



COMPANY PRESENTATION

September 2020



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COMPANY SNAPSHOT

LEADING IMMUNO-ONCOLOGY ANTIBODY PLATFORM



- Advancing Cancer Immunotherapy by overcoming tumor resistance
- Lead product, BI-1206, currently in Phase I/II for relapsed or refractory indolent Non-Hodgkin Lymphoma (iNHL) patients with early results from Phase I open label study expected in H2'2020
- Highly advanced antibody discovery platform with robust in-house manufacturing facilities

ROBUST PIPELINE FUELED BY STRONG, FULLY INTEGRATED RESEARCH ENGINE



- Growing portfolio: 2 proprietary programs in the clinic – 4 programs in the clinic by YE'2020
- Differentiated platform for functional screening to identify new relevant tumor targets and antibodies

TECHNOLOGY PLATFORM VALIDATED BY DEAL WITH PFIZER



- Discovery of new anti-tumor associated myeloid (anti-TAM) targets and antibodies
- Upfront technology access fee from Pfizer with potential milestones payments of up to >\$500 million
- BioInvent maintains participation in future commercial upside with up to double digit royalties

EXPERIENCED MANAGEMENT TEAM AND STRONG INSTITUTIONAL SHAREHOLDER BASE



- Broad scientific/clinical expertise
- Significant senior executive experience with strong focus on partnering/deal making
- Shareholders include Van Herk Investments, Omega, HBM, Swedbank Robur, AP4, Invus, Handelsbanken
- Listed on NASDAQ Stockholm since 2001 [NASDAQ OMX Stockholm \(BINV\)](#)

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Corporate overview

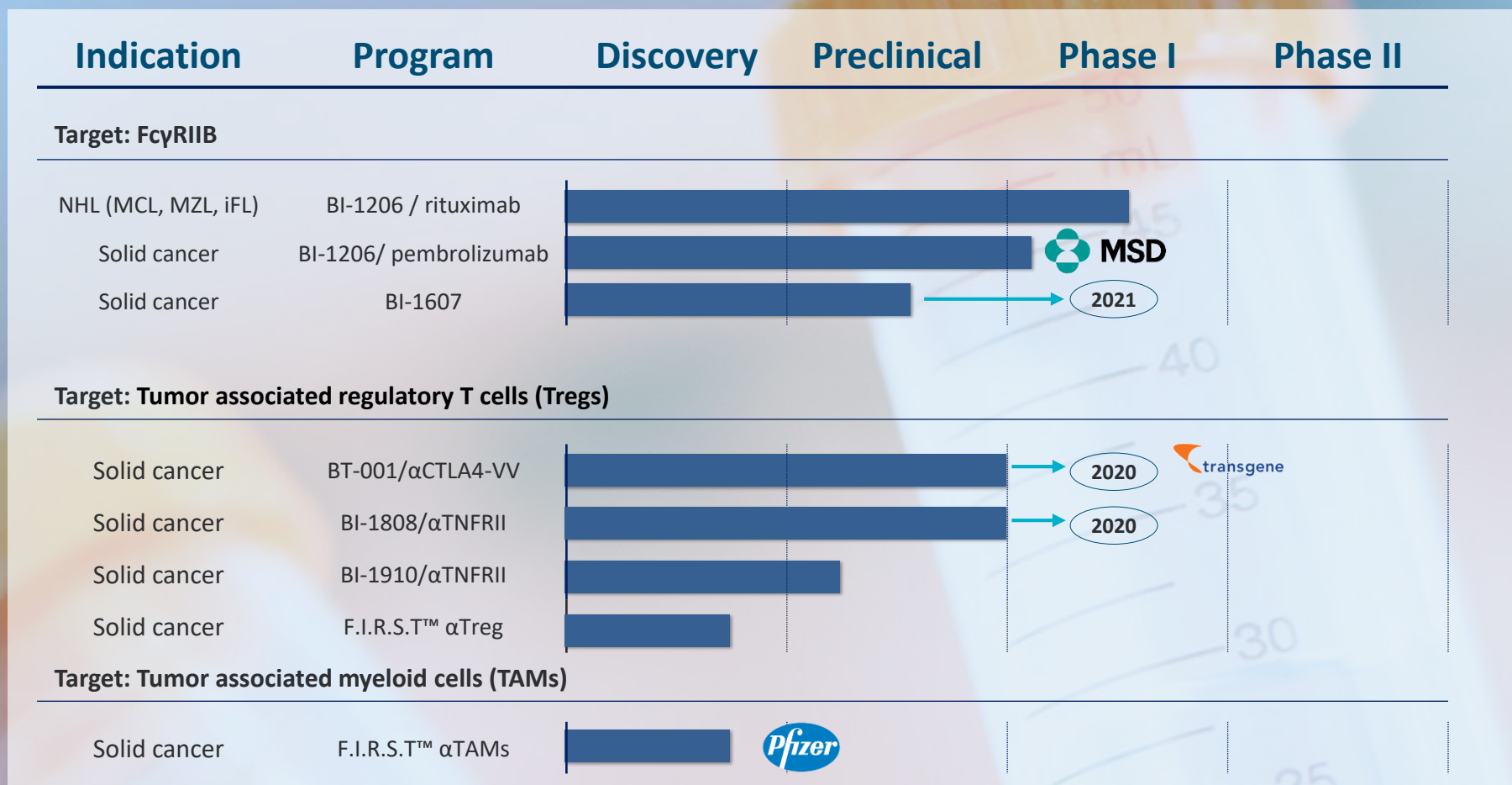
Products & Markets

Business development & Operations

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Appendix

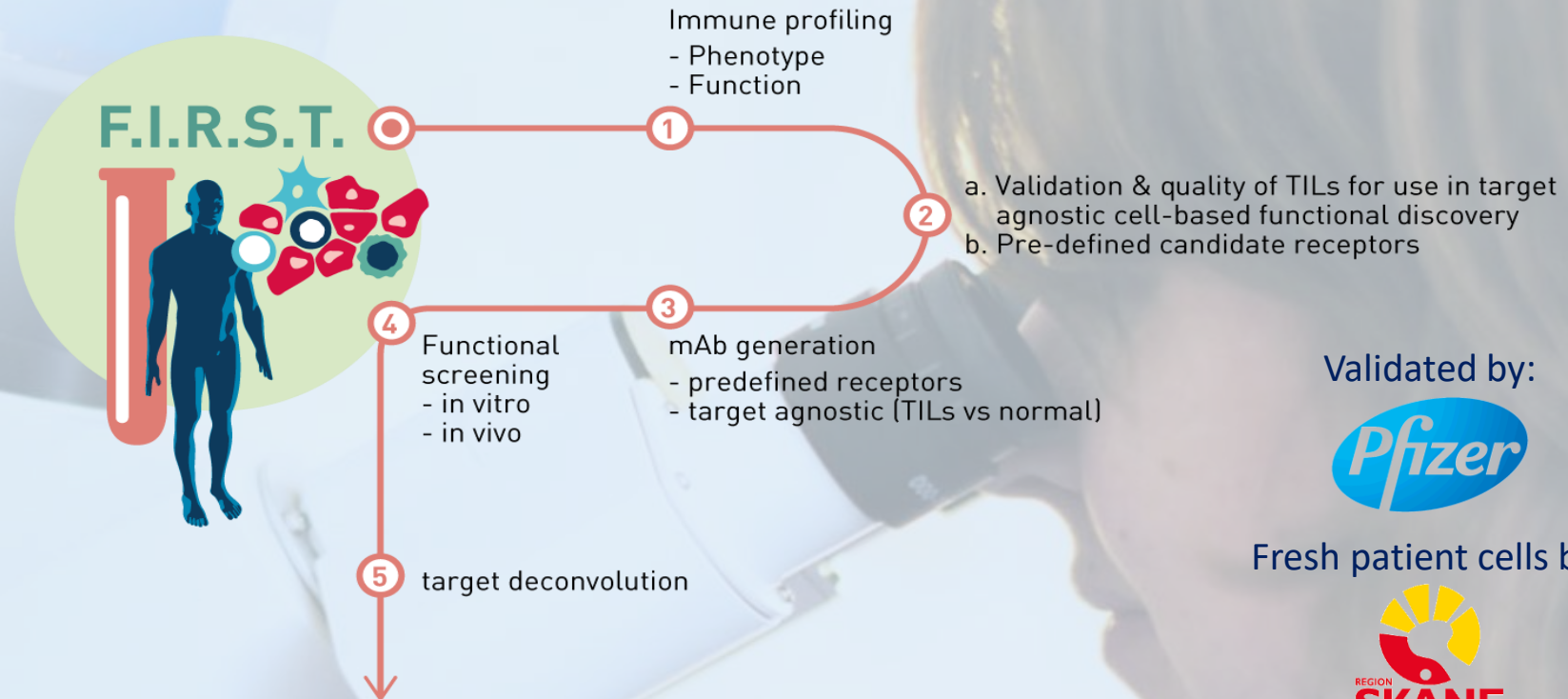
PIPELINE – MULTIPLE VALUE DRIVERS



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

BioInvent's proprietary platform

Fully integrated functional screening using proprietary models to identify relevant therapeutic targets



Validated by:



Fresh patient cells by:



Differentiators

1. Patient-Centric: development of the therapeutically most active antibodies using primary patient cells throughout discovery
2. Simultaneously identifies clinically relevant disease-associated targets and antibodies that bind to them
3. Allows for discovery of novel targets and mAbs

UPCOMING NEWS FLOW

Q4'19	✓ BI-1206 / pembrolizumab research and supply agreement with Merck (MSD) ✓ Pfizer selects second target for development from TAMs program collaboration ✓ BioInvent / Transgene announce promising preclinical data for BT-001 in solid tumors ✓ Promising preclinical data BI-1206 in mantle cell lymphoma presented at ASH 2019
2020	❑ Early results from Phase I open label study with BI-1206 / rituximab combination in indolent Non-Hodgkin Lymphoma (H2'2020) ❑ Potential additional milestones from collaborations ❑ Two new programs in the clinic – BT-001 and BI-1808
2021	❑ Early results from Phase I open label study with BI-1206 / pembrolizumab combination in solid tumors (H2'2021) ❑ Potential additional milestones from collaborations ❑ One new program in the clinic – BI-1607

