



# UNLEASHING IMMUNITY TO FIGHT CANCER

Function first drug discovery

Annual General Meeting  
April 27, 2023

# FORWARD-LOOKING STATEMENT

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# BIOINVENT IS TRANSLATING CANCER BIOLOGY INTO INNOVATIVE IMMUNO-ONCOLOGY THERAPIES

BioInvent 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

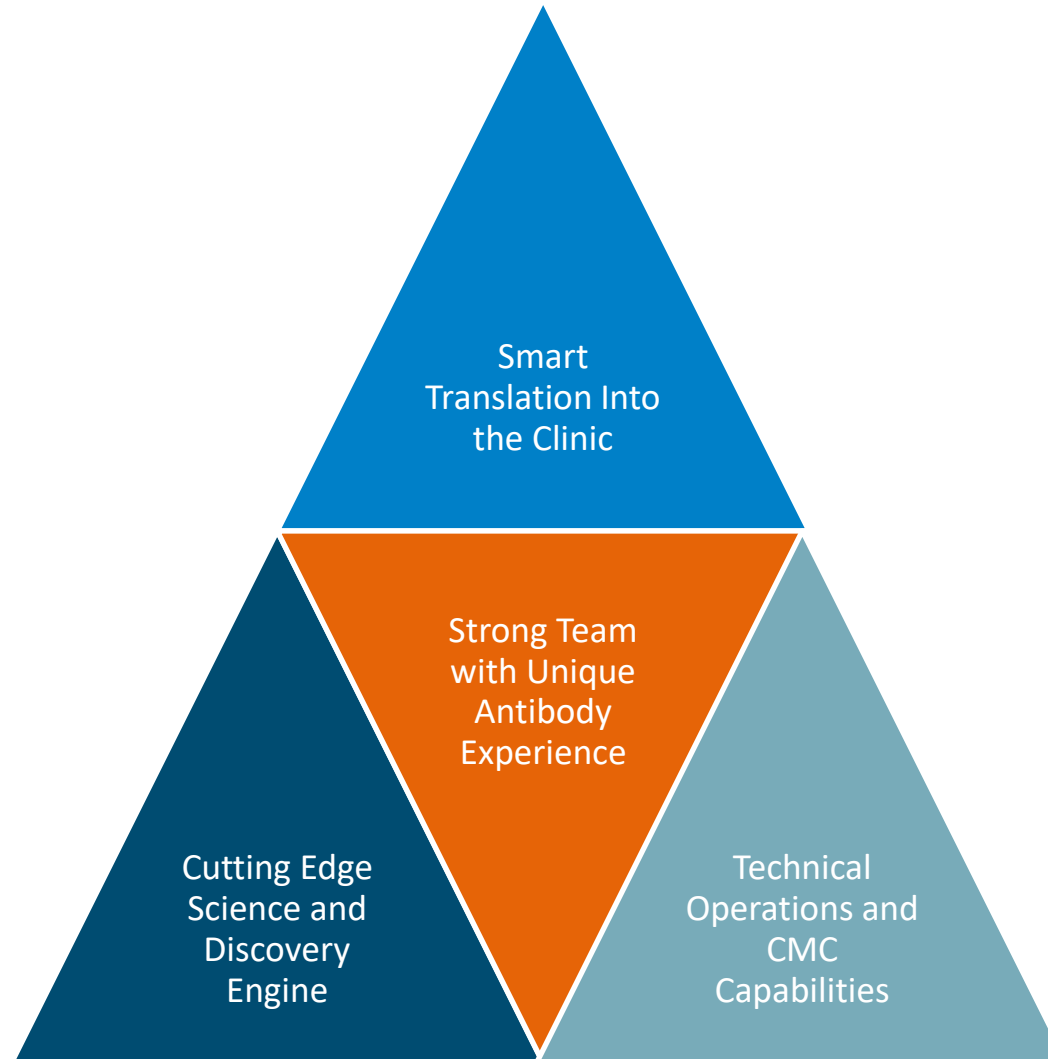
- Integrated research engine, functional screening and in-house GMP manufacturing

