BI-1206 in NHL Clinical Update

January 28th, 2021

BioInvent

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AGENDA

• 11:30 AM	Martin Welschof, CEO BioInvent	Welcome and introduction to today's speakers
• 11:35 AM	Andres McAllister, CMO BioInvent	BI-1206 update
• 11:50 AM	Mats Jerkeman, KOL	The treatment landscape: FL and MCL
• 12.05 PM	Wei-Wu He, Chair and CEO CASI	BI-1206 selection and potential in China
• 12.20 PM	Martin Welschof, CEO BioInvent	Next steps and Q&A

TODAY'S PRESENTERS

Mats Jerkeman, MD

- Professor in Clinical Oncology at Lund University, Sweden
- Coordinator of several ongoing clinical trials in diffuse large B-cell lymphoma and mantle cell lymphoma.
- Chairman of the Nordic Lymphoma Group
- Editor of ESMO Guidelines/ Lymphoma

Andres McAllister, CMO BINV

- CMO BioInvent since 2017
- Previously CSO at Debiopharm; senior roles at IDM and BioMerieux/Pierre Fabre
- Ph.D from Pasteur Institut, Paris

Wei-Wu He, Chair & CEO CASI

- Chair and CEO since 2018
- Executive Chair Human Longevity Inc.
- Founder Genentron Health
- Venture Partner IDG/Accel
- Ph.D in molecular biology, Baylor; MBA Wharton

Martin Welschof, CEO BINV

- CEO since 2018
- Previously Director Technology Axaron Bioscience; CEO Affitech, CEO Opsona Therapeutics
- Board member: APIM Therapeutics, Nextera AS and Uni Targeting Research
- Ph.D in recombinant antibody technology

PIPELINE – MULTIPLE VALUE DRIVERS

Indication	Program	Discovery	Preclinical	Phase I	Phase II	Partner
Target: FcγRIIB						
iNHL (MCL, MZL, iFL)	BI-1206/Rituximab					CASI Pharmaceuticals
Solid tumors	BI-1206/Pembrolizumab					MSD, CASI Pharmaceuticals
Solid tumors	BI-1607			H2 2021		
Target: Tumor associated regulatory T cells (Tregs)						
Solid tumors	BT-001 -α-CTLA4 Mab-VV					transgene
Solid tumors	BI-1808 -α-TNFR2 MAb					
Solid tumors	BI-1910 - α-TNFR2 MAb					
Solid tumors	F.I.R.S.T.™ αTreg					
Target: Tumor associated myeloid cells (TAMs)						
Solid tumors	F.I.R.S.T. ™ αTAMs					Pfizer

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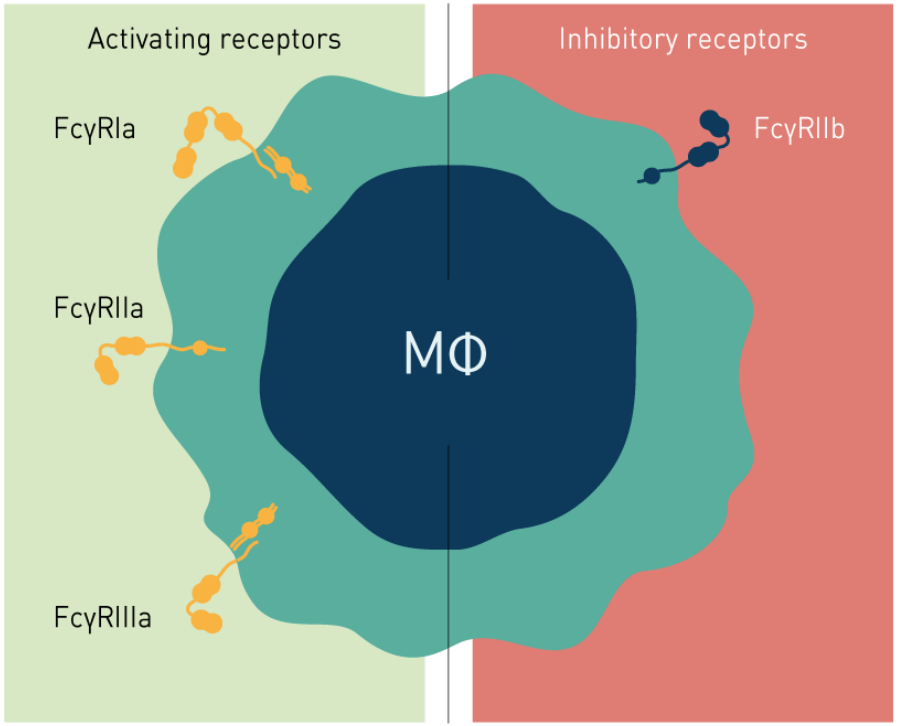
Solid tumors	F.I.R.S.T.™ αTreg					
Target: Tumor associated myeloid cells (TAMs)						
Solid tumors	F.I.R.S.T. ™ αTAMs					Pfizer

