

**COMPANY PRESENTATION** 

April 2019



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#### **COMPANY SNAPSHOT**

#### LEADING ANTIBODY IMMUNO-ONCOLOGY PLATFORM



- Advancing Cancer Immunotherapy by overcoming tumor resistance
- Validated by publications in top-tier journals e.g. Cancer Cell, and Immunity and partnerships with leading pharma companies such as Pfizer, Transgene, Bayer Pharma, Daiichi Sankyo and Mitsubishi Tanabe Pharma

#### ROBUST PIPELINE FUELED BY STRONG, FULLY INTEGRATED RESEARCH ENGINE

- 2 proprietary programs in the clinic key readouts 2019
- 50/50 partnership with Transgene to develop first-in-class antibody-expressing oncolytic viruses in solid tumors

#### VALIDATING DEAL WITH PFIZER



- Development of anti-tumor associated myeloid (anti-TAM) antibodies
- \$3 million upfront & \$6 million equity stake
- Potential milestones > \$500 million & up to double digit royalties



#### STRONG INSTITUTIONAL SHAREHOLDER BASE

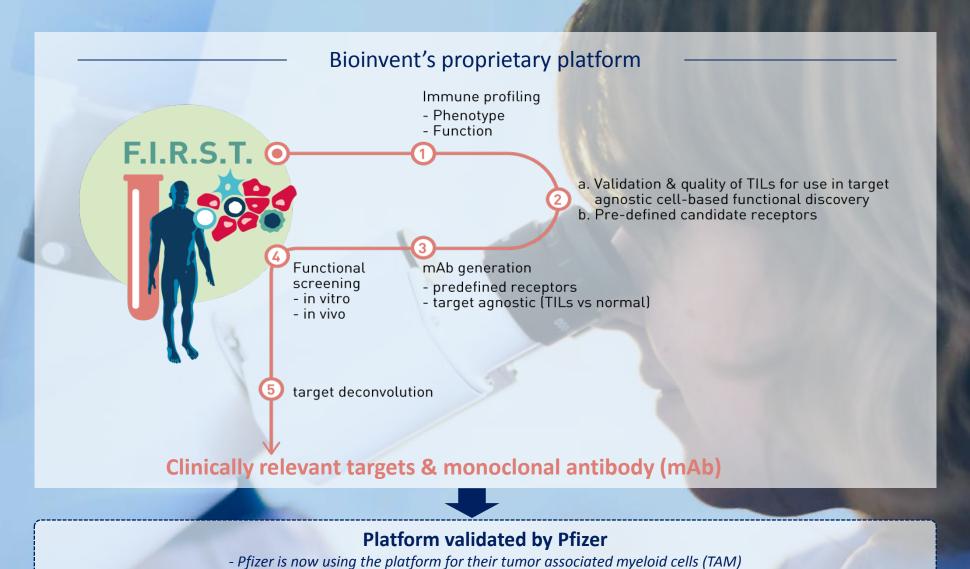
a.o. Pfizer, Omega Funds, Institut Mérieux, Van Herk Investments, Rhenman Healthcare Equity



#### EXPERIENCED MANAGEMENT TEAM WITH BIG PHARMA AND BIOTECH EXPERIENCE

- Broad scientific/clinical expertise
- Significant senior executive experience with strong focus on partnering/deal making

## F.I.R.S.T™- A PATIENT CENTRIC PLATFORM FOR DISCOVERY OF NOVEL ONCOLOGY TARGETS AND MAB



## NEW DRUGS AND MECHANISMS ARE NEEDED TO IMPROVE CANCER IMMUNOTHERAPY & SURVIVAL

## THE CONCEPT WORKS

New drugs direct the immune system to combat tumors

## ONLY A SUBSET OF PATIENTS RESPOND TO CURRENT DRUGS

New mechanisms and antibodies needed to improve outcomes

## A RAPIDLY GROWING MARKET

2016 sales<sup>1</sup>

43bn

(USD)

