



UNLEASHING IMMUNITY TO FIGHT CANCER

Function first drug discovery

Jefferies Healthcare Conference, New York
June 8, 2023
Martin Welschhof, CEO

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BIOINVENT IS TRANSLATING CANCER BIOLOGY INTO INNOVATIVE IMMUNO-ONCOLOGY THERAPIES

Biolnvent at a glance as of March 31, 2023

5

projects in
clinical development

10+

Licensing, supply and
collaboration agreements

102

employees
(full time equivalent)

1,546

SEKm
in liquid funds etc

- Five expanding clinical programs

- Integrated research engine, functional screening and in-house GMP manufacturing

- Technology validating deals with Exelixis, Daiichi Sankyo, Bayer Healthcare, Mitsubishi Tanabe, Takeda. Senior executive focus on partnering/deal making

- Strong international shareholder base - Redmile, Van Herk Investments, Forbion, HBM, Omega, AP4, Invus, Swedbank Robur, Handelsbanken, AXA

- Solid cash position, listed on NASDAQ OMX Stockholm Mid Cap (BINV)
Global commercial strategy

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

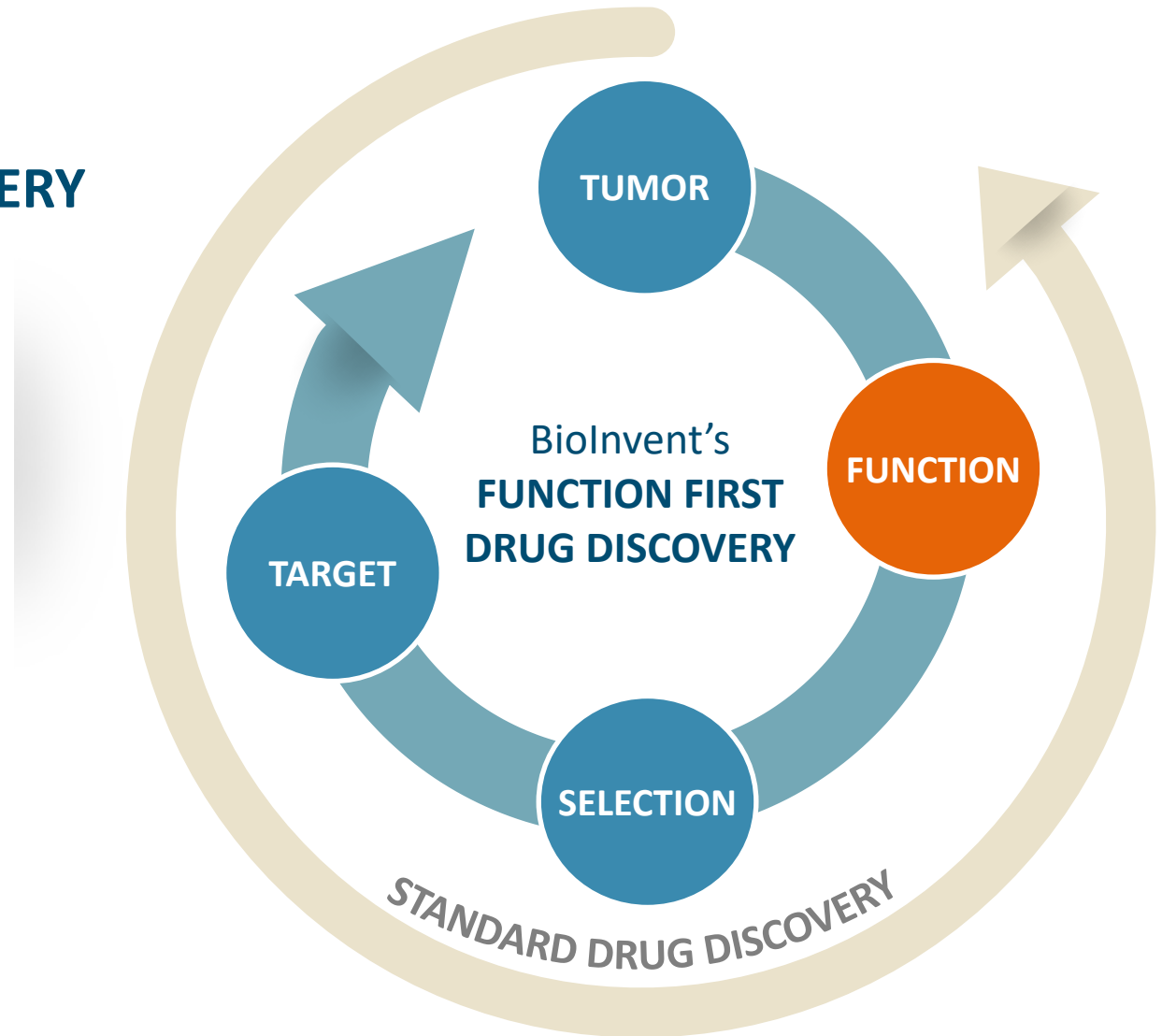
And most of these targets have failed to deliver therapies that work in the clinic