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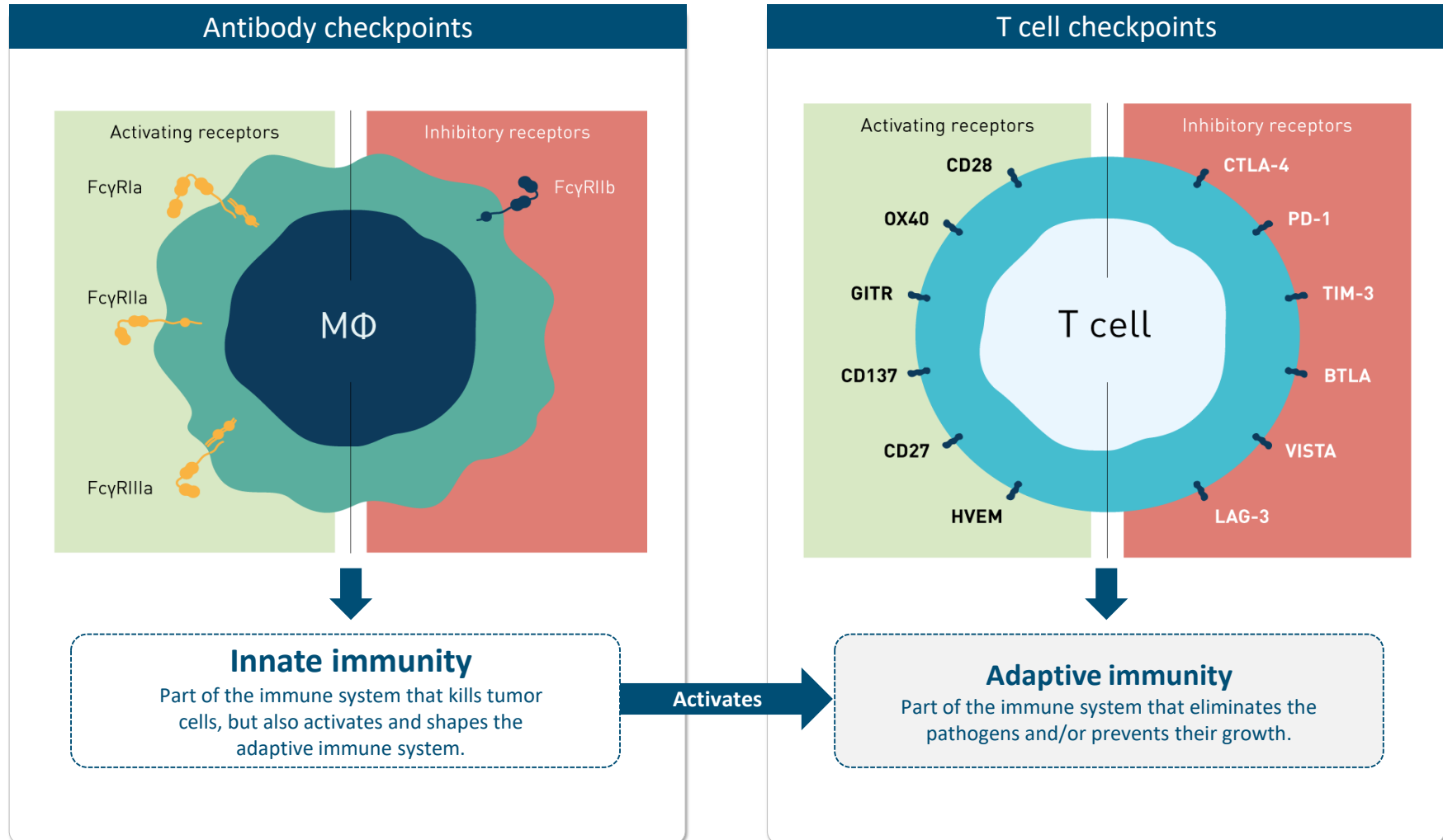
Summary

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BI-1206: PRODUCT OVERVIEW

Description	▪ BI-1206 blocks the FcγRIIB receptor ▪ Blocking FcγRIIB allows the immune system to find and kill the tumor cell by enhancing the anti-tumoral activity of other antibodies such as rituximab or anti-PD-1 antibodies
Opportunity	▪ Initially in development for relapsed or refractory indolent Non-Hodgkin Lymphoma (iNHL) patients who are resistant to rituximab ▪ The iNHL market potential for BI-1206 in the US is c. USD 200 million¹ ▪ BI-1206 can be expanded to treat other types of cancer – both liquid and solid tumors – significantly expanding the addressable population and market potential
Current status	▪ iNHL: currently in Phase I dose escalation, to be followed by a Phase IIa expansion cohort. Granted FDA Orphan Drug Designation for mantle cell lymphoma ▪ Solid tumors: initiating in H1'2020 – a Phase I dose escalation of BI-1206 + pembrolizumab will be followed by Phase IIa with expansion cohorts in different tumor types
Development path	▪ iNHL: Phase I/IIa open label study in relapsed or refractory iNHL patients enriched with mantle cell lymphoma – c. 24 patients across sites in US & EU – early results from Phase I expected in H2'2020 ▪ Solid tumors: Phase I/IIa study with advanced solid tumors who have relapsed or are refractory to anti-PD-1/PD-L1 – c. 60-70 patients across sites in US & SE – early results from Phase I expected in H2'2021

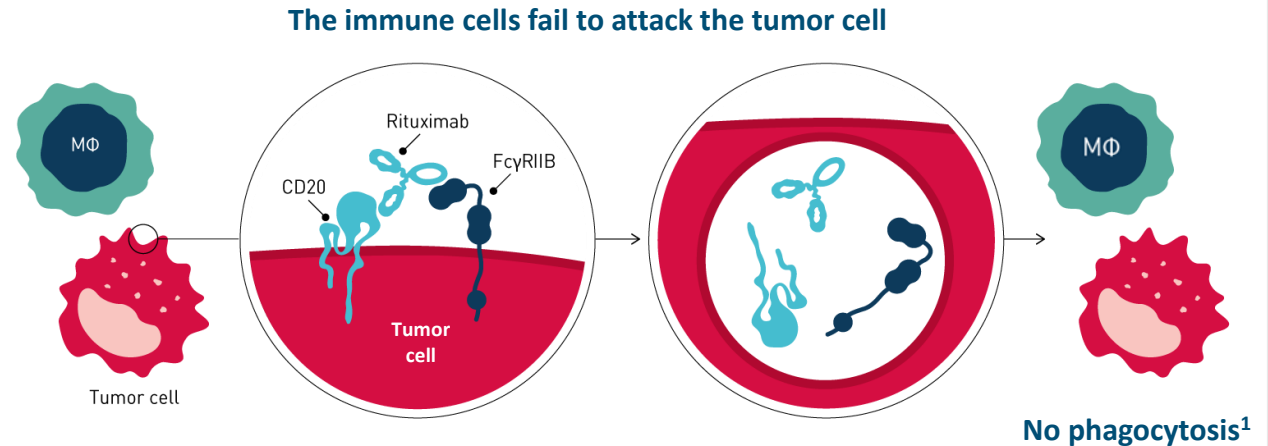
FcγRIIB – A SINGLE INHIBITORY ANTIBODY CHECKPOINT TO UNLOCK ANTI-CANCER IMMUNITY IN BOTH LIQUID AND SOLID TUMORS



BI-1206 IN NON-HODGKIN LYMPHOMA TURBOCHARGING ANTI-CD20

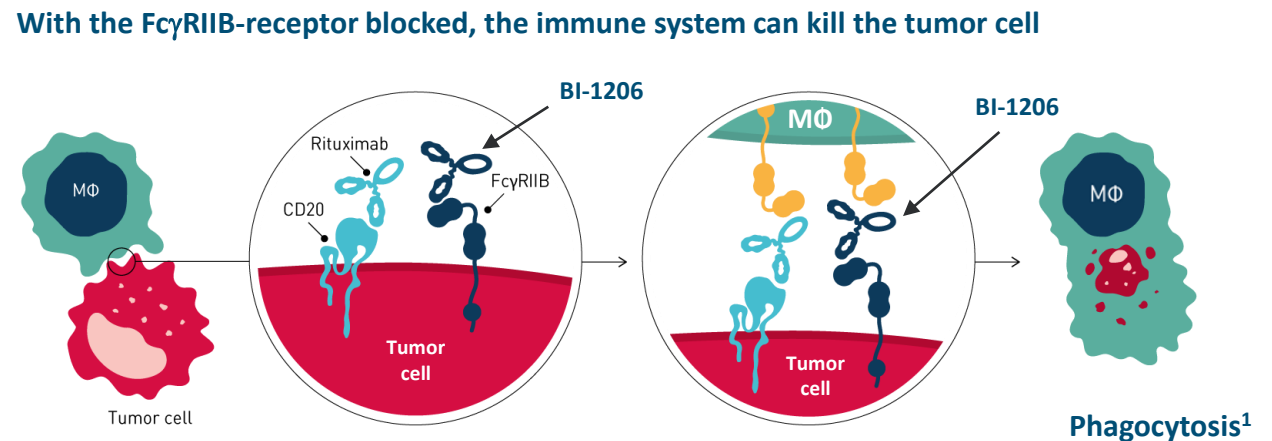
PRE BI-1206

- **Rituximab** (Roche's Rituxan® or Mabthera®) is a monoclonal antibody that kills malignant B cells by binding to **CD20** on the cell surface
- The **FcγRIIB**-receptor functions to remove rituximab from CD20, thus hampering its efficacy and protecting cancer cells from the immune system
- FcγRIIB overexpression is associated with a worse prognosis for the patient