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

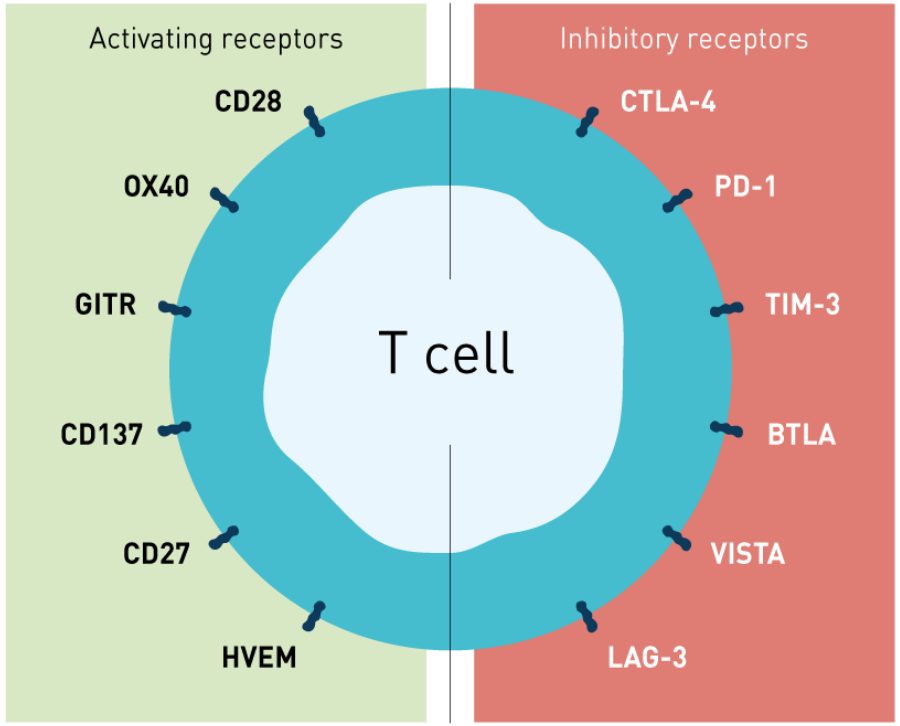
Antibody Checkpoints



Innate Immune System

Part of the immune system that kills tumor cells, but also activates and shapes the adaptive immune system.

T-Cell Checkpoints



Adaptive immune System

Part of the immune system that eliminates the pathogens and/or prevents their growth.

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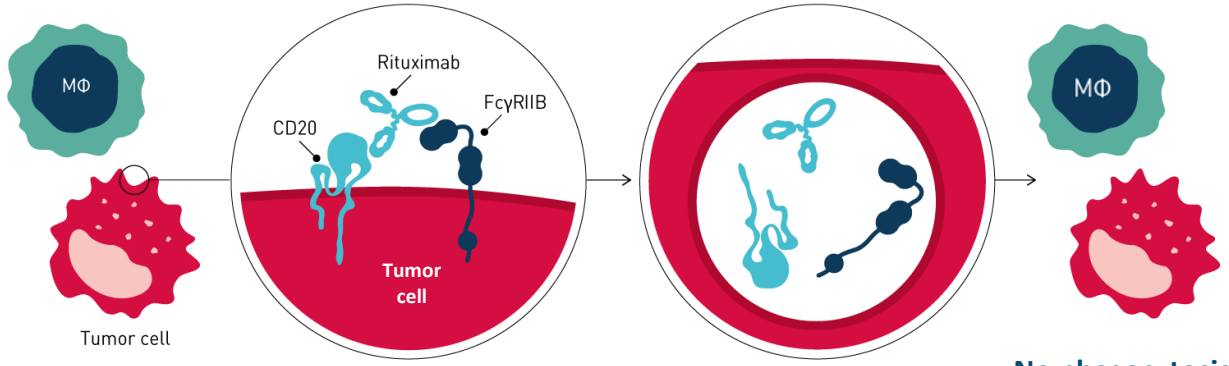
BI-1206 IN NON-HODGKIN LYMPHOMA TURBOCHARGING ANTI-CD20

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

The immune cells fail to attack the tumor cell

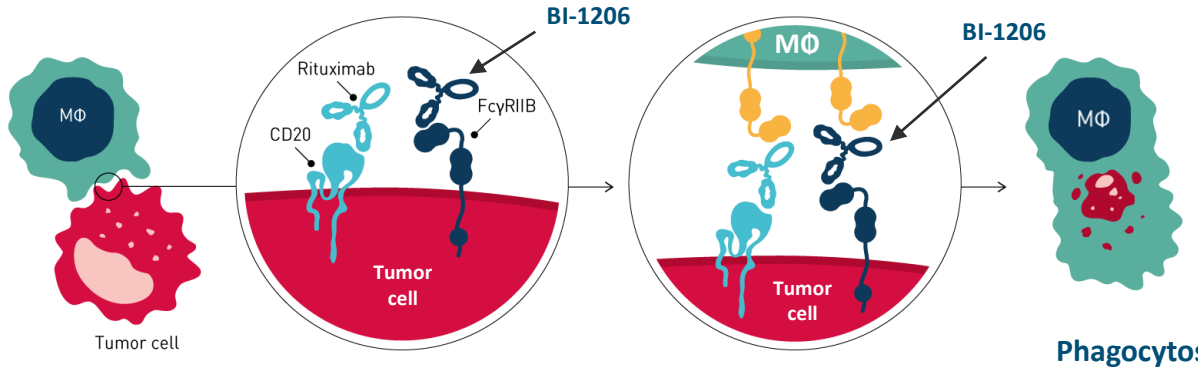


No phagocytosis[1]

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

With the FcγRIIB-receptor blocked, the immune system can kill the tumor cell



Phagocytosis[1]

Note:(**1**) Phagocytosis refers to the process by which cells (phagocytes) engulf foreign particles. This is a major mechanism for the immune system to remove pathogens and cell debris i.e. killing the tumor cell in this specific case.

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BI-1206 IN NON-HODGKIN LYMPHOMA: VALUE PROPOSTION – KEY SEGMENTS & VALUE DRIVERS

BI-1206 value drivers

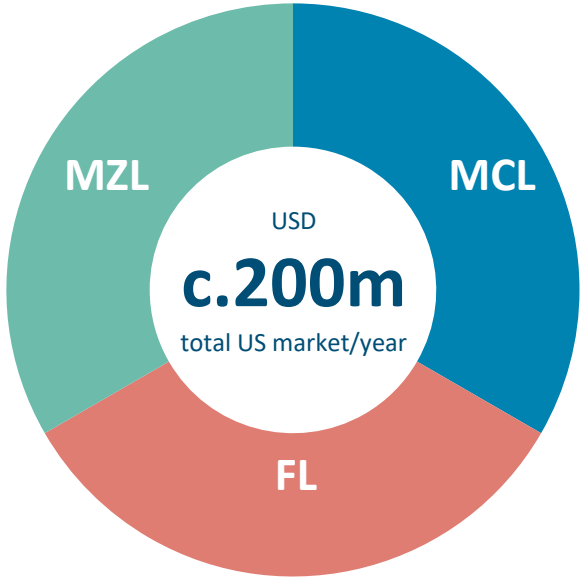
- Compelling scientific rationale in α-CD20 refractory B-cell lymphoma
- Chemo-free regimen
- Favorable safety profile
- Scalability of total addressable market