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

BIOINVENT IS TRANSLATING CANCER BIOLOGY INTO INNOVATIVE IMMUNO-ONCOLOGY THERAPIES

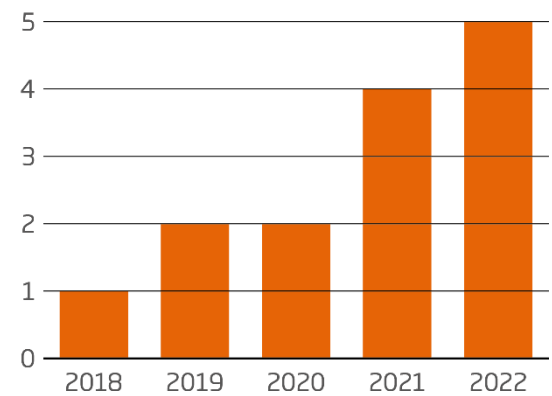
FUNCTION **F.I.R.S.T**™ DRUG DISCOVERY

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	Discovery	Preclinical	Phase 1	Phase 2	Partner
BI-1206/rituximab	NHL (MCL, MZL, iFL)	Completed	Ongoing	Up-coming		CASI ¹
BI-1206/pembrolizumab	Solid tumors	Completed	Ongoing	Up-coming		CASI ¹
BI-1607/ trastuzumab	Solid tumors	Completed	Ongoing	Up-coming		
Target: TNFR2 and CTLA-4						
BI-1808 (TNFR2)	Solid tumors	Completed	Ongoing	Up-coming		
BT-001 (CTLA-4, GM-CSF)	Solid tumors	Completed	Ongoing	Up-coming		transgene ²
BI-1910 (TNFR2)	Solid tumors	Completed	Ongoing	Up-coming		

Completed

Ongoing

Up-coming

¹Licensed to CASI for China, Hong Kong, Macau and Taiwan.