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

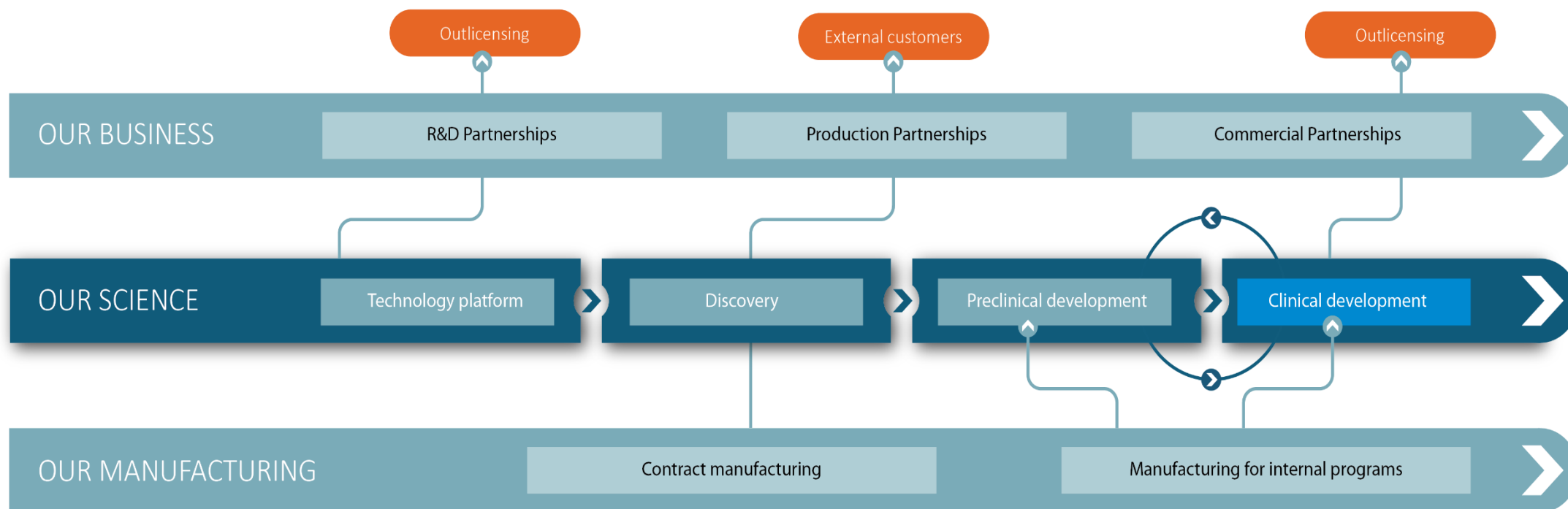
- Strong international shareholder base - Redmile, Van Herk Investments, HBM, Forbion, Omega, AP4, Invus, Swedbank Robur, Handelsbanken, AXA

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

# HIGHLY INTEGRATED COMPANY



# MULTIPLE POTENTIAL REVENUE STREAMS



**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

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**Eight approved agents are available** for 17 different malignancies

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**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**