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)

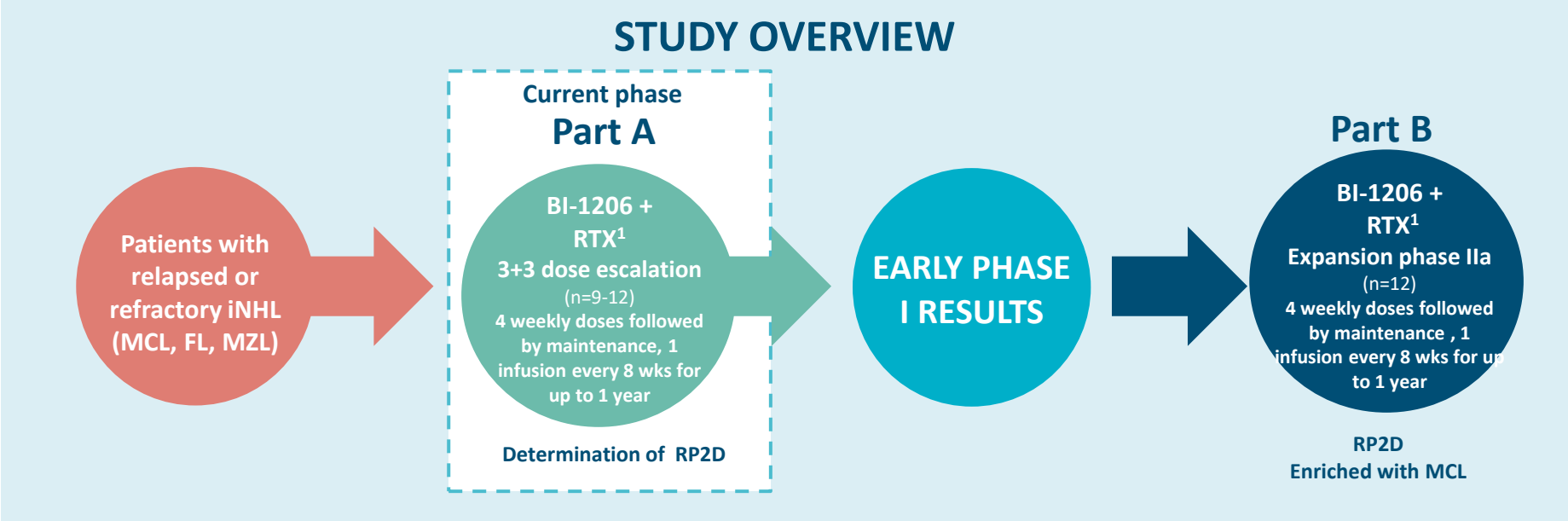
KEY SUB-SEGMENTS OF NON-HODGKIN LYMPHOMA (NHL)



- **Mantle Cell Lymphoma (MCL[1])** 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 (FL[1])** is the most common form of slow-growing non-Hodgkin lymphoma
- **Marginal Zone Lymphoma (MZL[1])** is a slow growing type of B cell lymphoma with a median age of diagnosis of 65 years

Note (**1**): Cello Health BioConsulting, 2019

BI-1206 IN COMBINATION WITH RITUXIMAB: OPEN LABEL PHASE I/IIA STUDY

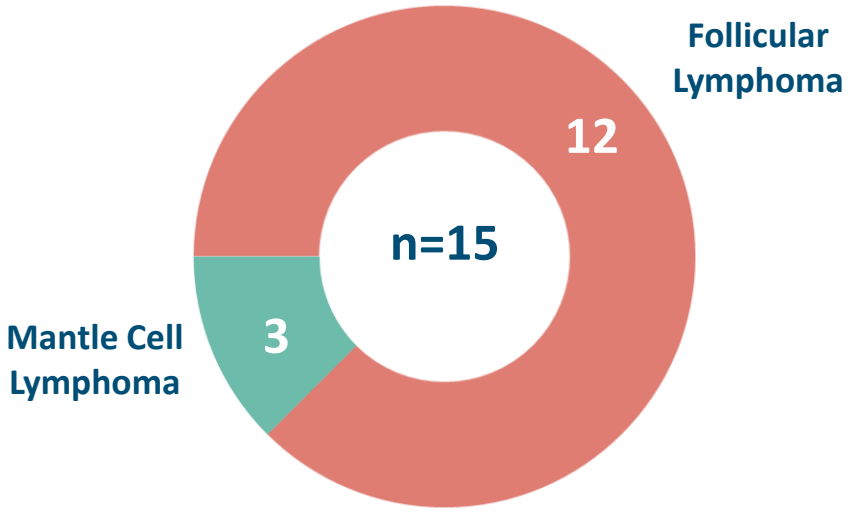


STUDY OBJECTIVES	INCLUSION CRITERIA
▪ Explore safety & tolerability of the combination ▪ Select recommended phase 2 dose (RP2D) ▪ Determine pharmacokinetic and pharmacodynamic profile ▪ Observe early signs of efficacy ▪ Biomarker exploration (B cell depletion, depletion of circulating tumoral cells, analysis of biomarkers predictive of response)	▪ Patients must have relapsed disease or disease that is refractory (R/R) to conventional treatment or for which no standard therapy exists. ▪ 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)