² 50/50 co-development collaboration with Transgene



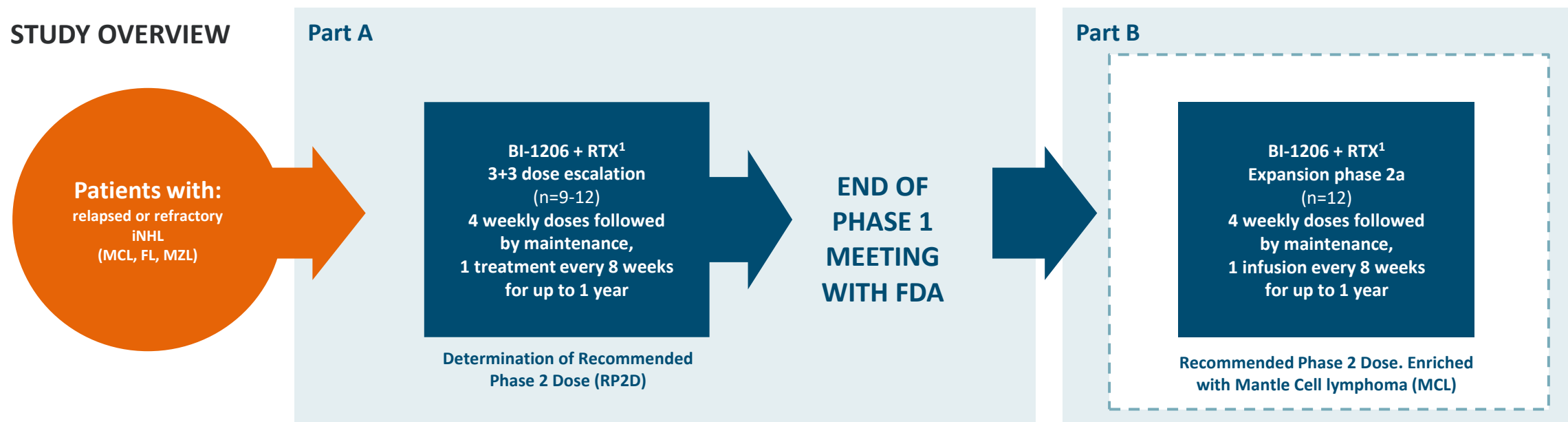
BI-1206 (α Fc γ RIIB)

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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