POST BI-1206

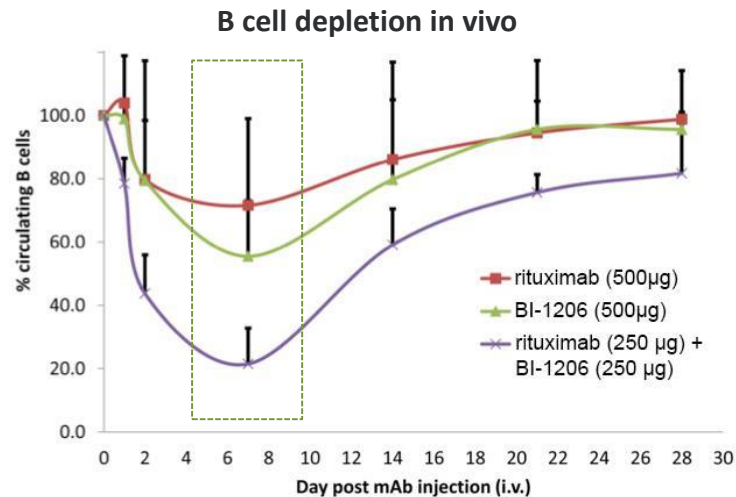
- **BioInvent's BI-1206** blocks the **FcγRIIB** receptor, suppressing the tumor's protection. Its activity helps restore and enhance rituximab's effect
- With the **FcγRIIB**-receptor blocked, a better anti-tumor activity is engaged allowing the immune system to find and kill the tumor cell



BI-1206 IN NON-HODGKIN LYMPHOMA: DUAL IMPACT ON B CELLS

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

Human CD20 FcγRIIB double transgenic mice



OBSERVATIONS

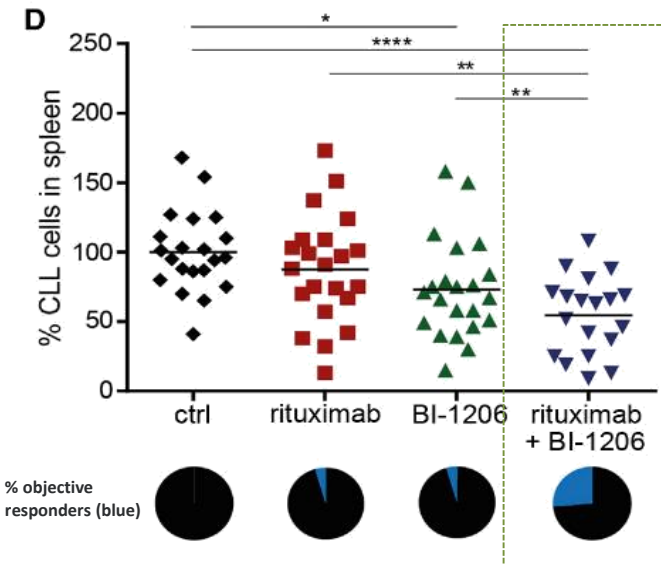
- By combining rituximab and BI-1206, results show a synergistically enhanced B cell depletion
- Validates the scientific rationale of the combination to decrease FcγRIIB-mediated endocytosis

**BOOSTING
RITUXIMAB'S EFFECT**



**OVERCOMING
RESISTANCE**

Humanized model of relapsed / refractory CLL¹



OBSERVATIONS

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

BI-1206 IN NON-HODGKIN LYMPHOMA:

VALUE PROPOSITION – KEY SEGMENTS & VALUE DRIVERS

BI-1206 value drivers

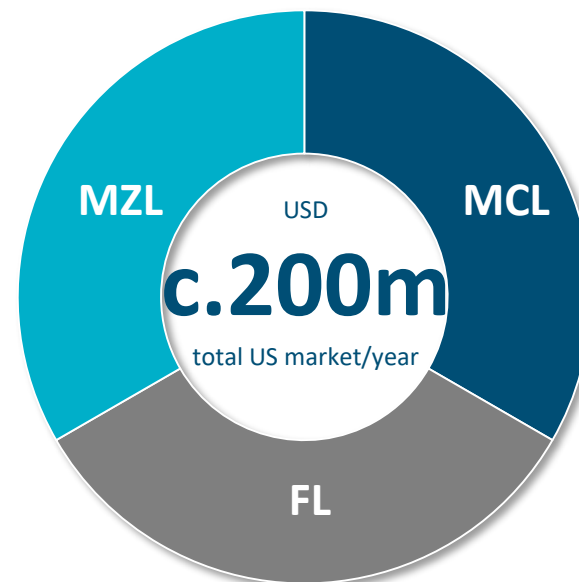
- Compelling scientific rationale in α -CD20 refractory B-cell lymphoma
- Chemo-free regimen
- Favorable safety profile
- Scalability of total addressable market

BI-1206 highlights

- First-in-class in hematology - no direct competitors
- High unmet need for chemotherapy-free, safer options in 2nd and 3rd lines
- Granted FDA Orphan Drug Designation for BI-1206 for MCL in January 2019

Possible label extension to all therapeutic areas where anti-CD20 mAbs are used (incl. autoimmune diseases)

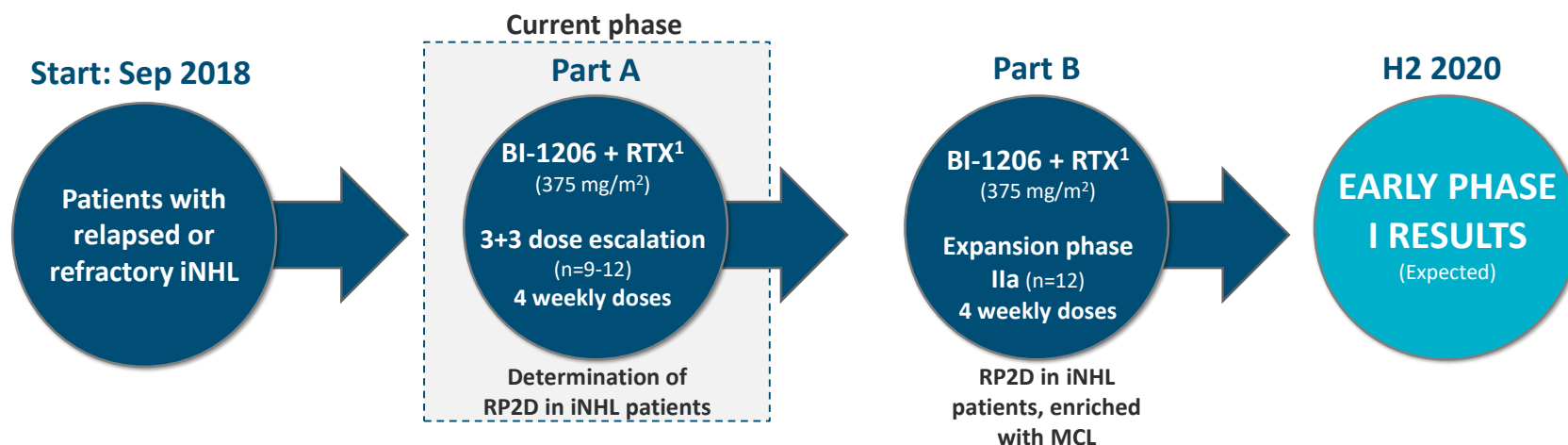
KEY SUB-SEGMENTS OF NON-HODGKIN LYMPHOMA (NHL)



- **Mantle Cell Lymphoma (MCL¹)** may be slow growing (indolent) but can also be fast-growing (aggressive). Usually diagnosed in people in their early 60s. Resistance to ibrutinib results in a very aggressive disease with few treatment options
- **Follicular Lymphoma (FL¹)** is the most common form of slow-growing non-Hodgkin lymphoma
- **Marginal Zone Lymphoma (MZL¹)** is a slow growing type of B cell lymphoma with a median age of diagnosis of 65 years

BI-1206 IN NON-HODGKIN LYMPHOMA: PHASE I/IIA STUDY

STUDY OVERVIEW



STUDY OBJECTIVES

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

INCLUSION CRITERIA

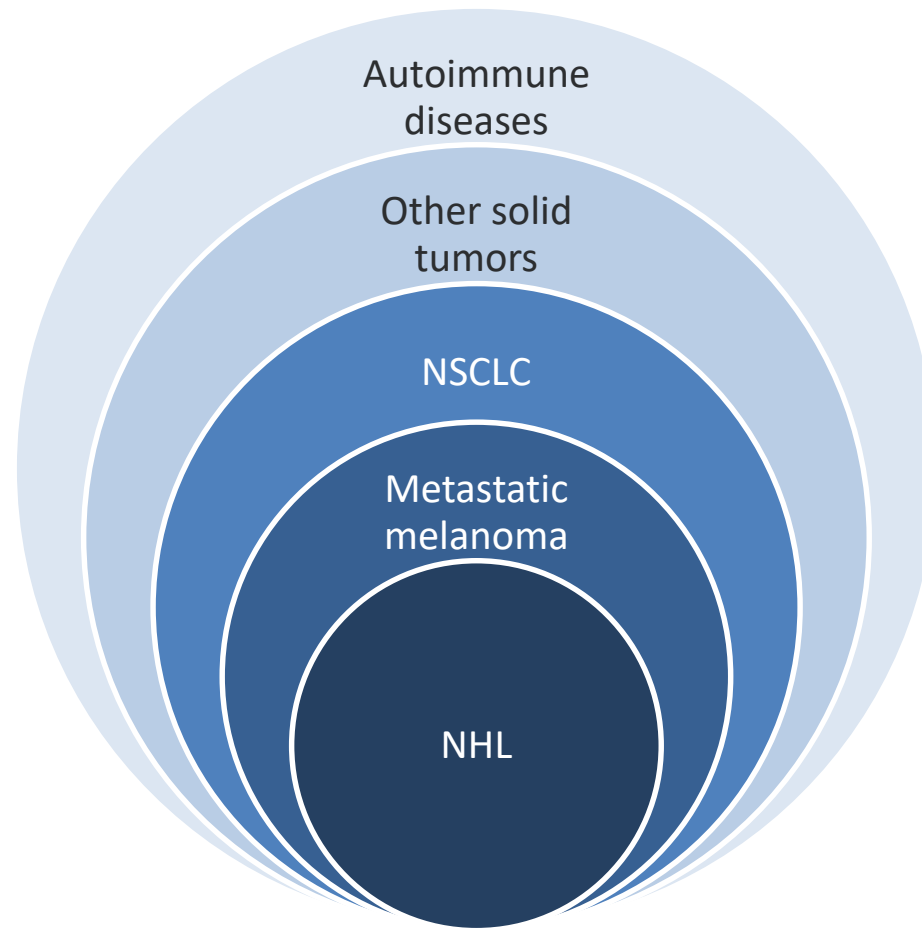
- Patients must have relapsed disease or disease (R/R) that is refractory to conventional treatment or for which no standard therapy exists.
- Lack of CR or PR during rituximab-containing treatment.
- Occurrence of progressive disease after completion of a regimen of rituximab-containing therapy.