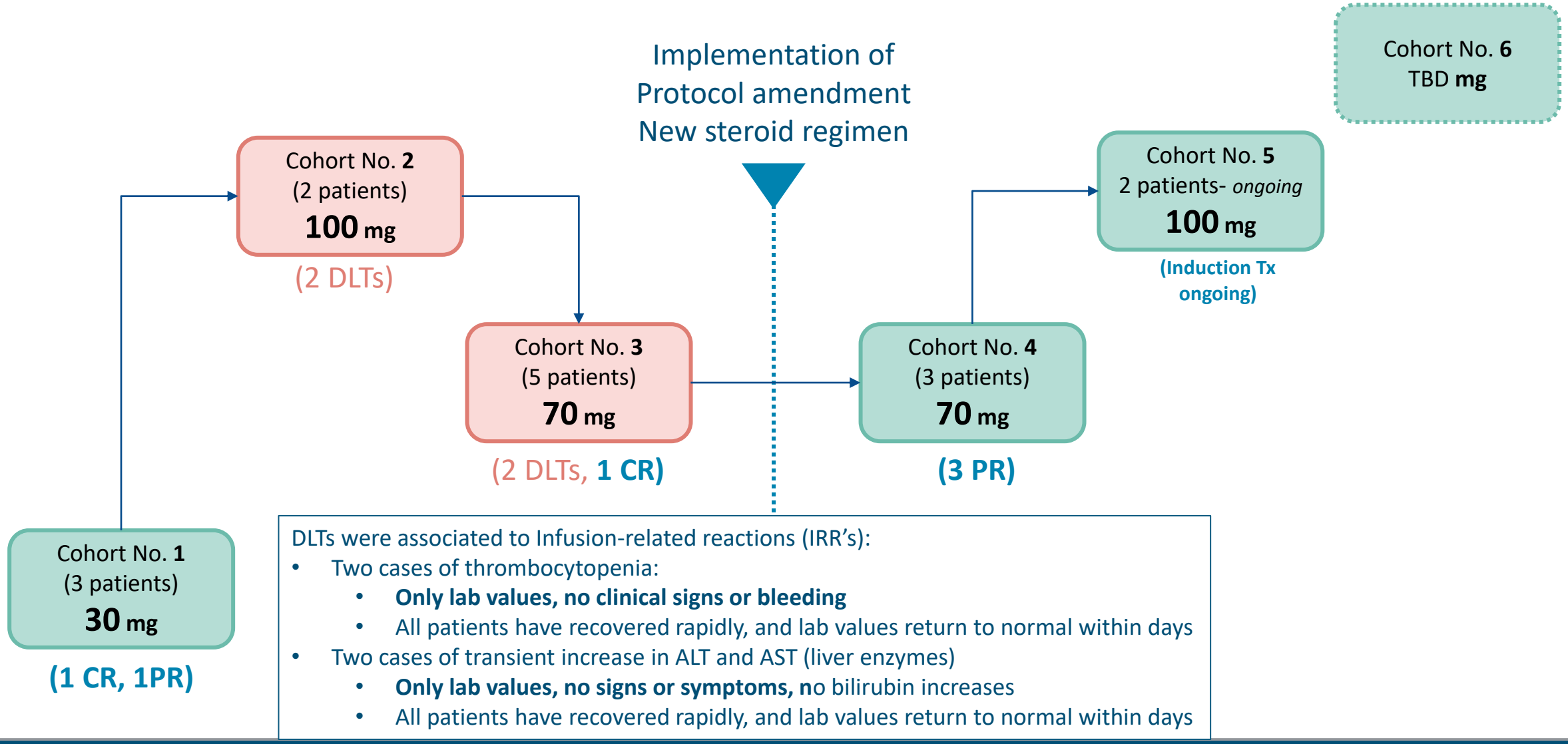
PATIENT DEMOGRAPHICS

PATIENTS RECRUITED IN PART A



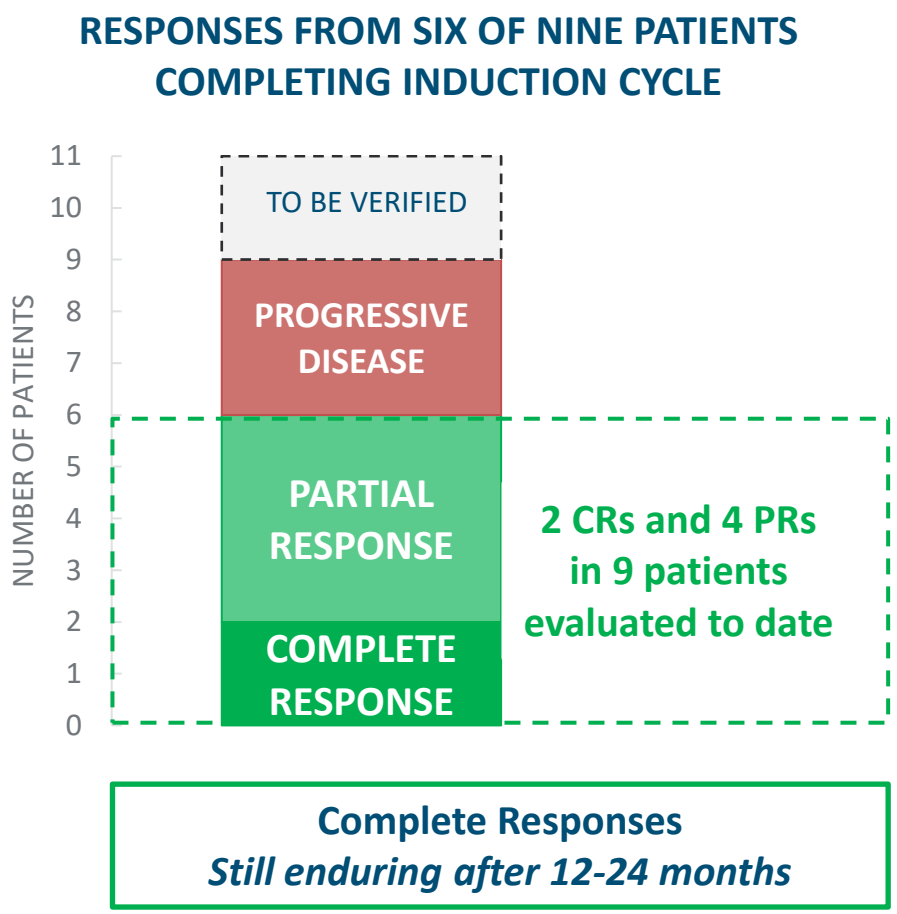
PATIENT DEMOGRAPHICS	TOTAL=15 PATIENTS	
Gender	Male, n=9 (60%)	Female, n=6 (40%)
Age	Range 53-80, Mean 70	
Disease type	FL, n=12 (80%)	MCL, n=3 (20%)
No. of prior lines of therapy	Range 1– 11, Mean 3.7	