BI-1206-02 TRIAL: A FOURTH COMPLETE RESPONSE, APRIL 2023

Responses From Seven Patients (out of 15) Completing Induction Cycle



A total of 4 CR:s in IV part 2 beyond 2 years after end of treatment

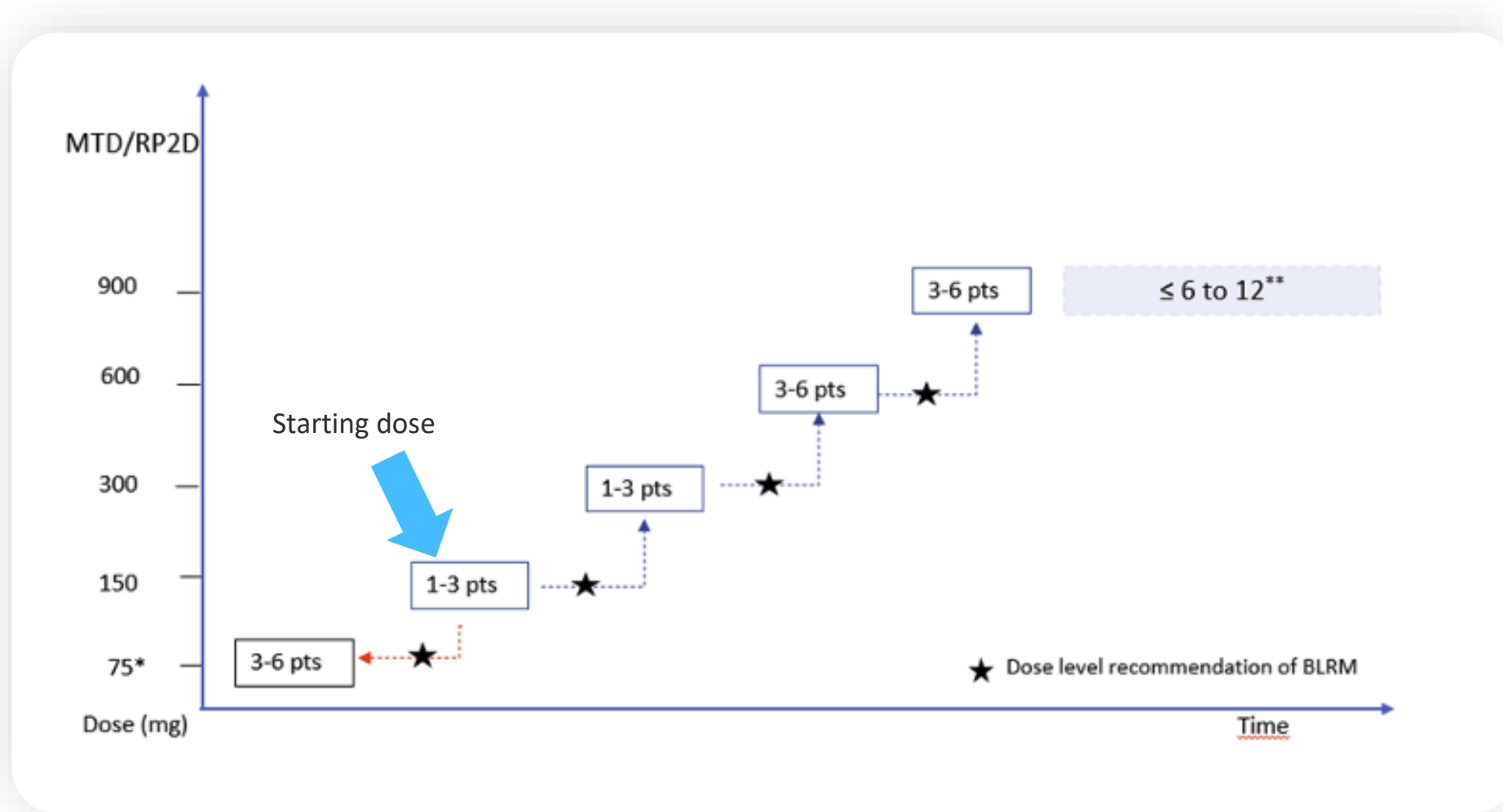
Long-lasting complete responses

Study of subcutaneous formulation (sc) of BI-1206 ongoing

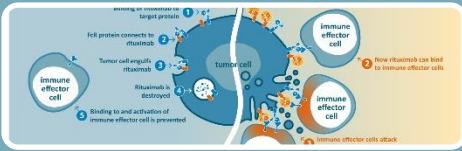
- Approved by all regulatory authorities in EU and US
- Adaptive design, with 1 patient cohort dose-escalation design