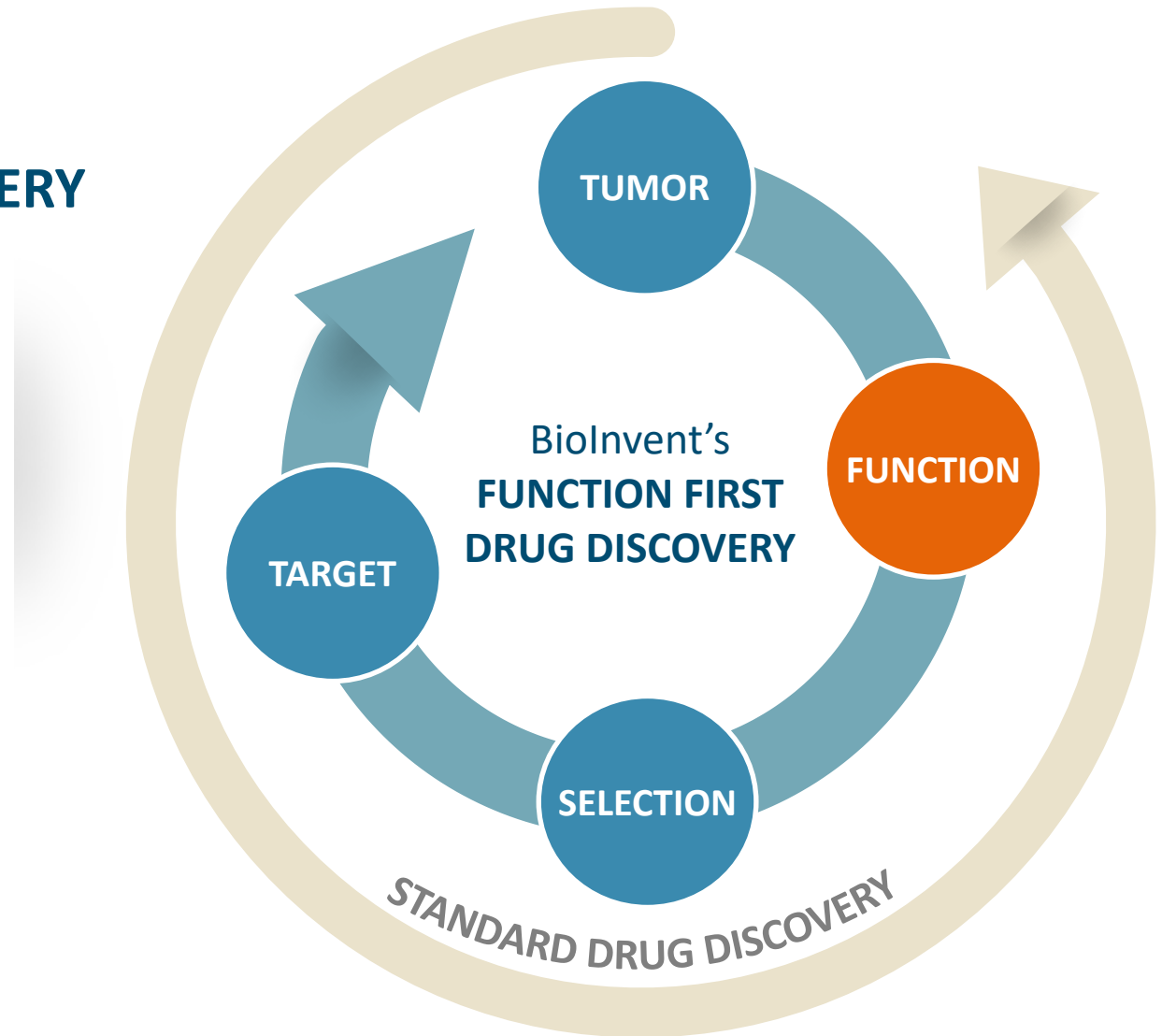
And most of these targets have failed to deliver therapies that work in the clinic

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

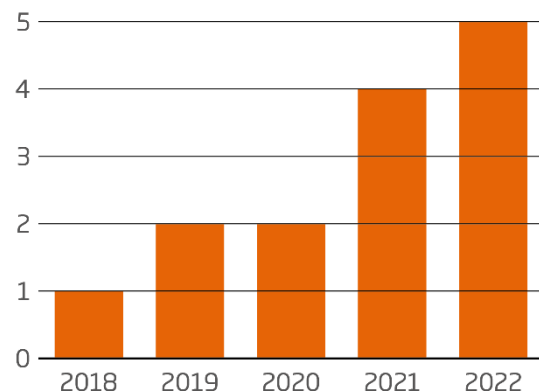
## FUNCTION **F.I.R.S.T™** DRUG DISCOVERY

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 <sup>1</sup>
BI-1206/pembrolizumab	Solid tumors	Completed	Ongoing	Up-coming		CASI <sup>1</sup>
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 <sup>2</sup>
BI-1910 (TNFR2)	Solid tumors	Completed	Ongoing	Up-coming		

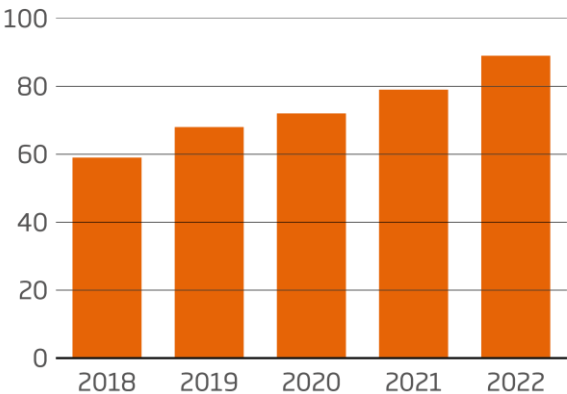
■ Completed  
■ Ongoing  
■ Up-coming

<sup>1</sup>Licensed to CASI for China, Hong Kong, Macau and Taiwan.