2022E sales<sup>1</sup>

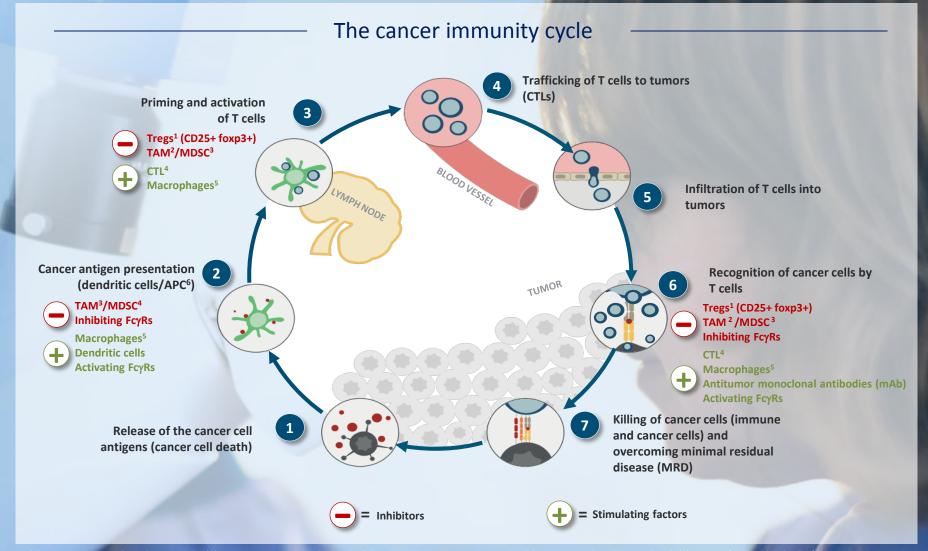
97bn

(USD)