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

BI-1206 IN COMBINATION WITH RITUXIMAB: OPEN LABEL PHASE 1/2a STUDY: SC DOSE ESCALATION ADAPTIVE DESIGN BLRM



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



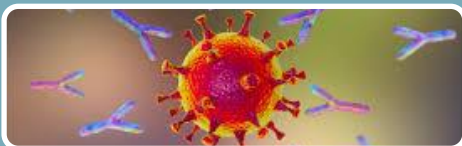
Compelling scientific rationale in anti-CD20 refractory B-cell lymphoma



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



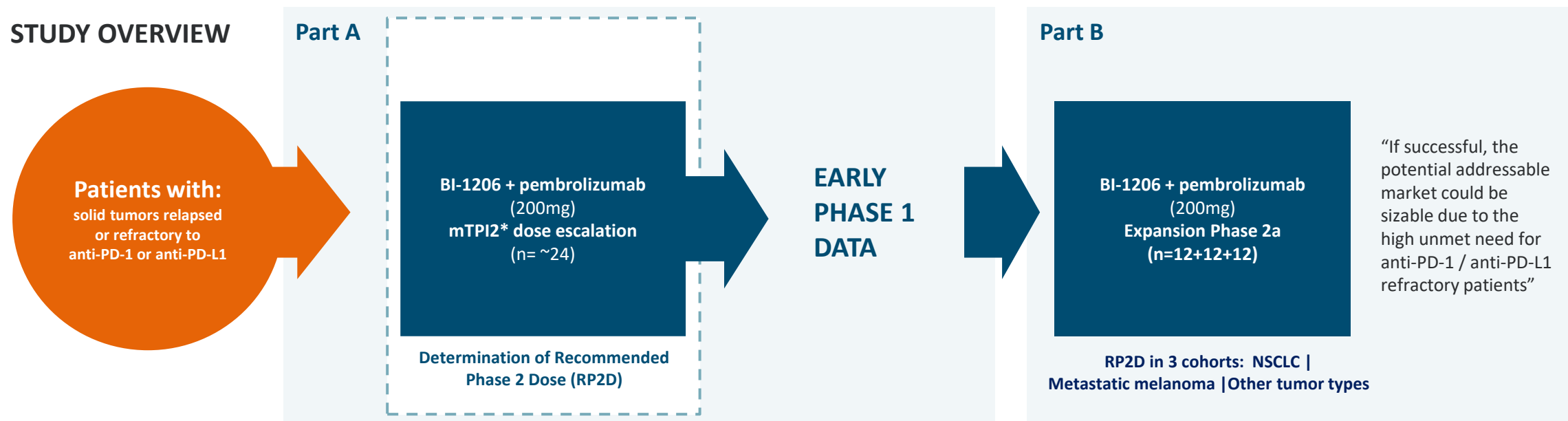
Long-lasting complete responses after end of treatment

