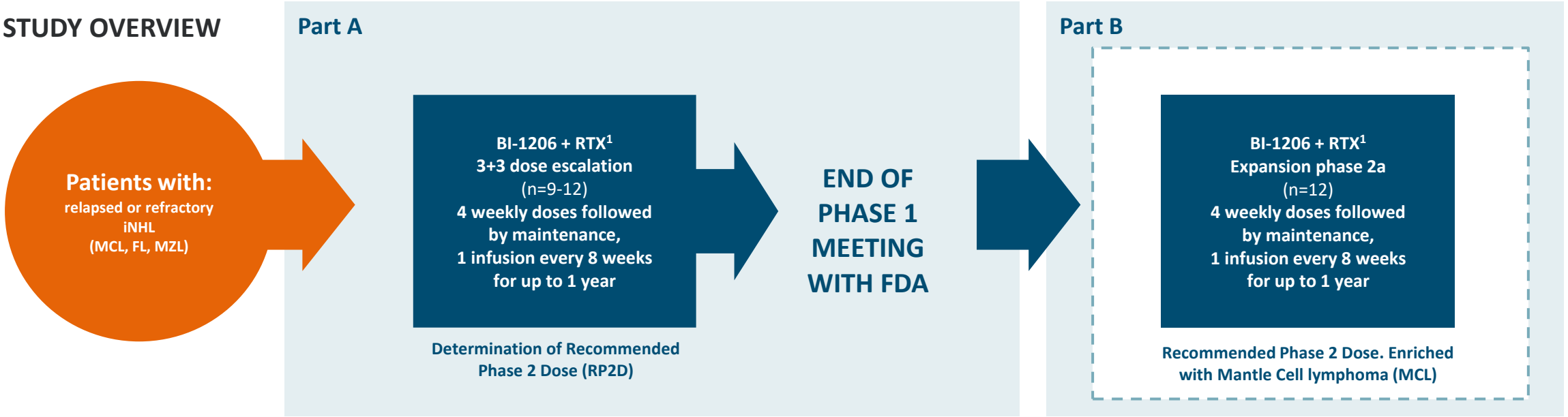
BI-1206 IN COMBINATION WITH RITUXIMAB: OPEN LABEL PHASE 1/2a STUDY

Ongoing phase

STUDY OVERVIEW



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

Note(1): RTX = rituximab (375 mg/m^2)

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BI-1206-02 TRIAL: IMPRESSIVE EARLY EFFICACY DATA IV (Dec 2022)

Responses From Seven Patients Completing Induction Cycle

4 partial responses,
1 of them ongoing

3 complete responses,
2 beyond 2 years after end of treatment

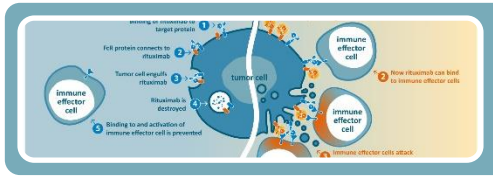
Long-lasting complete responses

Study of subcutaneous formulation (sc) ongoing since Dec 2022

- Approved by all regulatory authorities in EU and US
- Adaptive design, with 1 patient cohort dose-escalation design

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

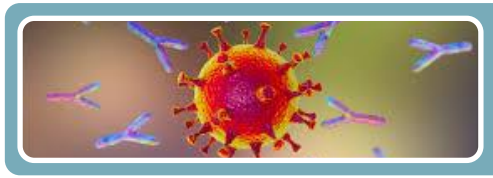
BI-1206 in Non-Hodgkin's Lymphoma: Unique Value Proposition