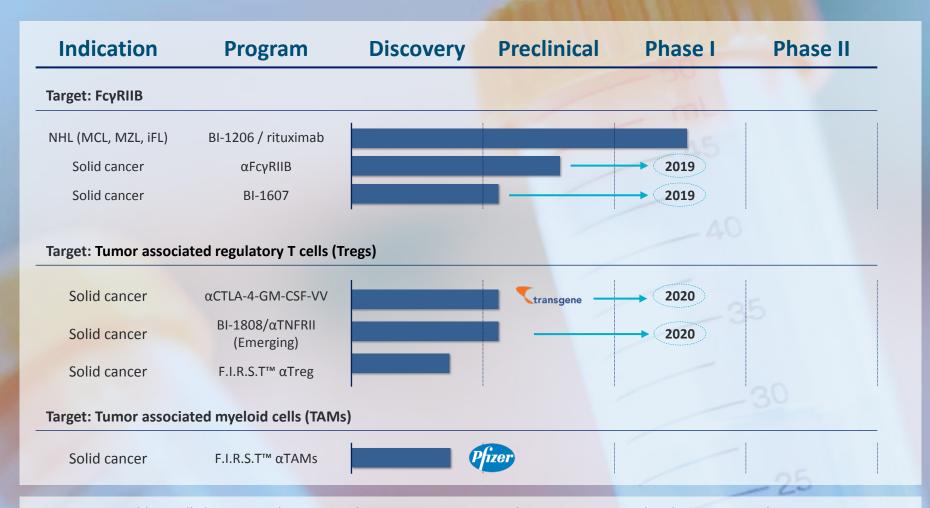
CAGR 2016-2022E1

14.6%

## & MECHANISMS TO BOOST ANTI-CANCER IMMUNITY

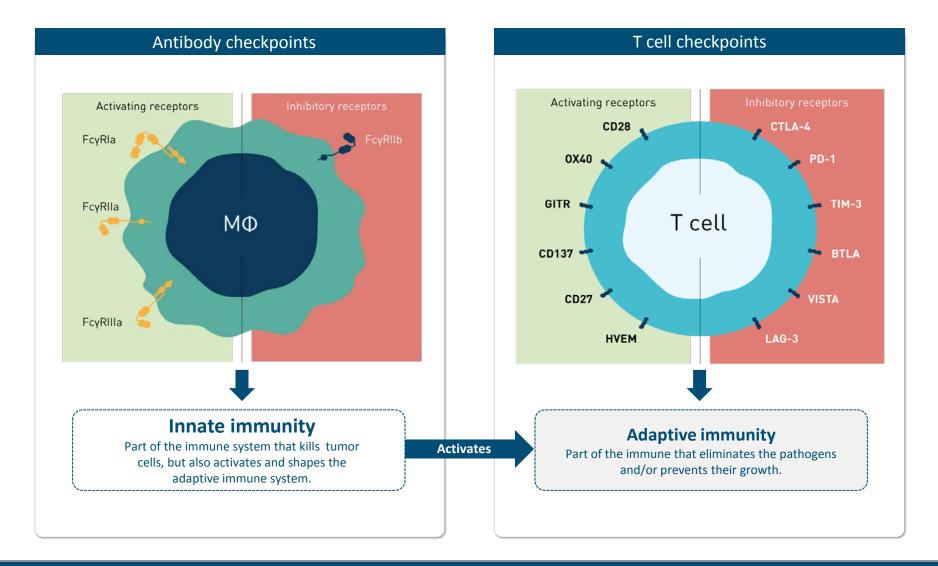


#### **PIPELINE – MULTIPLE VALUE DRIVERS**



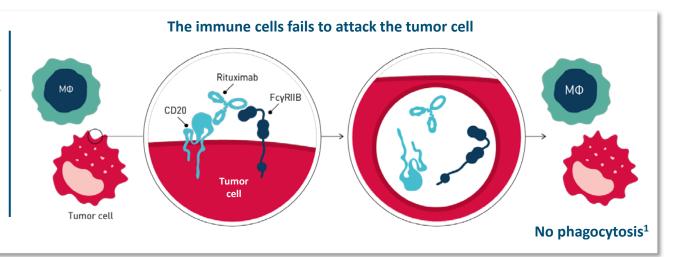
- BioInvent additionally has ownership in anti-PIGF programs TB-403 and THR-317 partnered with Oncurios and Oxurion
- Two parallel Clinical Phase I/II studies ongoing with BI-1206 (BioInvent and CRUK sponsored)

## FcγRIIB – A SINGLE INHIBITORY ANTIBODY CHECKPOINT TO UNLOCK ANTI-CANCER IMMUNITY



## **PRE BI-1206**

- Rituximab is effective when bound to CD20 on the cell surface, but its efficacy is hampered by FcγRIIBmediated endocytosis
- Rituximab is a monoclonal antibody (Rituxan®, Mabthera®, Roche) killing malignant B cells
- CD20 is an antigen expressed on the surface of B cells, as well as cancer cells derived from B-cells
- The FcyRIIB-receptor functions to remove Rituximab from CD20, i.e. protecting cancer cells from the immune system



## **POST BI-1206**

- BioInvent's BI-1206 blocks the FcyRIIB receptor, suppressing the tumor's protection. Its activity helps restore and enhance rituximab's effect
- With the FcyRIB-receptor blocked, a better anti-tumor activity is engaged allowing the immune system to find and kill the tumor cell

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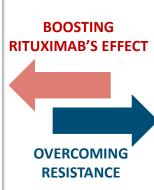
#### **BI-1206: CUTTING BOTH WAYS**

#### BI-1206 BLOCKS RITUXIMAB INTERNALIZATION AND IMPROVES ITS ANTI-TUMOR ACTIVITY

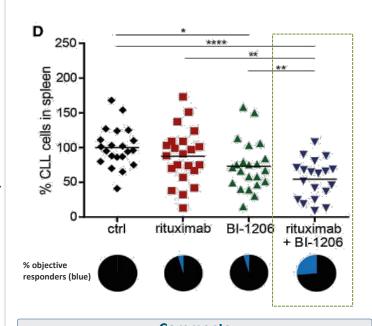
# B cell depletion in vivo 8 0.0 40.0 40.0 0 2 4 6 8 10 12 14 16 18 20 22 24 26 28 30 Day post mAb injection (i.v.)