BI-1206 IN NON-HODGKIN LYMPHOMA: PROMISING PRELIMINARY DATA FROM PHASE I/IIA STUDY

- Preliminary data shows early signs of efficacy
 - In the 30 mg cohort:
 - 1 patient with FL remained on treatment for the full maintenance period (1 year)
 - 1 patient with blastoid Mantle Cell lymphoma, showed complete depletion of circulating MCL cells after BI-1206 infusion
 - In the 70 mg cohort:
 - 1 FL patient has achieved a complete response
 - As described by the clinical investigator, the patient “has a very good general condition without toxicity”
- All responses observed thus far have been at dose levels that are below what is believed to be optimal
- The dose escalation continues as planned with additional data expected in H2’2020

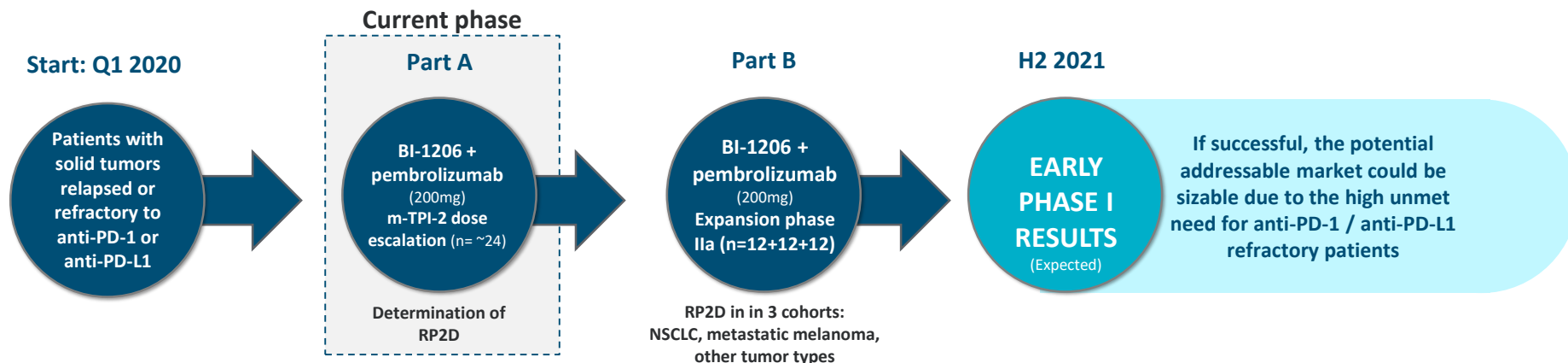
BI-1206 POSSESSES SUBSTANTIAL INDICATION GROWTH POTENTIAL

ESTABLISHING PROOF OF CONCEPT IN CERTAIN INDICATIONS CAN LEAD TO RAPID GROWTH IN TOTAL ADDRESSABLE MARKET



BI-1206 IN SOLID TUMORS: PHASE I/IIA STUDY WITH MERCK

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)

TREGS AND TAMS IN SOLID TUMORS: PRODUCT OVERVIEW

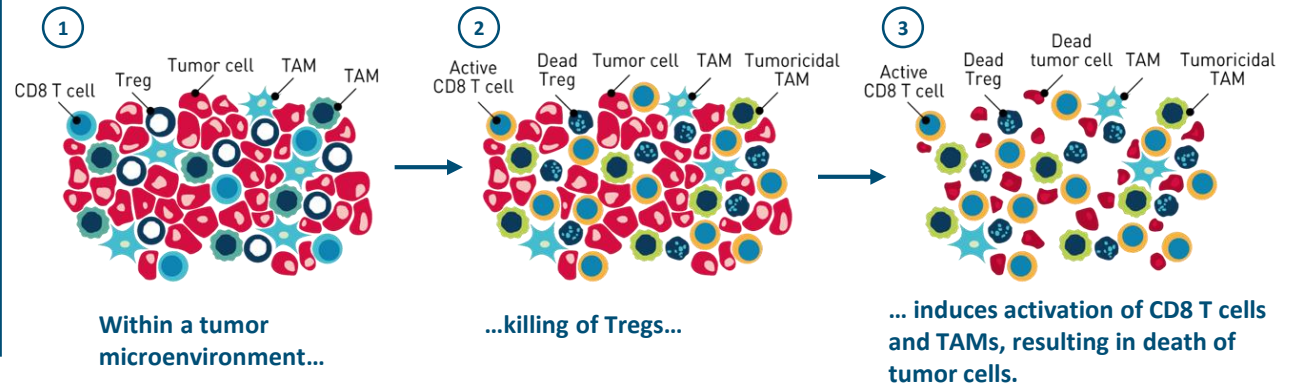
Description	▪ Identifies and characterizes new targets and monoclonal antibodies to cancer-associated Regulatory T cell (Treg) ▪ Discovers novel targets and therapeutic antibodies that may reverse or reduce tumor-associated myeloid cells (TAMs), which are immunosuppressive in nature
Opportunity	▪ Harnessing the immune system to kill tumor cells with potential across a variety of cancer types ▪ Validating technology access partnership with Pfizer, which is not exclusive allowing for further collaboration and market opportunity
Current status	▪ CTA for most advanced candidate, BI-1808 (anti-TNFR2), within the Treg program is expected to be submitted in H1'2020 ▪ Ongoing discovery efforts for new targets and antibodies to TAMs that will be available for development
Development path	▪ Opportunities for partnering and/or out-licensing of various targets is being explored

TARGETING TREGS AND TAMs TO MITIGATE IMMUNE SUPPRESSION

TARGETING TREGS

- 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 cancer-associated Treg targets in a function-first, target-agnostic manner
- BioInvent is also pursuing differentiated antibodies to known targets through novel mechanisms and pathways

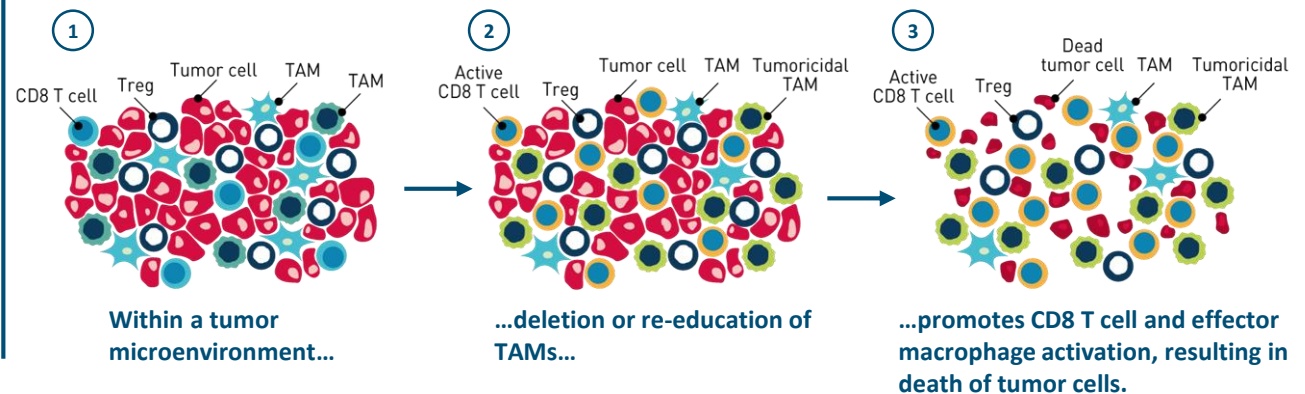
Developing antibodies that act on Tregs via novel or validated targets



TARGETING TAMs

- 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

Strategic collaboration with Pfizer – developing antibodies that act on TAMs



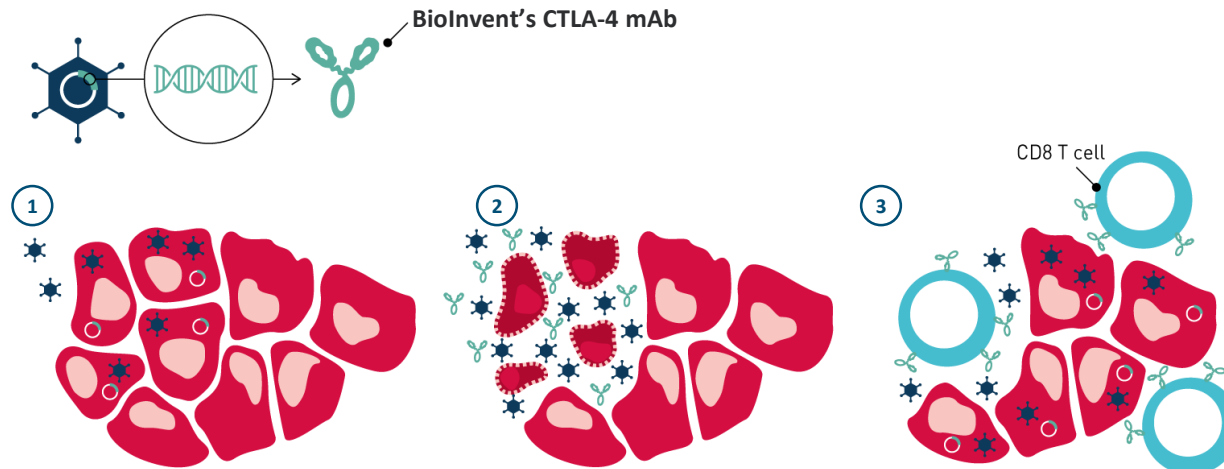
BT-001 IN SOLID TUMORS: PRODUCT OVERVIEW

Description	▪ Collaboration with Transgene to co-develop oncolytic virus candidates encoding an anti-CTLA-4 antibody sequence, potentially with additional transgenes, aimed at treating solid tumors ▪ The collaboration costs and profit are shared 50/50
Opportunity	▪ Builds on 3 clinically validated axes (CTLA-4, aPD-1/PD-L1, oncolytic viruses), with expected enhanced efficacy and improved tolerability in a variety of tumor types including metastatic melanoma, cutaneous melanoma, renal cell carcinoma, non-small cell lung cancer
Current status	▪ A clinical trial application was submitted in March 2020
Development path	▪ The plan is to have FPI before the end of 2020