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 end of treatment

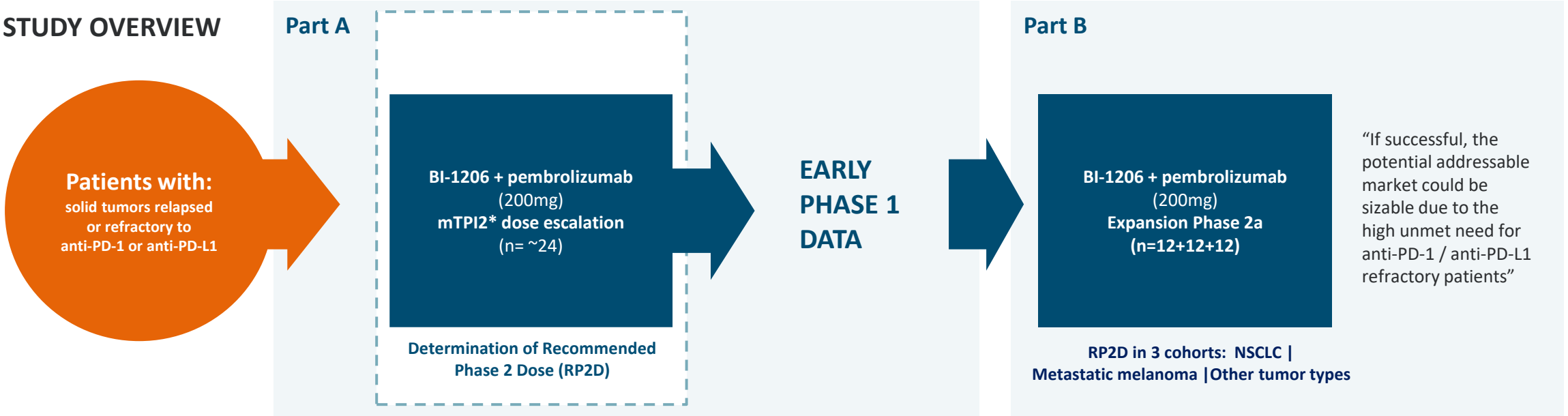
 | Note (1): Cello Health BioConsulting, 2019

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

Ongoing phase

MSD

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)

* modified Toxicity Probability Interval 2

STATUS SUMMARY BI-1206 IN SOLID TUMORS (Dec 2022)

- Early observations indicate that BI-1206 & pembrolizumab may reverse metastatic disease progression in patients who have previously progressed on PD-1/PDL-1 therapies.
  - 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.
- Aside infusion related reactions, no major safety concerns have been observed and dose-escalation will continue.

WHAT’S NEXT?

- Determine Recommended Phase 2 Dose (RP2D)
- Introduce s.c. formulation H1 2023E

BI-1607 FOR THE TREATMENT OF SOLID TUMORS

- Engineered for reduced Fc-binding, resulting in a differentiated mechanism of action vs BI-1206
- First-in-human clinical Phase 1/2a study (“CONTRAST”) ongoing since July 2022
- IND approval from the FDA November 2022
- Phase 1 part of the study will evaluate BI-1607 in combination with trastuzumab for the treatment of HER+ advanced or metastatic solid tumors
- Phase 1 part to include 12-26 patients at 7-12 sites in Spain, the UK, Germany and the US
- Phase 2a part aims to recruit 30 patients in two cohorts, 15 patients each. One cohort in breast, one cohort in gastric and gastroesophageal cancer

BI-1607 in solid tumors

Clinical Phase 1/2a evaluating BI-1607 & trastuzumab ongoing

BI-1808: ANTI-TNFR2 ANTIBODY FOR THE TREATMENT OF CANCER

KEYNOTE-D20: CLINICAL STUDY DESIGN

Ongoing phase

Phase 1: All Cancer Types

DOSE ESCALATION – PART A
BI-1808 administered at ascending doses – Single agent
– mTPI2[1] adaptive design

1000 mg
675 mg ✓
225 mg ✓
75 mg ✓
25 mg ✓
✓

BI-1808 single agent Recommended Phase 2 Dose (sRP2D)