<sup>2</sup> 50/50 co-development collaboration with Transgene

# ORGANIZATIONAL DEVELOPMENT

The number of employees has grown over the past years to meet the demands from BioInvent's expanding portfolio



Average number of FTE:s 2018-2022

## 2021-2023: Clinical/Reg functions added

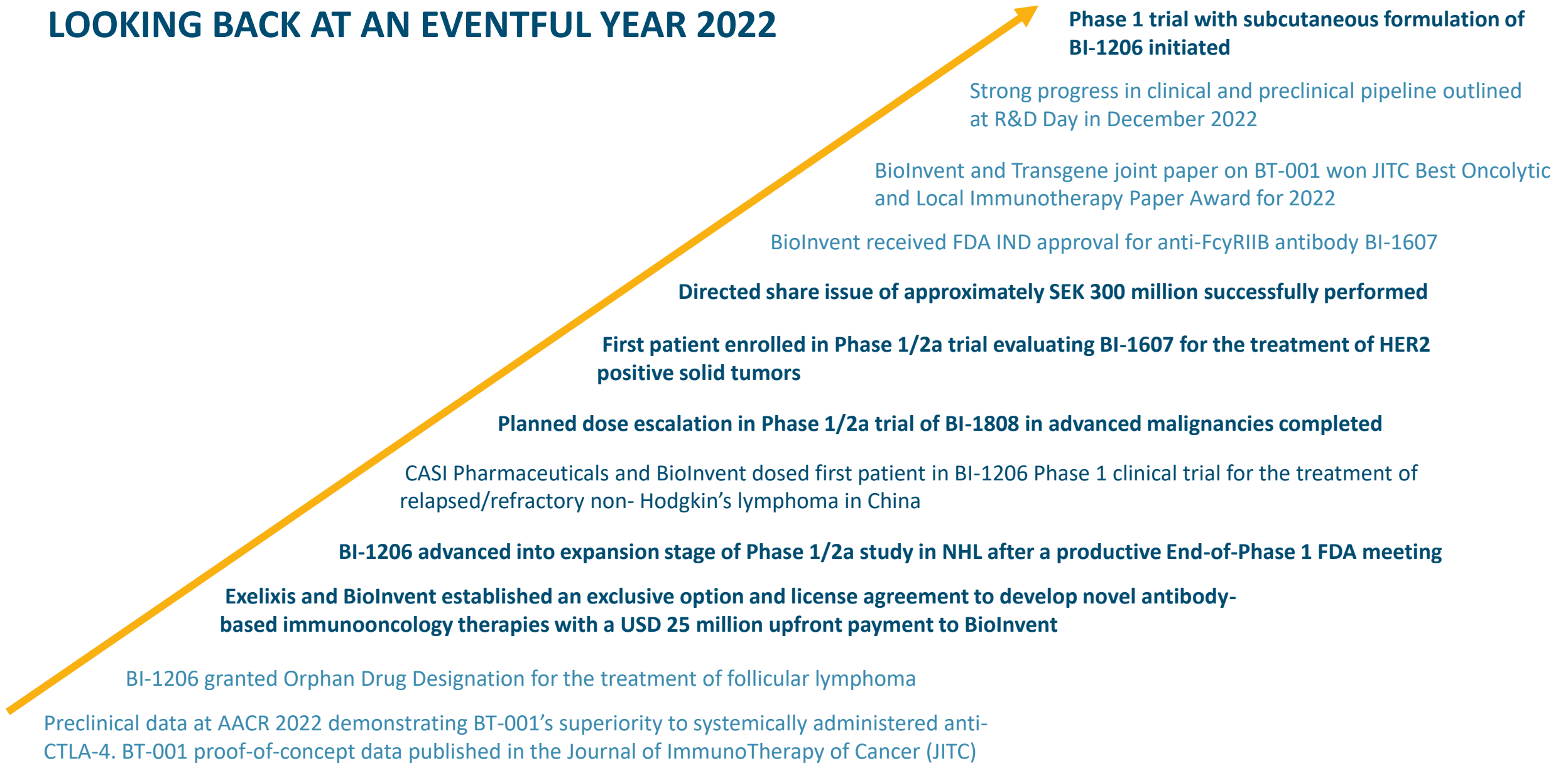
Senior Medical Director  
Medical Director  
VP Clinical Development  
Director Clinical Pharmacology  
Drug Supply Coordinator  
Project planner  
Director Regulatory Affairs  
Regulatory Affairs Manager  
Additional CPM:s