BT-001: MABS + ONCOLYTIC VIRUS TO TARGET SOLID TUMORS

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, which improves safety profile

Process

1

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

2

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

3

- Intratumorally produced anti-CTLA-4 depletes tumor Treg and induces T effector activation
- Tumor antigens are taken up by APCs fuelling activation of Tumor-specific T cells
- Systemic adaptive anti-tumor responses are induced and boost the “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. Additionally, its proprietary Vaccinia viruses, designed to directly and selectively destroy cancer cells by intracellular replication of the virus in the cancer cell, will be utilized
- 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.™ platforms.
- **Cost and profits are shared 50/50** between Transgene and BioInvent

Clinical status



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PARTNERSHIPS & COLLABORATIONS

Active partnerships & collaborations



- Partners since December 2016, first target discovered in July 2019, second target in December 2019
- BioInvent is eligible for potential future development milestones in excess of USD 500 million as well as double digit royalties



- Co-developing (50/50 split of costs and profits) of oncolytic virus candidates for solid tumors, leveraging BioInvent's n-CoDeR® and F.I.R.S.T™ platforms
- Sharing of technology platforms, knowledge, and expertise



- Clinical supply and collaboration partnership



- Antibody discovery partnerships
- Validation of n-CoDeR® antibody library



- Research collaborations

PROPRIETARY MANUFACTURING PLATFORM SINCE 1988



Provided courtesy of EMD Millipore Corporation

BioInvent has ample experience with in-house production of antibodies ensuring that no delays will occur when scaling up production to meet the demand for the various clinical trials

- Supports fast and flexible production of proprietary programs
- Approved for Phase I to III production
- State of the art single use bioreactor (SUB) technology: 40L -1,000L batch sizes
- 30 year track record of clean inspections
- Consistent source of near term revenues from external customers (Signing of manufacturing agreement with Cancer Research UK in 2019)
- BioInvent has produced drug substance for clinical trials in Europe, USA and Japan
- The production facility is located in Lund, Sweden

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UPCOMING NEWS FLOW

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2020	❑ Early results from Phase I open label study with BI-1206 / rituximab combination in indolent Non-Hodgkin Lymphoma (H2'2020) ❑ Potential additional milestones from collaborations ❑ Two new programs in the clinic – BT-001 and BI-1808
2021	❑ Early results from Phase I open label study with BI-1206 / pembrolizumab combination in solid tumors (H2'2021) ❑ Potential additional milestones from collaborations ❑ One new program in the clinic – BI-1607

DATA AVAILABLE AT CONFIDENTIAL LEVEL

ANTI-FcγRIIB BI-1206 & BI-1607	❑ FcγRIIB confers local resistance in the tumor microenvironment to antibody-based therapy, including anti-PD1, anti-PDL1 and anti-CTLA4 (and many others) ❑ Detailed efficacy and MoA data evaluating BI-1206 and BI-1607 differential uses with immune checkpoint blockers to enhance efficacy, overcome resistance and improve therapeutic window
Anti-TNFR2 BI-1808	❑ Preclinical rationale to develop two types of anti-TNFR2 with distinct molecular properties and MoA's, and potentially different applications ❑ Therapeutic effects in solid cancer models spanning “hot” and “cold” tumors ❑ Combination studies and synergistic activity with anti-PD-1 agents ❑ Careful mechanistic evaluation of matched Lead Human Candidate and surrogate antibodies for thorough understanding of TNFR2-targeting and critical guidance of clinical development ❑ BI-1808 Full GLP tox and PK to support planned clinical development
Anti-CTLA-4 OV BT-001	❑ Scientific rationale to develop tumor-targeted anti-CTLA-4 onco-virotherapy ❑ Careful preclinical characterization of unique Treg-depleting anti-CTLA-4 antibody, including benchmarking and differentiation from ipilimumab ❑ Therapeutic effects across wide range of solid cancers ❑ Therapeutic window ❑ Early tox data to support planned clinical development
Anti-TAM	❑ Human intratumoral expression profiling of three targets 100% proprietary to BioInvent ❑ Early in vivo data for one of these targets

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MANAGEMENT TEAM



Martin Welschhof

Chief Executive Officer
Holdings: 125,000 shares

Ph.D. (Dr.rer.nat.) in recombinant antibody technology. Born 1961. Lives in Oslo, Norway. Employed since 2018. He did his post-doctoral training at the German Cancer Research Center, Department for Recombinant Antibody Technology and at the University of Heidelberg, Department of Transplantation Immunology both in Heidelberg, Germany. Martin has a broad international experience from executive positions within the biotech industry, including Director of Technology at Axaron Bioscience AG, Heidelberg, Germany, CEO of Affitech (Nasdaq Copenhagen) and CEO of Opsona Therapeutics, Dublin, Ireland. Member of the Board of APIM Therapeutics, Nextera and Uni Targeting Research.



Stefan Ericsson

Chief Financial Officer
Holding: 145,892 shares; 115,825 options

MBA, Lund University. Born 1963. Lives in Lund, Sweden. Employed since 1998. Chief Financial Officer since 2016 and has previously served as Director Business Control. He was employed by the Swedish Tax Authority 1996–1997. Previously he worked as an auditor at PricewaterhouseCoopers 1990–1995.



Björn Frendéus

Chief Scientific Officer
Holdings: 483,083 shares; 270,258 options

Doctor of Immunology. Born 1973. Lives in Lund, Sweden. Employed since 2001. Graduated from the Swedish Foundation for Strategic Research funded Biomedicine programs within the Infection & Vaccinology program. Visiting Professor at University of Southampton.



Kristoffer Rudenholm Hansson

Senior Vice President, Technical Operations
Holdings: 522,882; 114,059 opt.

Master of Science in Chemical engineering. Born 1974. Lives in Malmö Sweden. Employed since 2016 and is responsible for process development and production of antibodies for clinical studies. He has more than 15 years' experience from managing manufacturing of antibodies and other proteins for clinical use. Kristoffer has held a numerous positions within CMC Biologics A/S, DAKO A/S and Symphogen A/S.



Andres McAllister

Chief Medical Officer
Holdings: 91,656 options

Doctor in Medicine and Surgery from the Universidad del Rosario (Bogotá), and holds a PhD from the Pasteur Institut/Université Paris. Born 1956. Lives in Geneva, Switzerland. He has performed academic work at the Pasteur Institut and the University of California San Francisco on cancer immunotherapy. Andres joins BioInvent from a position as Chief Scientific Officer at Debiopharm, and has previously held senior roles at IDM and BioMérieux/Pierre Fabre.

Scientific Advisory Board

- **Mark Cragg (Chairman)**, Professor of Experimental Cancer Research within Medicine at the University of Southampton and is director of the i4PhD Cancer Immunology Pathway. Dr. Cragg's group is interested in two main areas - antibodies and small molecule inhibitors with the aim of understanding how these therapeutics function to delete tumor cells and how they might be augmented.
- **Falk Nimmerjahn**, Professor in experimental immunology and immune therapy at the Friedrich-Alexander University Erlangen-Nürnberg. Leading scientist within FcγR biology and its impact on the therapeutic efficacy and tolerability of antibodies.
- **Rienk Offringa**, Professor at the German Cancer Research Center. Head of a European consortium engaged in immune stimulating anti-cancer antibodies. Formerly Principal Scientist at Genentech.
- **Tony Tolcher**, former Director of Clinical Research at South Texas Accelerated Research Therapeutics (START) and now active in the company NEXT Oncology. Dr. Tolcher specializes in early phase clinical testing of exploratory anti-cancer drugs.
- **Alexander Rudensky**, Chair of the Immunology Program at Sloan Kettering Institute. Dr Rudensky is a world-leading scientist within the area of regulatory T-cells, specialized in CD4-T cell regulation and homeostasis, and its role in autoimmunity and cancer.
- **Stephen Beers**, Professor of Immunology and Immunotherapy at the Centre for Cancer Immunology in the Faculty of Medicine at the University of Southampton. Dr. Beers' group is interested in how antibodies work to result in tumor regression and how the tumor microenvironment can be manipulated to enhance antibody efficacy in patients.

BOARD OF DIRECTORS



Leonard Kruimer

Chairman

Holdings: 319,720



MBA, CPA in the New York State. Resident of the Netherlands. He served as a Board Member in BioInvent between 2016–2017. He served as CFO and member of the board of Crucell NV from 1998 to 2011. He held senior executive positions at Royal Boskalis N.V., GE Capital and Continental Can Company. Chairman of the Board since 2018. Chairman of the Remuneration Committee and member of the Audit Committee. Born 1958.



Vessela Alexieva

Board member

Holdings: 20,850 shares

M.Sc. in Molecular and Functional biology. Lives in Lund, Sweden. Senior Research Engineer. Member of the Board since 2013. Born 1959.



Kristoffer Bissessar

Board member

Holdings: 200,000 shares

Broad experience from the financial industry, operative in banking and finance between 1989 – 2012, with experience from asset management, institutional equity sales and investment banking. Previously held senior positions at Svenska Handelsbanken AB, Deutsche Bank AG and Nordea Bank AB and served as board member of the Swedish Securities Dealers Association. Board member of BioInvent during 2018-2019. Member of the Board since 2020. Chairman of Audit Committee. Born 1968.