DOSE ESCALATION – PART B
Ascending doses of BI-1808 in combo with pembro (200 mg) to define cRP2D[2]. Q3W (every 3 weeks) mTPI2 design

BI-1808 RP2D
BI-1808 RP2D -1

Recommended combo Phase 2 Dose (cRP2D)

Phase 2a: Tissue-specific cohorts - 12 patients each

BI-1808 at **RP2D - Single agent**

1. Non-small cell lung cancer (NSCLC)

2. Ovarian Cancer (OC)

3. CTCL (Sézary Syndrome and Mycosis Fungoides)

BI-1808 at c**RP2D** in **combination** with pembrolizumab 200 mg

4. NSCLC

5. OC

MSD

[1] modified Toxicity Probability Interval 2
[2] combination recommended Phase 2 dose

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STATUS SUMMARY: BI-1808 +/- PEMBROLIZUMAB (Dec 2022)

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

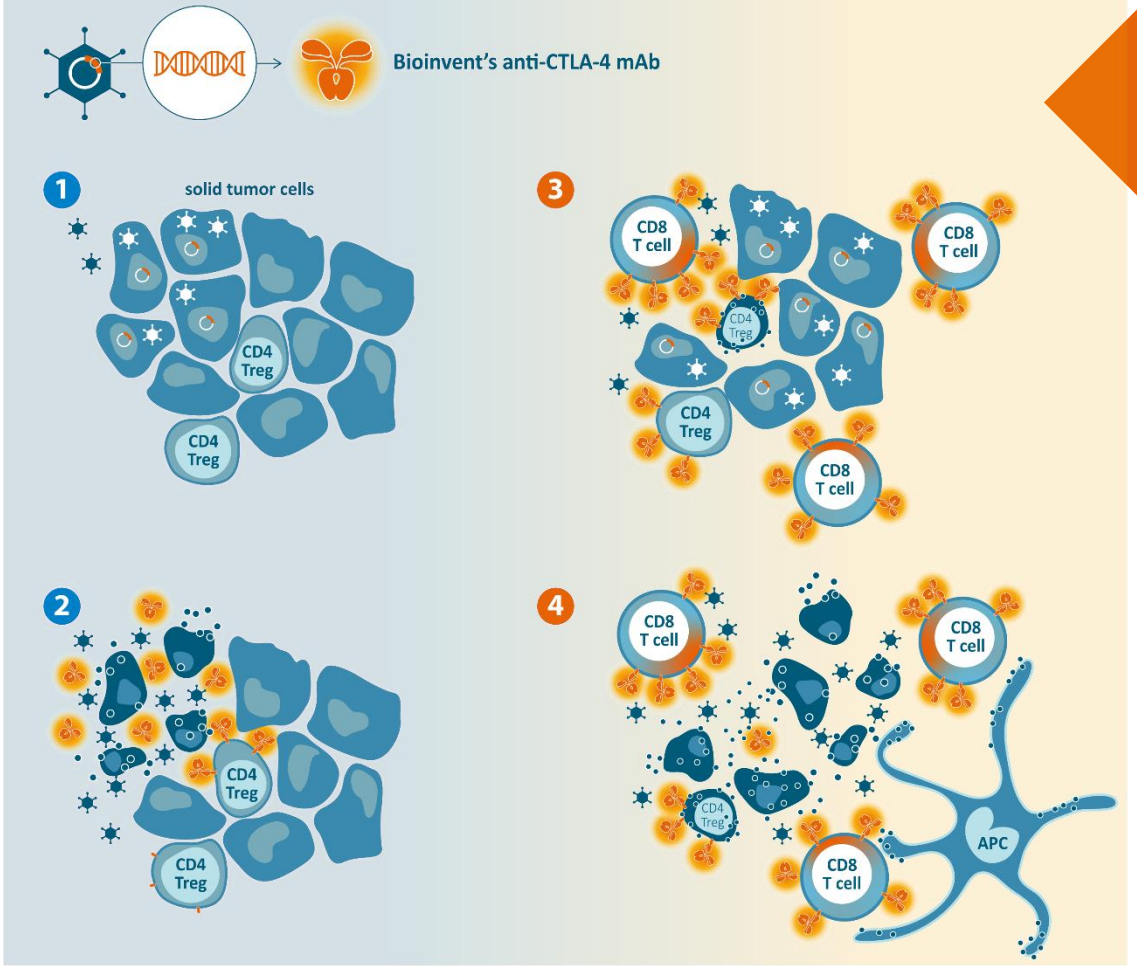
- Phase 1 Part A (single agent): Cohort no. 5 ongoing (1000mg)
- Phase 1 Part B combination open (225 mg BI-1808/200mg pembrolizumab): Cohort filled and patients are in observation period. First CTCL patient treated
- Responses observed:
  - 3 SDs that have subsequently progressed
  - 1 Interesting SD -NSCLC patient with 20% tumor reduction
- No safety and tolerability concerns