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

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)

STATUS SUMMARY BI-1206 IN SOLID TUMORS (June 2023)

- 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) > 90 weeks; > 50% reduction in lesions.
 - One pseudo-progression: sarcoma patient; enrolled June 2021, PD in Jan 2022 but with clear clinical improvement. “Compassionate patient protocol” started treatment on Feb 2022.
- New data in June 2023 show:
 - One patient experiencing a long-lasting stable disease, with more than 80 weeks of treatment in the study
 - Additional patient experiencing a PR.

Both patients have melanoma, and both had previously been treated with immune checkpoint inhibitors. The latter had progressed after previous lines of those agents. Aside infusion related reactions, no major safety concerns have been observed.

WHAT'S NEXT?

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



BI-1607 (α Fc γ RIIB)

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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-1808 (α TNFR2)

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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

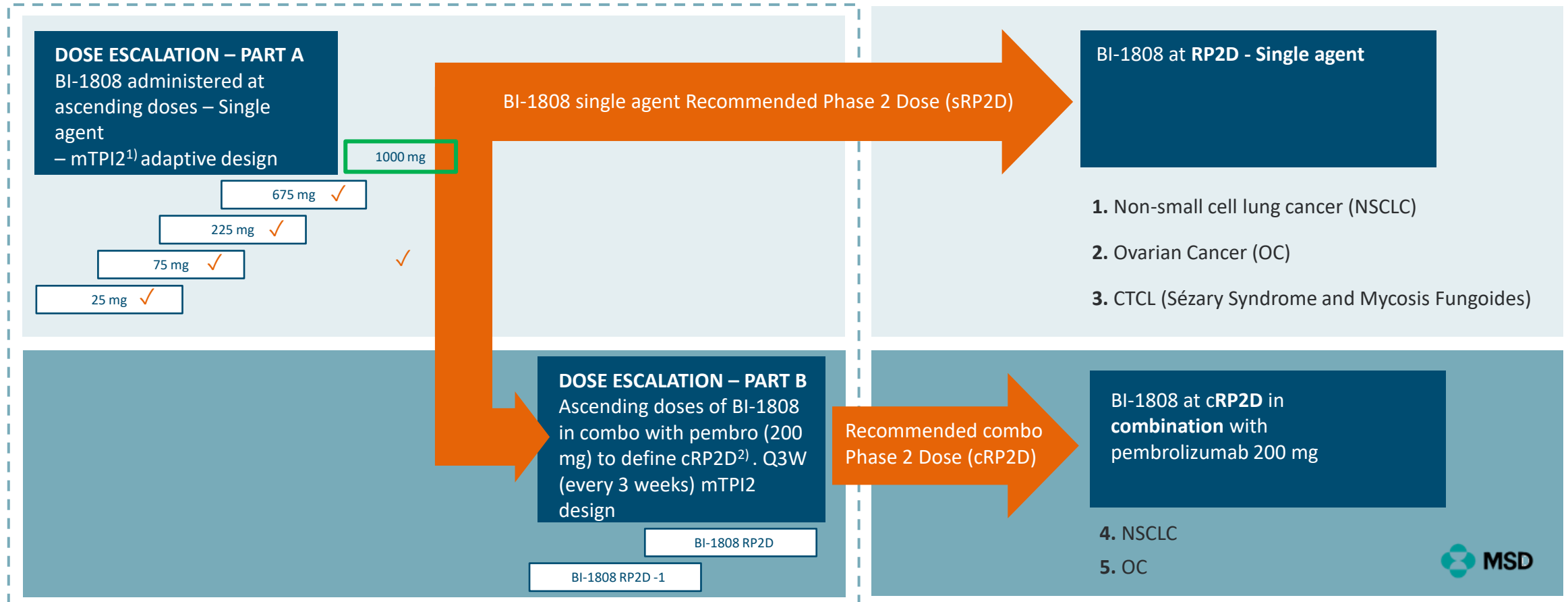
BI-1808: ANTI-TNFR2 ANTIBODY FOR THE TREATMENT OF CANCER

KEYNOTE-D20: CLINICAL STUDY DESIGN

Ongoing phase

Phase 1: All Cancer Types

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



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

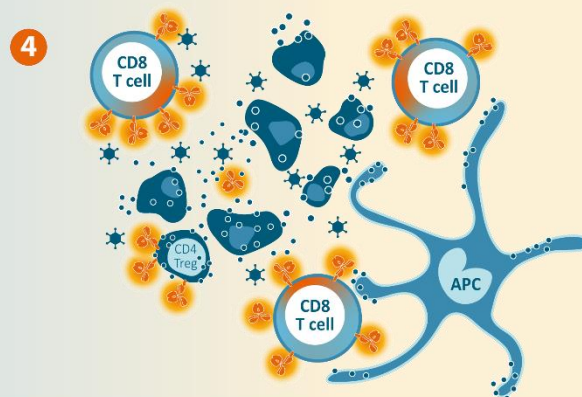
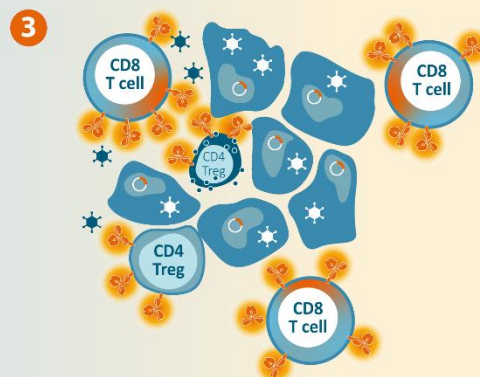
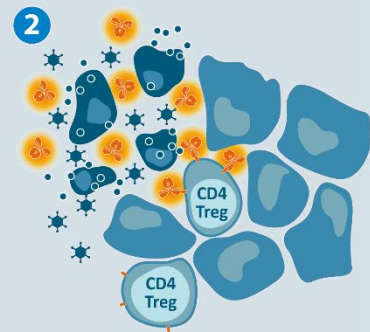
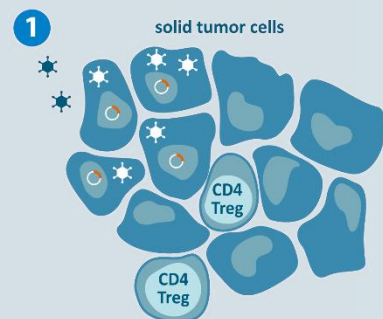
(Vectorized T_{reg}-depleting αCTLA-4)