GOOD SAFETY PROFILE AND MANAGEABLE IRRs



 CR: complete response; PR: partial response; DLT: dose limiting toxicity

ENCOURAGING RESPONSES FROM PATIENTS COMPLETING INDUCTION CYCLE INCLUDING TWO ENDURING COMPLETE RESPONSES



- To date, 15 patients enrolled in Part A
- 9 patients have been evaluated for response, 2 still on treatment
  - Two complete responses (one at 30mg, one at 70mg)
  - Both complete responses continue today, 12-24 months out
  - One MCL patient with blastoid histology who achieved *complete depletion* of peripheral tumor cells, and achieved a PR
  - Four partial responses (one at 30mg, three at 70mg)
  - Two patients (100 mg) not evaluated for response yet
- Next steps:
  - Read-out from 2 patients at 100mg in coming weeks, including one MCL patient with blastoid histology
  - 3rd patient being recruited
  - Determine RP2D and start Part B

UPCOMING KEY MILESTONES

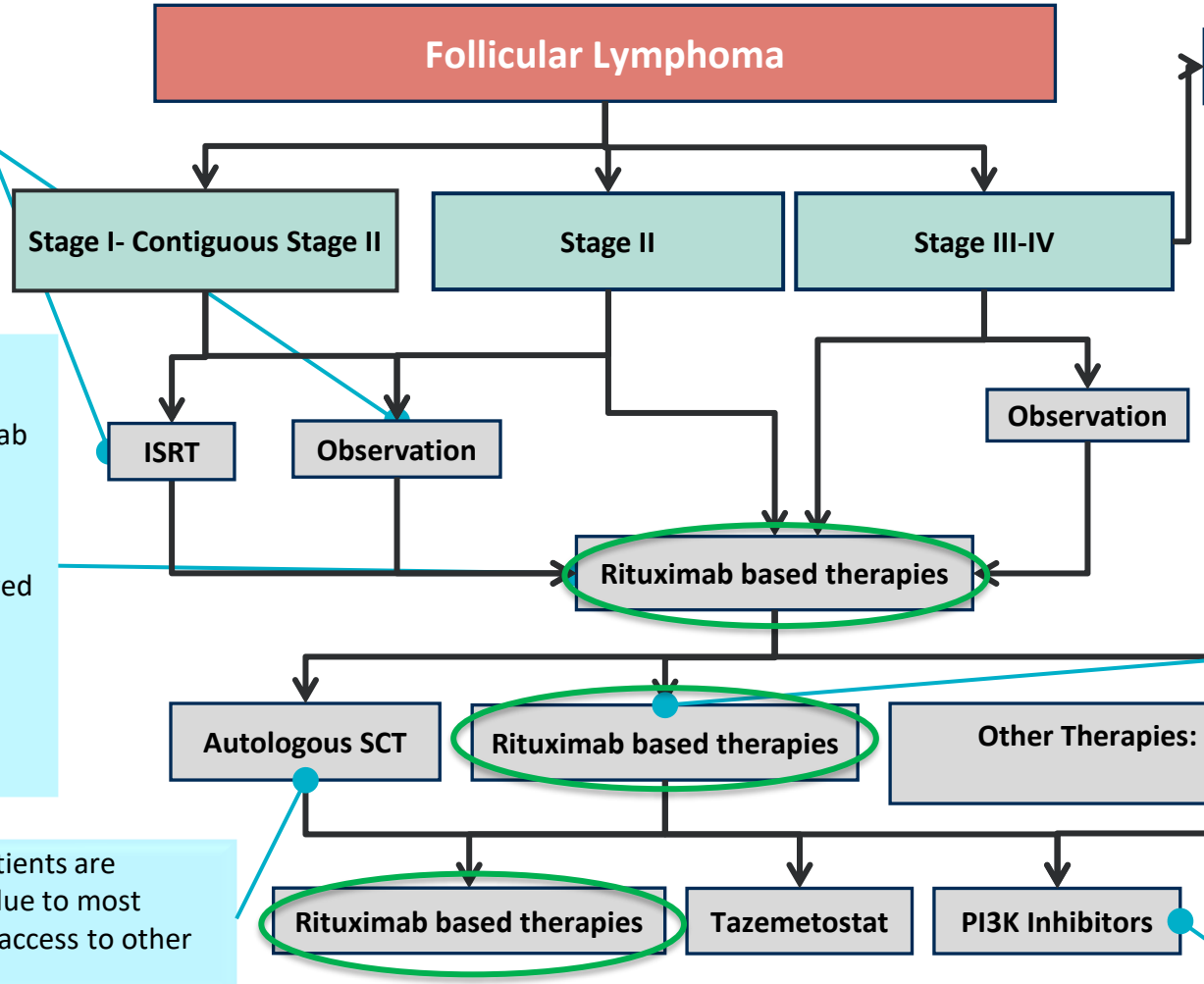
- Select RP2D, and move to expansion phase (Part B) of the study (same patient population)
- Include China in global clinical development strategy: implement part B of the study
- EoP1 meeting with FDA planned for Q3/2021
  - Discuss RP2D and **new** phase 2 study design (potentially pivotal study)
- Start implementation of **new** phase 2 study in US, Europe and China
- Determine quickest path to registration
  - Orphan drug designation in MCL obtained
  - Fast track designation
  - Breakthrough therapy designation

RITUXIMAB-CHEMOTHERAPY BASED REGIMENS ARE ADMINISTERED EXTENSIVELY ACROSS ALL STAGES OF FL, HOWEVER THERE IS A LACK OF PREFERRED SOC TREATMENTS IN R/R FL

- Large fraction of low grade, early stage patients are observed initially, especially in the community.
- However, most wait and watch patients progress to requiring systemic therapies eventually.