WHAT'S NEXT?

- Preliminary results Phase 1, single agent H1 2023E
- Preliminary results Phase 1, Keytruda combination H2 2023E

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

JITC PUBLICATION, JANUARY 2022:
"Vectorized Treg-depleting anti-CTLA-4 elicits antigen cross-presentation and CD8+ T cell immunity to reject "cold" tumors"*

Winner of the 2022 JITC Best Oncolytic and Local Immunotherapy Paper Award

transgene

* doi: 10.1136/jitc-2021-003488

STATUS SUMMARY BT-001 (latest readout Q2 2022)

In June 2022: Positive progress and safety data in the ongoing Phase 1/2a trial

- Initial data from Phase 1 part A demonstrate that BT-001 alone is well tolerated, with first signs of anti-tumor activity in a hard-to-treat population and confirmed the mechanism of action of BT-001 as a single agent. The initial findings are as follows:
  - Virus found in the tumors several days after administration. This suggests that BT-001 is able to persist and replicates within tumors.
  - Expression of the anti-CTLA-4 observed in the tumor with no detectable systemic exposure.
  - No spreading in blood or biological fluids has been detected, suggesting high tumor specificity.
  - Tumor shrinkage was observed in one patient in the first cohort.
  - No safety or tolerability concerns

WHAT'S NEXT?

- Completion of part A (single agent dose-escalation) of Phase 1
- Start of Phase 1 part B; BT-001 in combination with pembrolizumab, H2 2023E

EXTERNAL PIPELINE IN DEVELOPMENT BY OUR LICENSEES

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	Myastenia Gravis					Takeda
Orticumab	anti-ApoB100	Psoriasis					Abcentra
TAK-169/MT-0169	anti-CD38	Multiple Myeloma					Molecular Templates
DS-1055	anti-GARP	Solid tumor					Daiichi-Sankyo
HMI-115	anti-PRLR	Endometriosis					Hope Medicine/Bayer

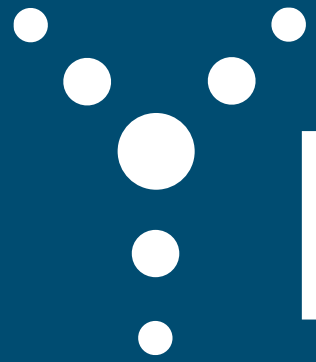
BioInvent's external projects are a seal of excellence for the quality of the company's research and development capabilities.

Ongoing early development deals:

- Option and license agreement with Exelixis 2022; identification and development of novel I/O targets and antibodies
  - 25 MUSD upfront payment. Dev and commercialization milestones, as well as tiered royalties on the annual net sales of any products
- Pfizer currently developing antibodies selected under a research collaboration with BioInvent 2017-2020
  - USD 6.6 million received so far in milestone payments besides research funding
  - Potential future development milestones in excess of USD 100 million and up to double digit royalties on future sales

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	H2 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



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