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”*

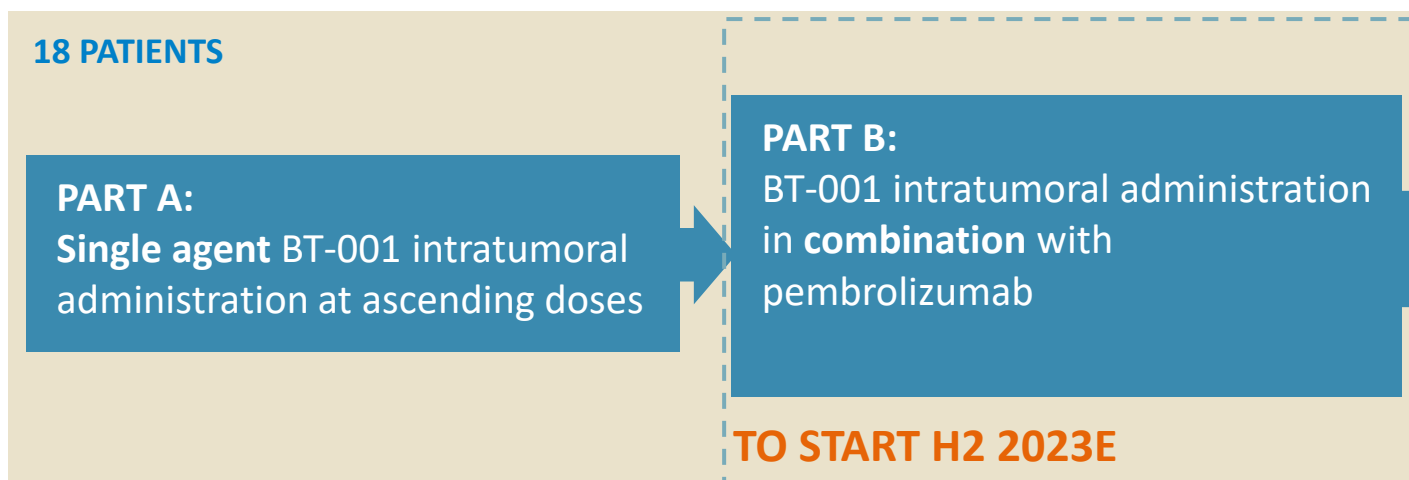
Winner of the 2022 JITC Best Oncolytic and Local Immunotherapy Paper Award



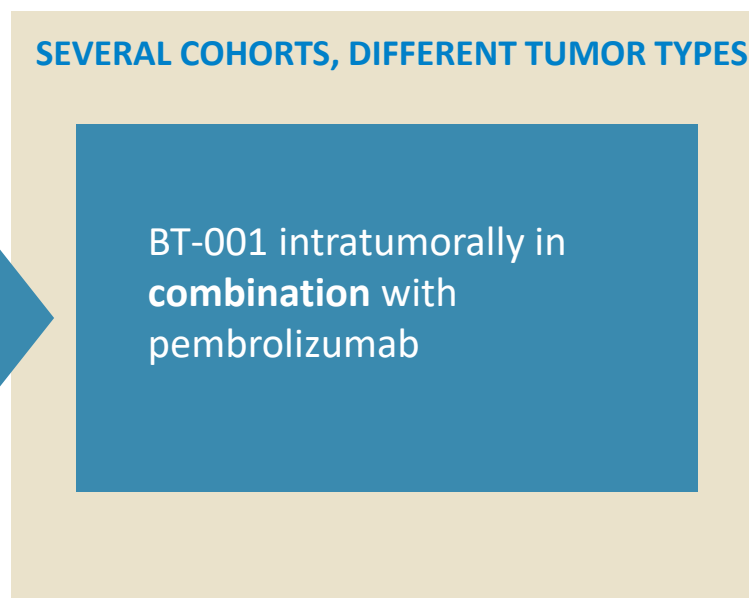
BT-001: ONCOLYTIC VIRUS ARMED WITH ANTI-CTLA-4

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

PHASE 1 - PART A & B



PHASE 2A



upcoming phase

STATUS SUMMARY BT-001 PHASE 1/2A

May 25, 2023: Positive progress and safety data in the ongoing Phase 1/2a trial

- Treatment of all Phase 1a cohorts in monotherapy completed with no safety concerns
- Stabilization of injected lesions in 11/18 patients
- Objective antitumor activity, defined as decrease of injected lesion size of 50% or more, was observed in two patients
- An independent Safety Review Committee approved initiation of the combination trial with pembrolizumab

WHAT'S NEXT?

- Start of Phase 1 part B; BT-001 in combination with pembrolizumab, H2 2023E

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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