- Rituximab based frontline therapies include RCHOP, BR, RCVP and rituximab monotherapy for older patients and patients with sub-optimal PS.
- BR is more toxic than the other rituximab based regimens, and reserved for younger, more healthy patients.
- Frontline therapies are effective, however the majority of patients will progress within 6-8 years.

- Only a small fraction of the R/R FL patients are administered the transplant, mainly due to most patients being older (>65 years), and access to other treatment options/clinical trials.



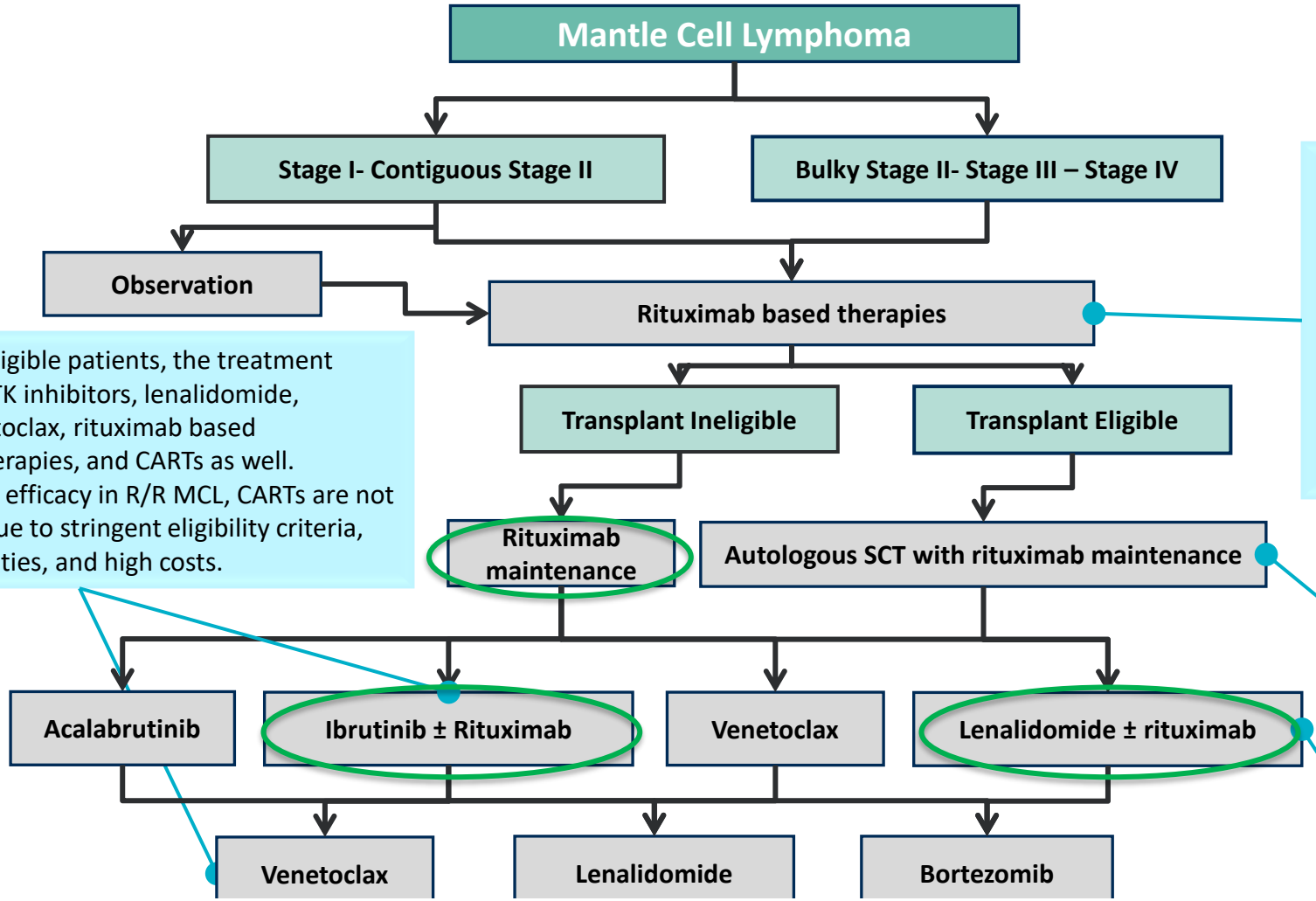
Diagnosis

Treatment

- Currently, Lenalidomide plus rituximab (R^2) and lenalidomide plus obinutuzumab (OR) are reasonably used in R/R FL.
- These regimens appear to have similar efficacy to other chemo-immunotherapies and superior efficacy vs anti-CD20 monotherapies, but different toxicities.
- Lenalidomide causes embryo-fetal toxicity, hematologic toxicity, and venous and arterial thromboembolism.

- Currently approved PI3K inhibitors like copanlisib are associated with high toxicity, resulting in lack of robust usage.

WHILE RITUXIMAB BASED REGIMENS CONTINUE TO BE PREFERRED TO TREAT FRONTLINE ADVANCED DISEASE, TARGETED THERAPIES LIKE BTKI AND BCL-2I ARE OFTEN ADMINISTERED IN THE R/R SETTINGS



Diagnosis

Treatment

- For transplant ineligible patients, the treatment options include BTK inhibitors, lenalidomide, bortezomib, venetoclax, rituximab based chemoimmunotherapies, and CARTs as well.
- Despite promising efficacy in R/R MCL, CARTs are not used robustly in due to stringent eligibility criteria, logistical complexities, and high costs.

- Rituximab based chemoimmunotherapies like BR, R-CHOP, R^2-CHOP, R-hyper-CVAD are preferred in the frontline setting.
- Frontline response rates are high (ORR: ~85-90%), with mPFS of 2-3 years..
- R^2 is sometimes used as well, with a long-term study demonstrating that the doublet continues to show clinically relevant, durable responses, with a manageable safety in frontline MCL.