Dharminder Chahal

Board member

Holdings: 5,882,661 shares



M.Sc. in Aerospace Engineering and M.Sc. in Business Economics. Lives in the Netherlands. CEO of SkylineDx since 2013. He is also currently the Managing Director at Exponential BV and Fund Manager at Swanbridge Capital. Extensive board experience within life science, in current and previous board roles at Agendia, Bioinvent (2013-2016), deVGen, Innate Pharma, and OctoPlus. Member of the Board since 2017. Chairman of the Audit Committee. Born 1976.



An van Es Johansson

Board member

Holdings: 183,584 shares



M.D. Lives in Stockholm, Sweden. Previously different executive positions in Clinical Development, Medical Affairs, Business Development and Commercial within Swedish Orphan Biovitrum, Eli Lilly, Roche, Pharmacia & Upjohn and biotech companies in USA, the Netherlands, Switzerland and Sweden. Member of the BioInvent Board since 2016. Member of the Remuneration Committee. Born 1960.



Thomas Hecht

Board member

Holdings: -

Doctor of Medicine. Previously experience as Vice President Marketing at Amgen Europe, and has held various positions of increasing responsibility in clinical development, medical affairs and marketing at Amgen between 1989 and 2002. Prior to joining the biopharmaceutical industry, Thomas Hecht was certified in internal medicine and served as Co-Head of the Program for Bone Marrow Transplantation at the University of Freiburg, Germany. Currently Managing Partner at HHC Healthcare Consulting. Member of the BioInvent Board since 2020. Born 1951.



Anette Mårtensson

Board member, Employee Representative

Holdings: 5,563

Master's degree in protein chemistry. Analytical Engineer. Previously laboratory engineer at Innovagen AB and laboratory assistant at Lund University. Born 1982.



Bernd Seizinger

Board member

Holdings: 107,464



Doctor of Medicine and Doctor of Neurobiology. Lives in Stockton, New Jersey, USA. Serves currently as chairman and board member in a number of biotech companies in the U.S., Europe and Canada. Previously President & CEO of GPC Biotech, Executive Vice President and Chief Scientific Officer of Genome Therapeutics. Vice President of Oncology Drug Discovery and - in parallel - Vice President of Corporate and Academic Alliances at Bristol-Myers Squibb. Senior Faculty

Bernd Seizinger cont'd

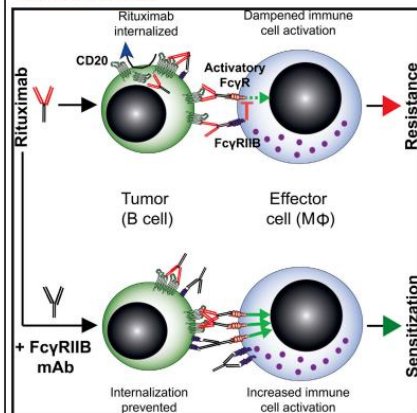
Member at Harvard Medical School, Massachusetts General Hospital, and Princeton University. Member of the BioInvent Board since 2018. Chairman of the Science Committee, and member of the Remuneration Committee. Born 1956.

VALIDATION BY TIER-1 SCIENTIFIC JOURNALS

Cancer Cell

Antagonistic Human Fc γ RIIB (CD32B) Antibodies Have Anti-Tumor Activity and Overcome Resistance to Antibody Therapy In Vivo

Graphical Abstract



Highlights

- Fully human hFc γ RIIB (CD32B) antibodies overcome resistance to therapeutic antibodies
- hFc γ RIIB mAbs augment standard-of-care anti-CD20 therapy in vitro and in vivo
- hFc γ RIIB mAbs restore drug responsiveness in refractory CLL cells in vivo
- hFc γ RIIB mAbs help overcome cell- and niche-specific resistance mechanisms

Authors

Ali Roghanian, Björn Frenndéus

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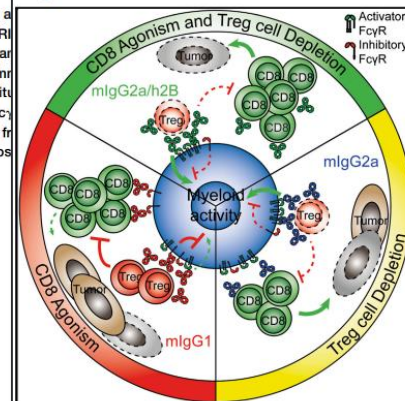
In Brief

Roghanian et al. reveal that blocking Fc γ RI of anti-CD20 is maximizing immune-mediated antibody targeting of Fc γ in xenografts for clinically relapse

Immunity

Antibodies to Costimulatory Receptor 4-1BB Enhance Anti-tumor Immunity via T Regulatory Cell Depletion and Promotion of CD8 T Cell Effector Function

Graphical Abstract



Highlights

- Anti-4-1BB IgG2a depletes intratumoral Treg cells; IgG1 promotes CD8 T cell function
- The efficacy of anti-4-1BB mIgG1 and anti-4-1BB mIgG2a depends on different Fc γ Rs
- Optimal tumor therapy requires sequential anti-4-1BB IgG2a and IgG1 or PD-1 blockade
- Hinge-engineered anti-4-1BB mIgG2a/h2B mAb harnesses both mechanisms of action

Authors

Sarah L. Buchan, Lang D. Marcus Remer, ..., Juliet Aymen Al-Shamkhani, Stephen A. Beers

Correspondence

j.c.gray@soton.ac.uk (J.C.G.), a.al-shamkhani@soton.ac.uk (A.A.S.), sab@soton.ac.uk (S.A.B.)

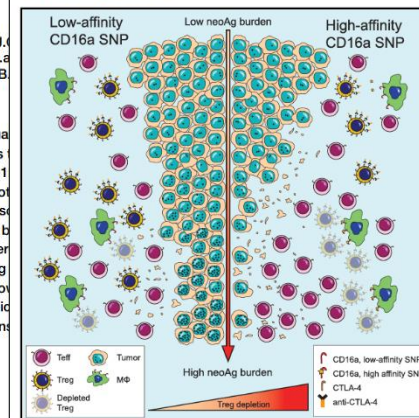
In Brief

Buchan et al. reveal dual activities for antibodies stimulating receptor 4-1BB and checkpoint blockade and antibodies engineered both Treg cell depleting agonism properties show tumor activity in preclinical the groundwork for translation.

Cancer Cell

Fc Effector Function Contributes to the Activity of Human Anti-CTLA-4 Antibodies

Graphical Abstract



Highlights

- Anti-CTLA-4 of hIgG1 and hIgG2 isotypes promote depletion of intra-tumoral Treg cells
- hIgG2 antibodies mediate *in vivo* depletion of intra-tumoral Treg cells via CD32a
- Anti-CTLA-4 with enhanced Fc effector function improves therapeutic outcomes
- The CD16-V158F SNP is associated with response to ipilimumab in inflamed tumors

Authors

Frederick Arce Vargas, Andrew J.S. Furness, Kevin Litchfield, ..., Charles Swanton, Karl S. Peggs, Sergio A. Quezada

Correspondence

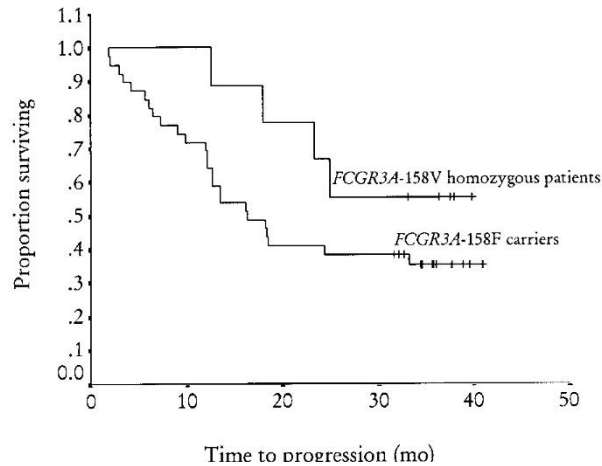
k.peggs@ucl.ac.uk (K.S.P.), s.quezada@ucl.ac.uk (S.A.Q.)

In Brief

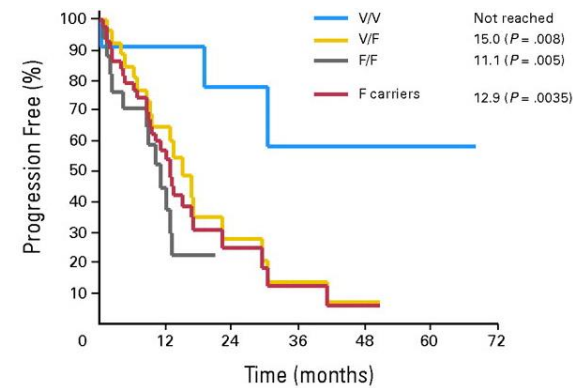
Arce Vargas et al. use a mouse model expressing human Fc γ Rs to show that antibodies with isotypes equivalent to ipilimumab increase the CD8⁺ to Treg ratio by depleting intra-tumoral Tregs to promote tumor rejection. In melanoma patients, response to ipilimumab is associated with a high affinity Fc γ R polymorphism.