Clinical team as of 2020:  
CMO and ~3 Clinical Project Managers

## Other new functions added

Director Computational Biology  
Chief Operational Officer  
Chief Business Officer  
Senior CMC Regulatory Affairs  
Manager  
IT manager  
Senior Director IR  
CMC Project Director  
Purchasing Manager

# LOOKING BACK AT AN EVENTFUL YEAR 2022



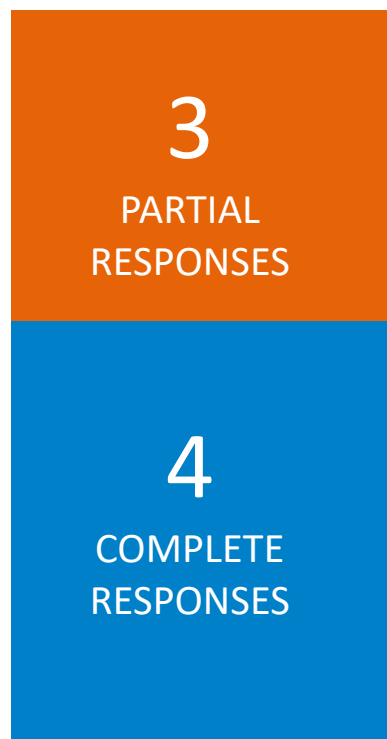
## JANUARY 2023: STRATEGIC COLLABORATION WITH LEUKEMIA & LYMPHOMA SOCIETY

- Strategic equity investment of USD 3 million received in January 2023 to support
  - Clinical advancement of BI-1206 in Non-Hodgkin's Lymphoma, and
  - The clinical development of BI-1808 in cutaneous T-cell lymphoma
- LLS TAP is a strategic funding initiative to accelerate innovative blood cancer therapeutics. LLS has dedicated more than USD 100 million over the past several decades, through both grants and TAP investments, to advancing pioneering approaches that harness immunotherapies to fight blood cancers.