- Transplant is typically reserved for patients with good PS (Younger patients, who respond well (CR) to the frontline treatments.

- R^2 is not the preferred $2^{nd}/3^{rd}$ line regimen, but the doublet has demonstrated significantly better efficacy vs. lenalidomide monotherapy in multiple trials.

Thanks!

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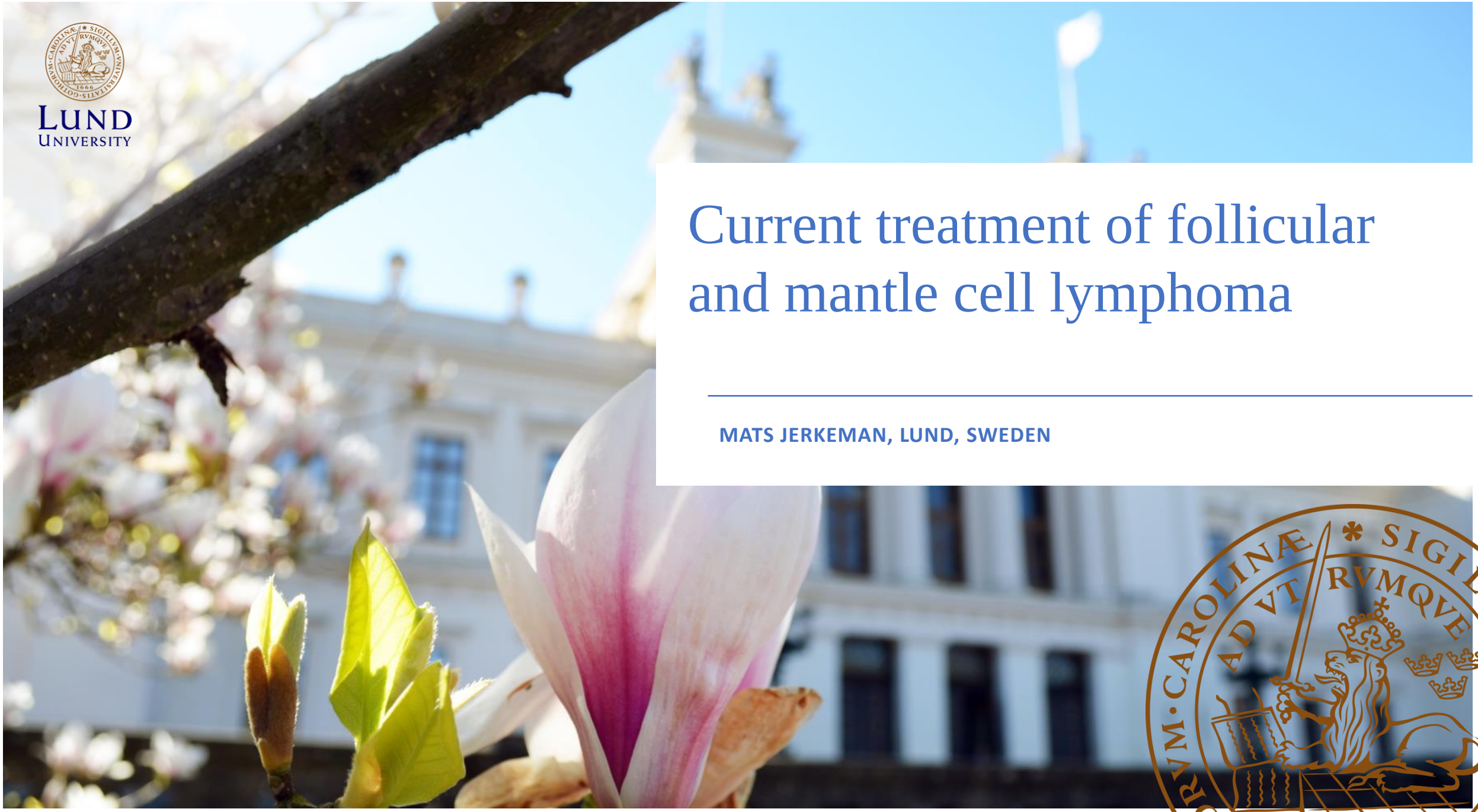
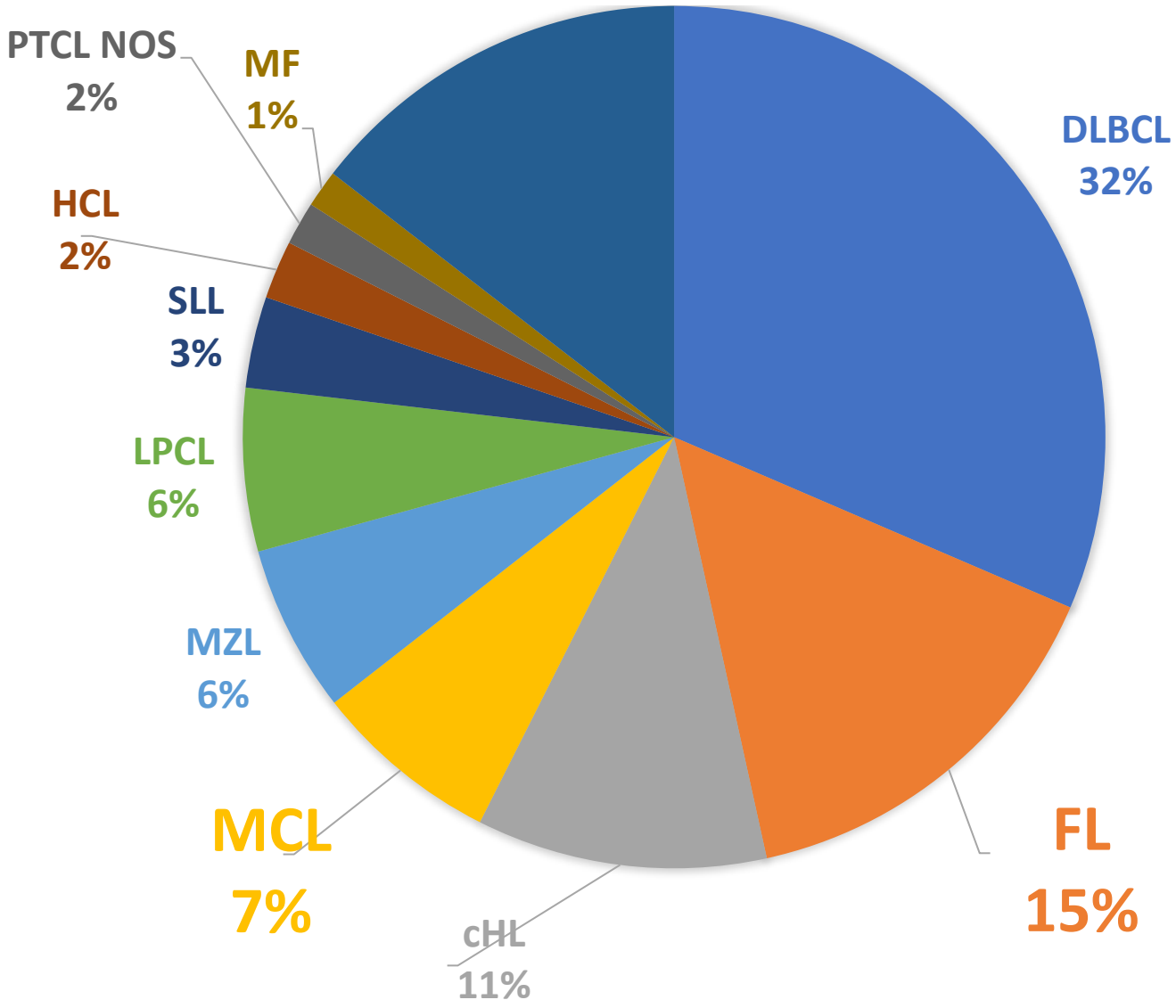