ANTIBODY Fc:FcγR-INTERACTIONS DETERMINE TUMOR-TARGETING MAb EFFICACY

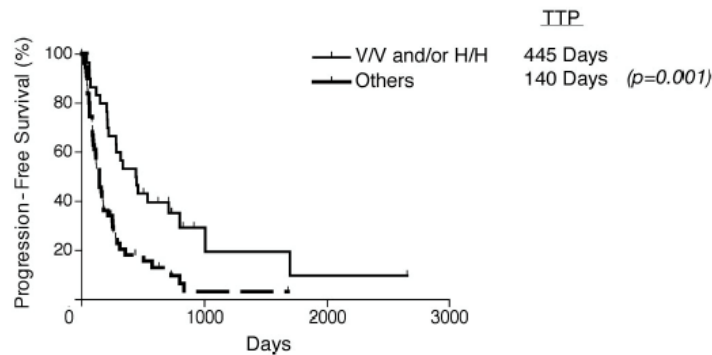
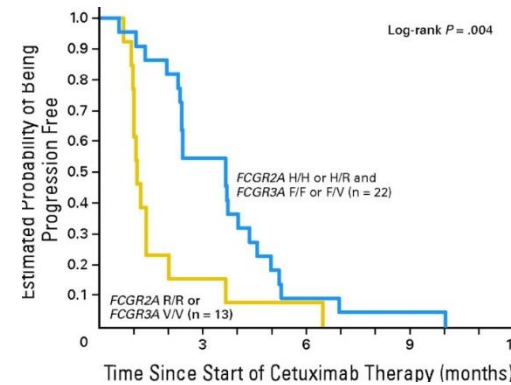
rituximab (anti-CD20) - NHL



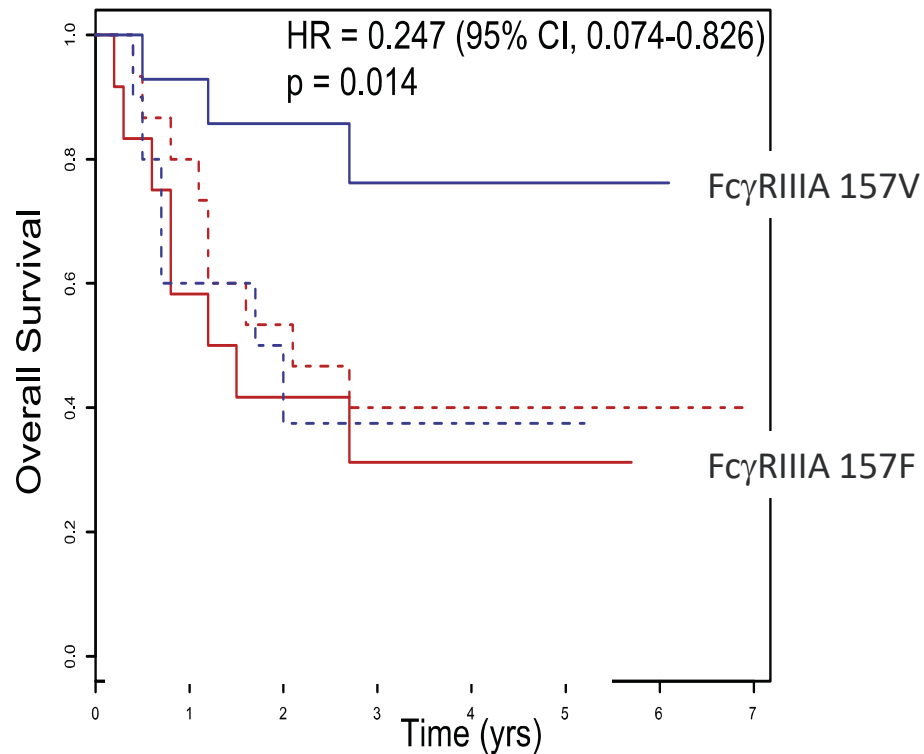
herceptin (anti-Her2) - breast cancer



cetuximab (anti-EGFR) – colorectal cancer



IPIILIMUMAB HAS FcγR-DEPENDENT ANTITUMOR IMMUNITY

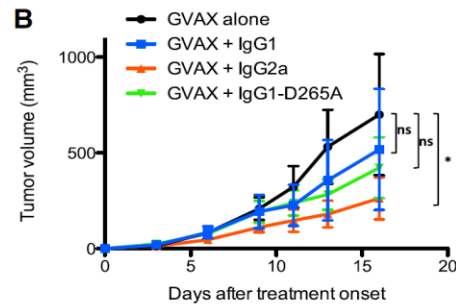
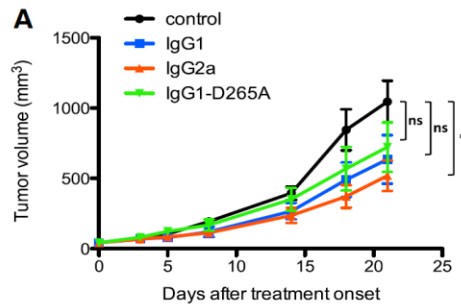


- Two cohorts of melanoma patients treated with ipilimumab
- Activating antibody checkpoint polymorphism (FcγRIIIa V157F) associated with survival
 - Only in inflamed (T cell infiltrated) tumors (solid lines)

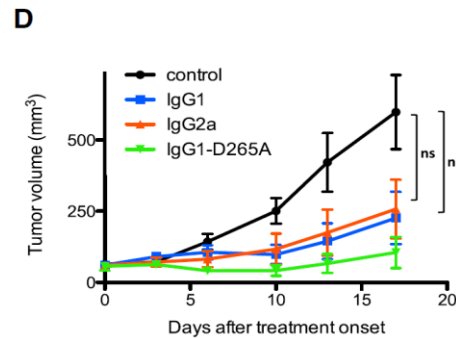
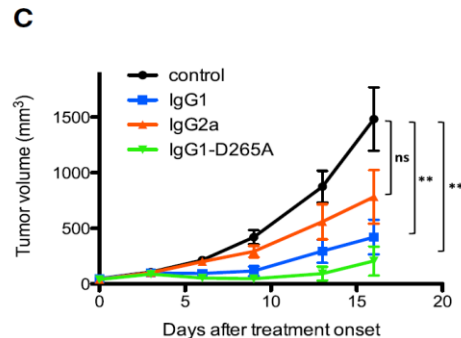
Fc γ R-INTERACTIONS MODULATE THE ANTI-TUMOR ACTIVITY OF ANTIBODIES TARGETING PD-1/PD-L1 AXIS

"Fc γ R engagement augments the anti-tumor activity of anti-PD-L1 Abs but compromises the anti-tumor activity of anti-PD1 Abs."