- By combining Rituximab and BI-1206, results show a synergistically enhanced B cell depletion
- Demonstrating that BI-1206 is truly boosting Rituximab's effect



#### Humanized model of relapsed / refractory CLL<sup>1</sup>



#### **Comments**

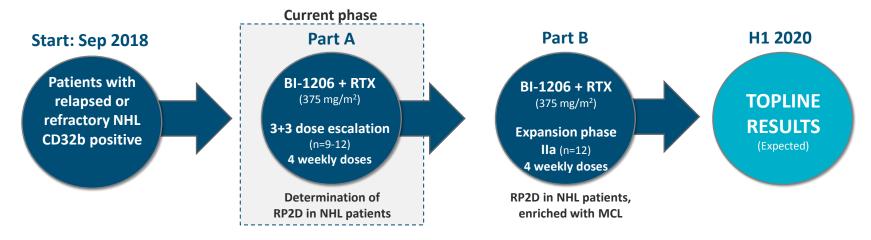
- Adding BI-1206 re-sensitizes tumor cells to rituximab mediated leukemic cell depletion
- Demonstrating that BI-1206 can overcome rituximab resistance in vivo



#### BI-1206: EXPANDING THERAPEUTIC POTENTIAL - PHASE I/IIA STUDY

#### **STUDY OVERVIEW**

- A multicenter, open label, Phase I/IIa study in relapsed or refractory indolent Non-Hodgkin Lymphoma (iNHL) patients enriched with Mantle Cell Lymphoma approximately 24 patients across sites in US & EU
- High proportion of patients expressing FCyRIIB in enriched population
- High unmet medical need despite the availability of targeted therapies



#### **OBJECTIVES**

- Safety & tolerability of BI-1206 in combination with rituximab
- PK/PD¹ of the antibody
- Recommended phase 2 dose (RP2D)
- Signs of efficacy of the combination treatment
- Biomarker exploration (B cell depletion, phosphorylation of FCyRIIB)
  - FCyRIIB overexpression is associated with a worse prognosis for the patient



#### **BI-1206: VALUE PROPOSTION – KEY SEGMENTS & VALUE DRIVERS**

#### **KEY SUB-SEGMENTS OF NON-HODGKIN LYMPHOMA (NHL)**



- MCL<sup>1</sup>, mantle cell lymphoma develops in the outer edge of a lymph node called mantle cell. Usually diagnosed in people in their early 60s. MCL may be slow growing (indolent) but can also be fastgrowing (aggressive).
- **FL**<sup>1</sup>, follicular lymphoma is typically very slow-growing and is the most common form of slow-growing non-Hodgkin lymphoma.
- MZL<sup>1</sup>, marginal zone lymphoma is a slow growing type of B cell non-Hodgkin lymphoma that begins forming in the marginal zones of lymph tissue. Median age for diagnosis is 65.