# APRIL 2023: A FOURTH COMPLETE RESPONSE IN BI-1206 + RITUXIMAB TRIAL

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



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

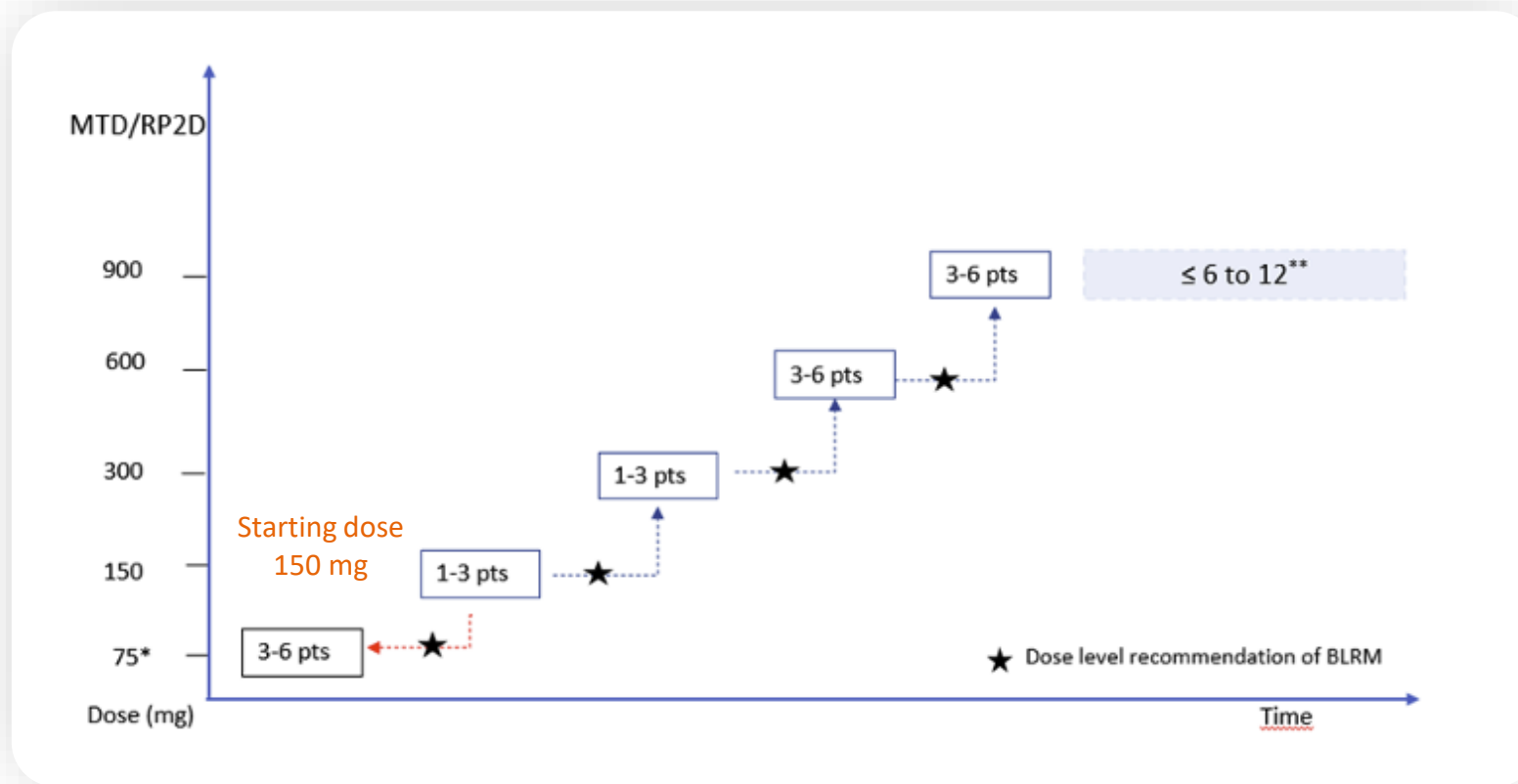
**Long-lasting complete responses**

## ONGOING PHASE 1/2a TRIAL SUBCUTANEOUS FORMULATION (SC) OF BI-1206

- 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

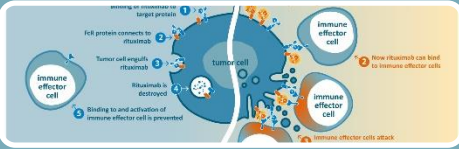
# BI-1206 IN COMBINATION WITH RITUXIMAB: OPEN LABEL PHASE 1/2a STUDY: SC DOSE ESCALATION ADAPTIVE DESIGN BLRM



## WHAT'S NEXT?

- First data from BI-1206 SC + rituximab expected H1 2023

# BI-1206 IN NHL: UNIQUE VALUE PROPOSITION



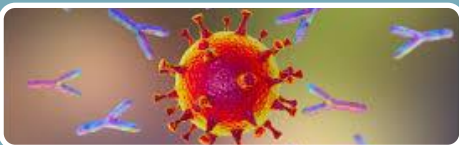
Compelling scientific rationale in anti-CD20 refractory B-cell lymphoma



First-in-class in hematology with no direct competitors



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



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



Long-lasting complete responses after end of treatment

# STATUS SUMMARY BI-1206 IN COMBINATION WITH PEMBROLIZUMAB

(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

## STATUS SUMMARY BI-1607 IN COMBINATION WITH TRASTUZUMAB

- 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
- The study is progressing well with the first two dose cohorts completed with no safety or tolerability concerns and no infusion-related reactions observed at doses and exposures that provide high receptor occupancy

### WHAT'S NEXT?

- First results from the ongoing Phase 1 study H2 2023E

## 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

## 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	<div></div>	<div></div>	<div></div>	<div></div>	Mitsubishi Tanabe
TAK-079	anti-CD38	Myasthenia Gravis	<div></div>	<div></div>	<div></div>	<div></div>	Takeda
Orticumab	anti-ApoB100	Psoriasis	<div></div>	<div></div>	<div></div>	<div></div>	Abcentra
TAK-169/MT-0169	anti-CD38	Multiple Myeloma	<div></div>	<div></div>	<div></div>	<div></div>	Molecular Templates
DS-1055	anti-GARP	Solid tumor	<div></div>	<div></div>	<div></div>	<div></div>	Daiichi-Sankyo
HMI-115	anti-PRLR	Endometriosis	<div></div>	<div></div>	<div></div>	<div></div>	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 deal with Exelixis

- Option and license agreement signed in 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

## 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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