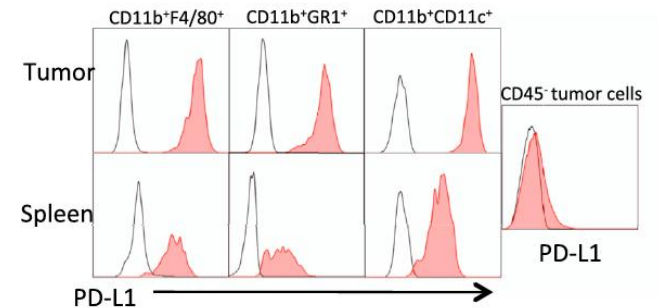
Anti-PD-L1



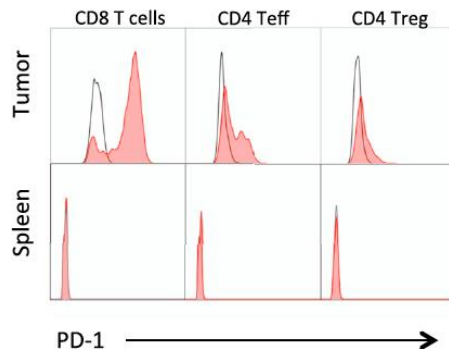
Anti-PD-1



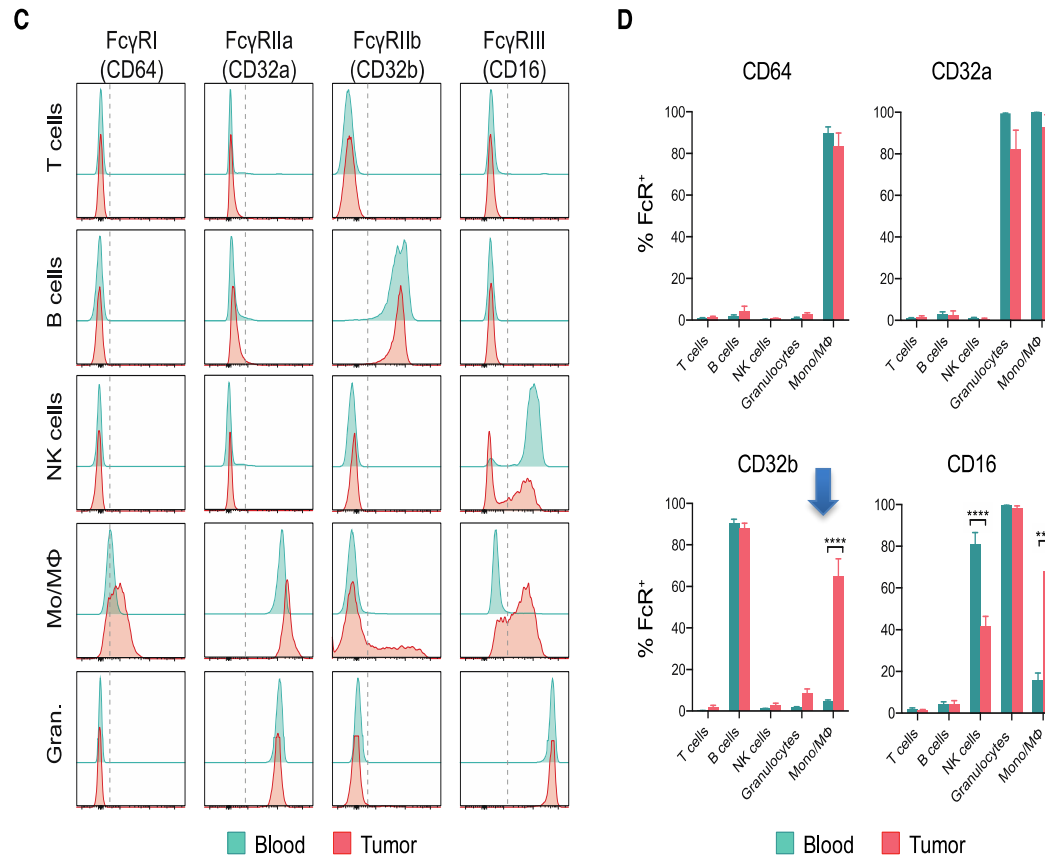
TAM vs effector M Φ PD-L1 expression



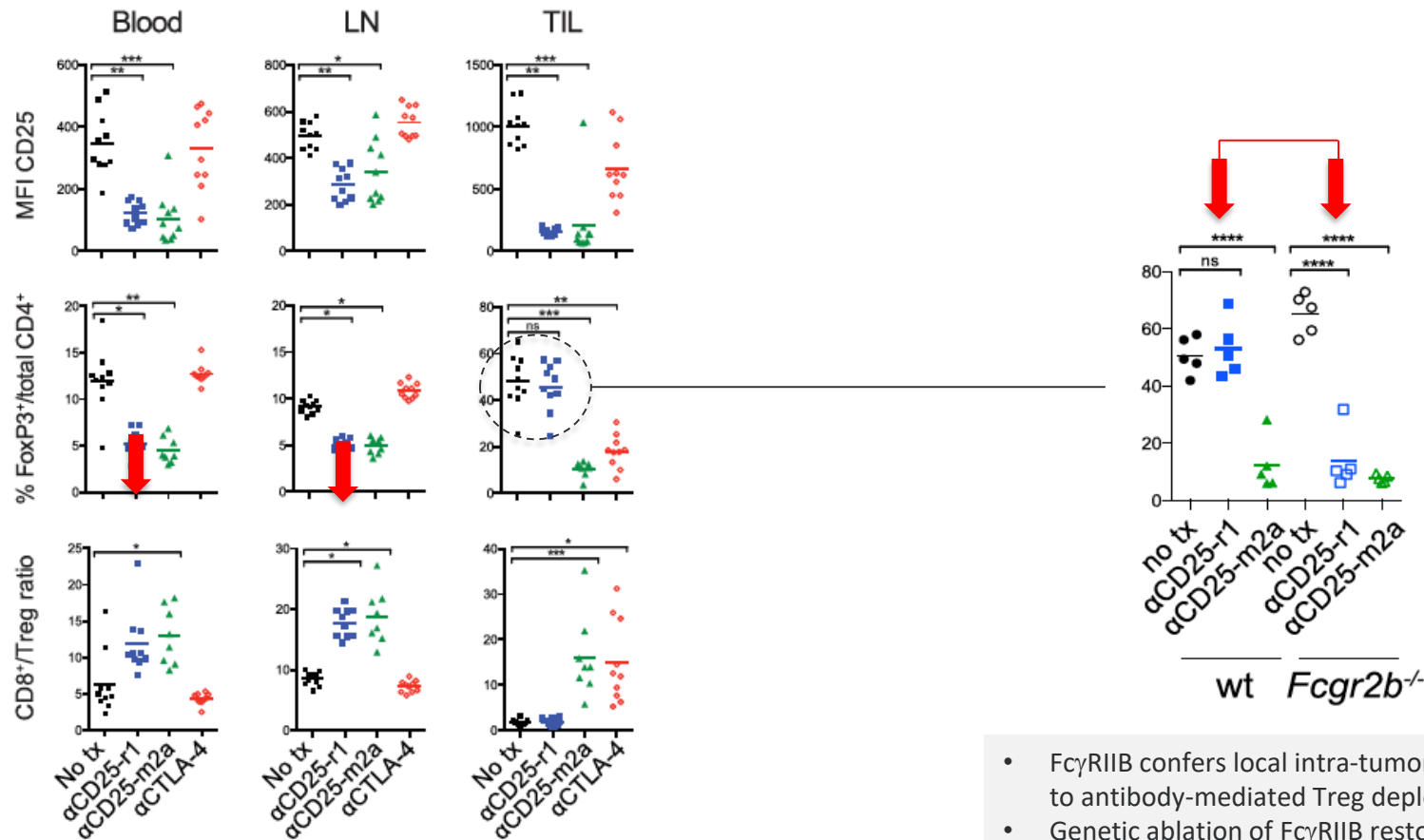
CD8 vs Treg PD-1 expression



FC γ RIIB IS STRONGLY UPREGULATED ON IMMUNE EFFECTOR CELLS IN THE HUMAN TUMOR MICROENVIRONMENT



FcγRIIB CONFERS LOCAL RESISTANCE TO ANTIBODY-THERAPY IN TUMORS



- Antibody-mediated Treg depletion is effective in blood and in lymph nodes (red arrows)
- The tumor is resistant to antibody-mediated Treg depletion (dotted circle)

- FcγRIIB confers local intra-tumoral resistance to antibody-mediated Treg depletion
- Genetic ablation of FcγRIIB restores antibody-mediated intra-tumoral depletion of Treg

SELECTED 2019 MILESTONES

Regulatory & Clinical

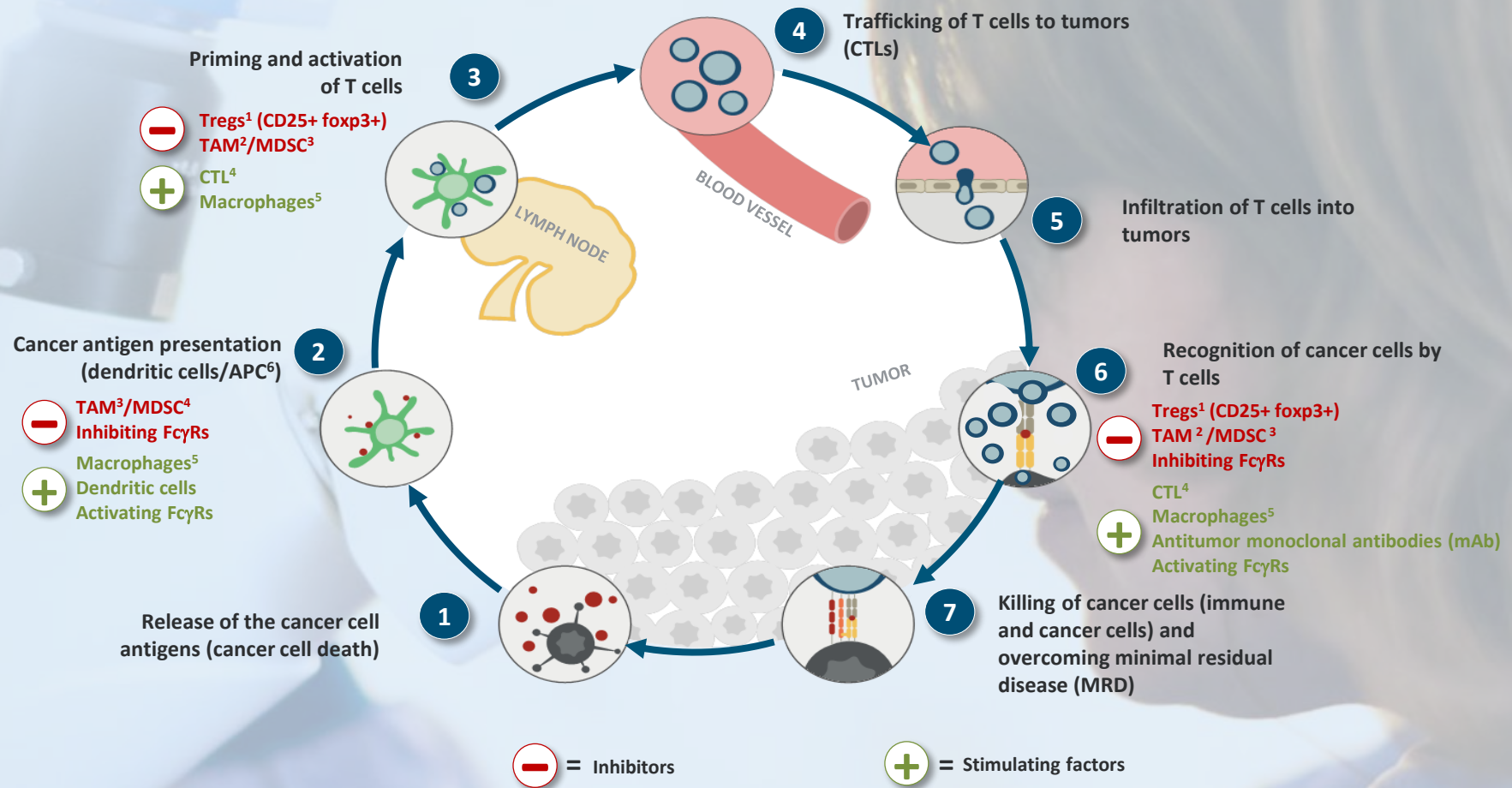
- Presented BI-1206 preclinical data in mantle cell lymphoma at ASH 2019. Single agent BI-1206 had potent anti-MCL activity in the FcγRIIb-expressing MCL PDX model to overcome ibrutinib-venetoclax dual resistance.
- Acceptance by FDA of an IND application for a Phase I/IIa clinical trial of BI-1206 in combination with KEYTRUDA® in solid tumors.
- Received FDA orphan designation for BI-1206 for mantle cell lymphoma
- Published first data from two parallel Phase I/IIa clinical trials of BI-1206.

Collaborations

- Pfizer selected the first and second target and extended the research collaboration and license agreement for BioInvent's proprietary F.I.R.S.T™ technology platform. Payments of \$0.3 million were triggered for each selected target
- Entered into a Clinical Trial Collaboration and Supply Agreement with MSD to Evaluate BI-1206 in combination with KEYTRUDA® in advanced solid tumors
- Received €0.75 million milestone payment from Mitsubishi Tanabe Pharma Corporation in connection with enrollment of the first patient in a Phase II clinical trial of an antibody identified from BioInvent's proprietary n-CoDeR® antibody library.
- Received \$0.5 million milestone from XOMA Corporation related to the acceptance by FDA of the IND application for TAK-169.
- Signing of manufacturing agreement with Cancer Research UK expected to generate approximately SEK 30 million (~\$3 million)

BIOINVENT TARGETS KEY IMMUNE SUPPRESSIVE CELLS & MECHANISMS TO BOOST ANTI-CANCER IMMUNITY

The cancer immunity cycle



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 ¹		2022E sales ¹
43bn	▷	97bn
(USD)		(USD)

CAGR 2016-2022E¹

14.6%