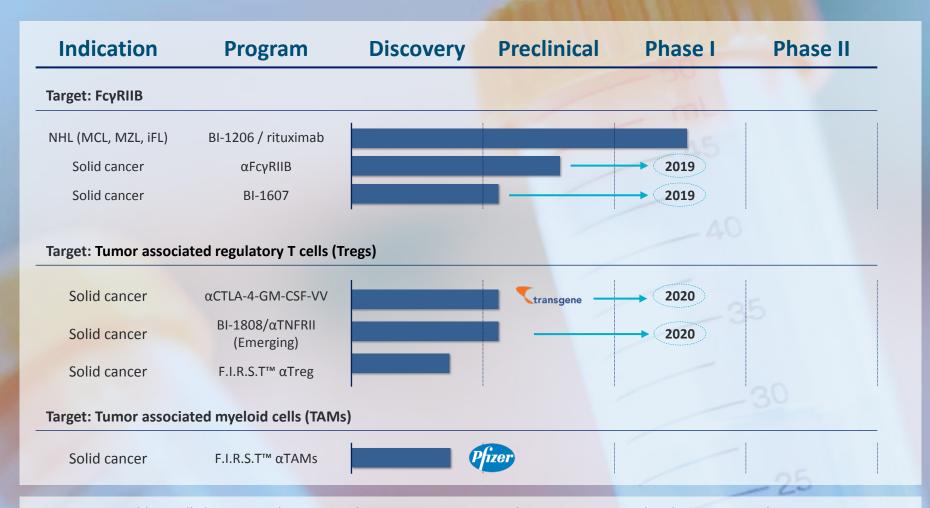
#### **Value drivers**

Safety, chemo-free regimen and scientific rationale in anti-CD20 refractory B-cell lymphoma are key drivers of BI-1206 attractiveness.

- First-in-class in hematology no direct competitors
- BI-1206 shows a favorable safety profile
- High unmet need for chemotherapy-free, safer options in 2<sup>nd</sup> Line
  - in Rituximab-refractory patients
  - in aggressive disease such as MCL
  - in transplant ineligible and elderly MCL patients
  - In patients ineligible for chemo or targeted therapies
- Shorter clinical trials in 2<sup>nd</sup> Line and 3<sup>rd</sup> Line MCL (~2-3 years)
- Strong scientific rationale
- Possible label extension to all therapeutic areas where anti-CD20 mAbs are used
- BioInvent has received Orphan Drug Designation from the FDA for BI-1206 in MCL in January



#### **PIPELINE – MULTIPLE VALUE DRIVERS**



- BioInvent additionally has ownership in anti-PIGF programs TB-403 and THR-317 partnered with Oncurios and Oxurion
- Two parallel Clinical Phase I/II studies ongoing with BI-1206 (BioInvent and CRUK sponsored)

**TAMS** 

**TARGETING** 

#### TARGETING TREGS AND TAMS TO MITIGATE IMMUNE SUPPRESSION

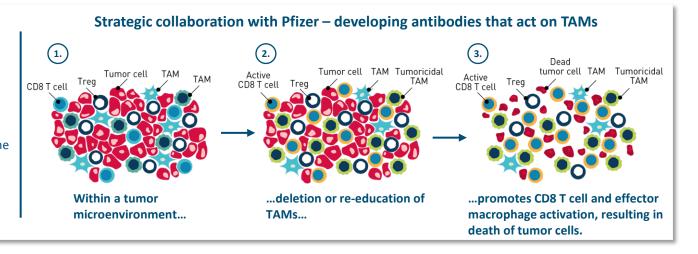
#### Regulatory T cells (Tregs) can substantially inhibit immune responses, enabling tumor cells to escape detection.

- BioInvent is utilizing its F.I.R.S.T.™ platform to identify and characterize monoclonal antibodies to cancerassociated Treg targets in a functionfirst, target agnostic, manner.
- BioInvent is also pursuing differentiated antibodies to known targets through novel mechanisms and pathways.

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#### ■ In partnership with Pfizer Inc., BioInvent works to identify novel oncology targets and therapeutic antibodies that may either reverse the immunosuppressive activity of tumor-associated myeloid cells (TAMs) or reduce the number of tumor-associated myeloid cells in the tumor.

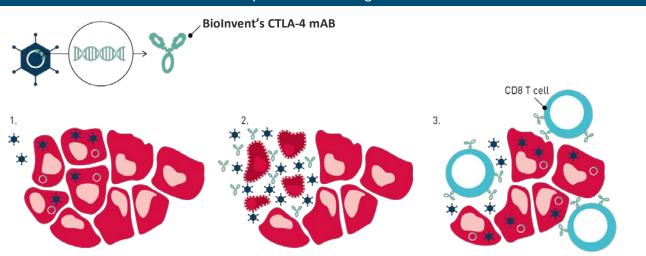
 BioInvent is eligible for potential future development milestones in excess of \$500 million.



#### MABS + ONCOLYTIC VIRUS TO TARGET SOLID TUMORS

#### 50/50 PARTNERSHIP WITH TRANSGENE TO DEVELOP NEXT GENERATION ONCOLYCTIC VIRUS

#### MAbs and oncolytic virus attacking the solid tumor



Oncolyctic virus & anti-CTLA-4 antibody combination elicits stronger antitumor response & targeted expression of anti-CTLA-4 antibody, which improves safety profile

#### **Comments**



- Virus-particles infect tumor cells
- Virus replicates and persists in tumor cells without integrating into host genome in a safe manner



- Virus infected tumor cells produce human Treg depletion optimised anti-CTLA-4 antibody
- Virally infected tumor cells lyse as a result of viral infection
- Tumor antigens are released into tumor microenvironment



- Intratumorally produced anti-CTLA-4 depletes Tumor Treg and induce Teff activation
- Tumor antigens are taken up by APCs fuelling activation of Tumor-specific T cells
- Systemic adaptive anti-tumor responses are induced and boosted "abscopal effect"

#### **ABOUT THE COLLABORATION**





- BioInvent and Transgene collaborate to co-develop oncolytic virus (OV) candidates encoding a validated anti-CTLA-4 antibody sequence, potentially with additional transgenes, aimed at treating solid tumors
- Transgene is contributing both its OV design and engineering expertise, as well as its proprietary Vaccinia viruses, designed to directly and selectively destroy cancer cells by intracellular replication of the virus in the cancer cell (oncolvsis).
- BioInvent is providing its cancer biology and antibody expertise to the collaboration, as well as anti-CTLA-4 antibody sequences generated through its proprietary n-CoDeR®/F.I.R.S.T.TM platforms.
- Cost and profits are shared 50/50 between Transgene and BioInvent

Clinical status



2020 (Expected)

#### **KEY MILESTONES**

TIMING	EVENTS
H2 2018	✓ Start Phase I/IIa BI-1206/rituximab combination trial in NHL
	✓ Preclinical rationale Anti-CTLA-4/oncolytic virus, SITC Poster
H1 2019	✓ BI-1206 /rituximab orphan drug designation (ODD) in mantle cell lymphoma
	✓ Podium Presentation SLAS 2019 Washington on F.I.R.S.T tm
	<ul> <li>Anti-FcγRIIB antibody/anti-PD1 start Phase I/IIa</li> </ul>
	<ul> <li>BI-1206/rituximab poster presentation at Int. Conf. on Malignant Lymphoma</li> </ul>
H2 2019	Pfizer collaboration: TAM target antibodies selection
	<ul> <li>Start phase IIa BI-1206/rituximab combination trial in NHL</li> </ul>
	<ul> <li>BI-1607 (anti-FcγRIIB antibody)/checkpoint inhibitor, start Phase I PoC trial</li> </ul>
H1 2020	■ Anti-FcyRIIB antibody/anti-PD1 start Phase IIa
	BI-1206/rituximab I/IIa in NHL topline results
	■ Anti-FcyRIIB antibody/anti-PD1 Phase I/IIa, ASCO poster
	■ BI-1808 +/- anti-PD1, start Phase I
H2 2020	■ Transgene collaboration: Anti-CTLA-4/oncolytic virus, start Phase I/lia
	■ Anti-FcyRII antibody/anti-PD1 Phase I/IIa, topline results
µ1 2021	P. D. 1206 (vituaringala Phase I /IIIa in NIIII woodout
H1 2021	<ul> <li>BI-1206/rituximab Phase I/IIa in NHL readout</li> </ul>

#### PROPRIETARY MANUFACTURING PLATFORM SINCE 1988



Provided courtesy of EMD Millipore Corporation

- Supports fast and flexible production of proprietary programs
- State of the art single use bioreactor (SUB) technology: 40L -1,000L batch sizes
- Approved for Phase I to III production
- Track record of 30 years inspections
- Consistent source of near term revenues from external customers
- BioInvent has produced drug substance for clinical trials in Europe, USA and Japan
- The production facility is located in Lund,
   Sweden
- In November 2018 BioInvent signed a manufacturing agreement with an undisclosed U.S. cell therapy company for the production of cGMP compliant material
  - The agreement is expected to generate revenue of c. USD 1.5 million mainly in 2019