Current treatment of follicular and mantle cell lymphoma

MATS JERKEMAN, LUND, SWEDEN

Swedish Lymphoma Register



Common features and differences FL/MCL

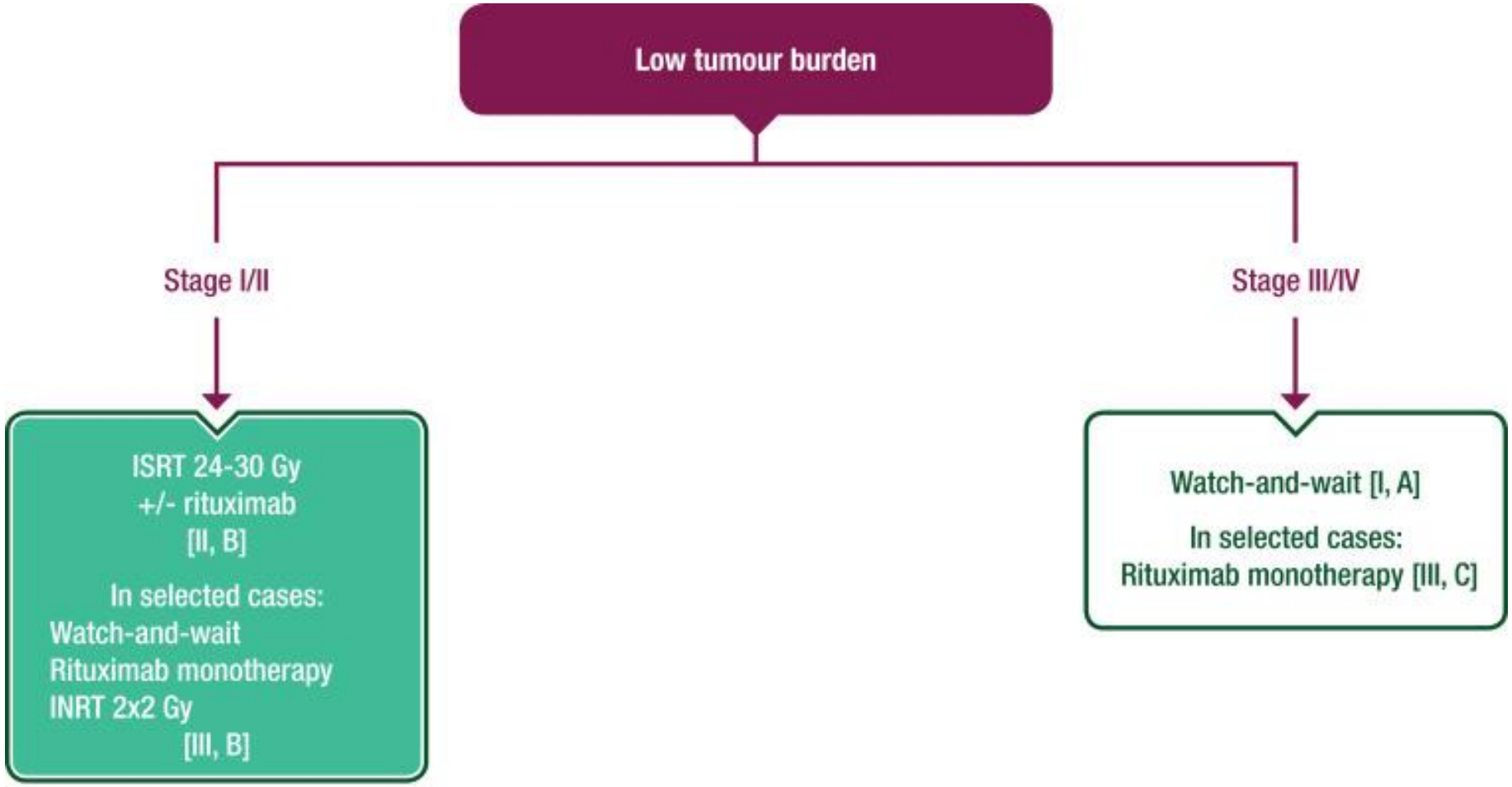
Common

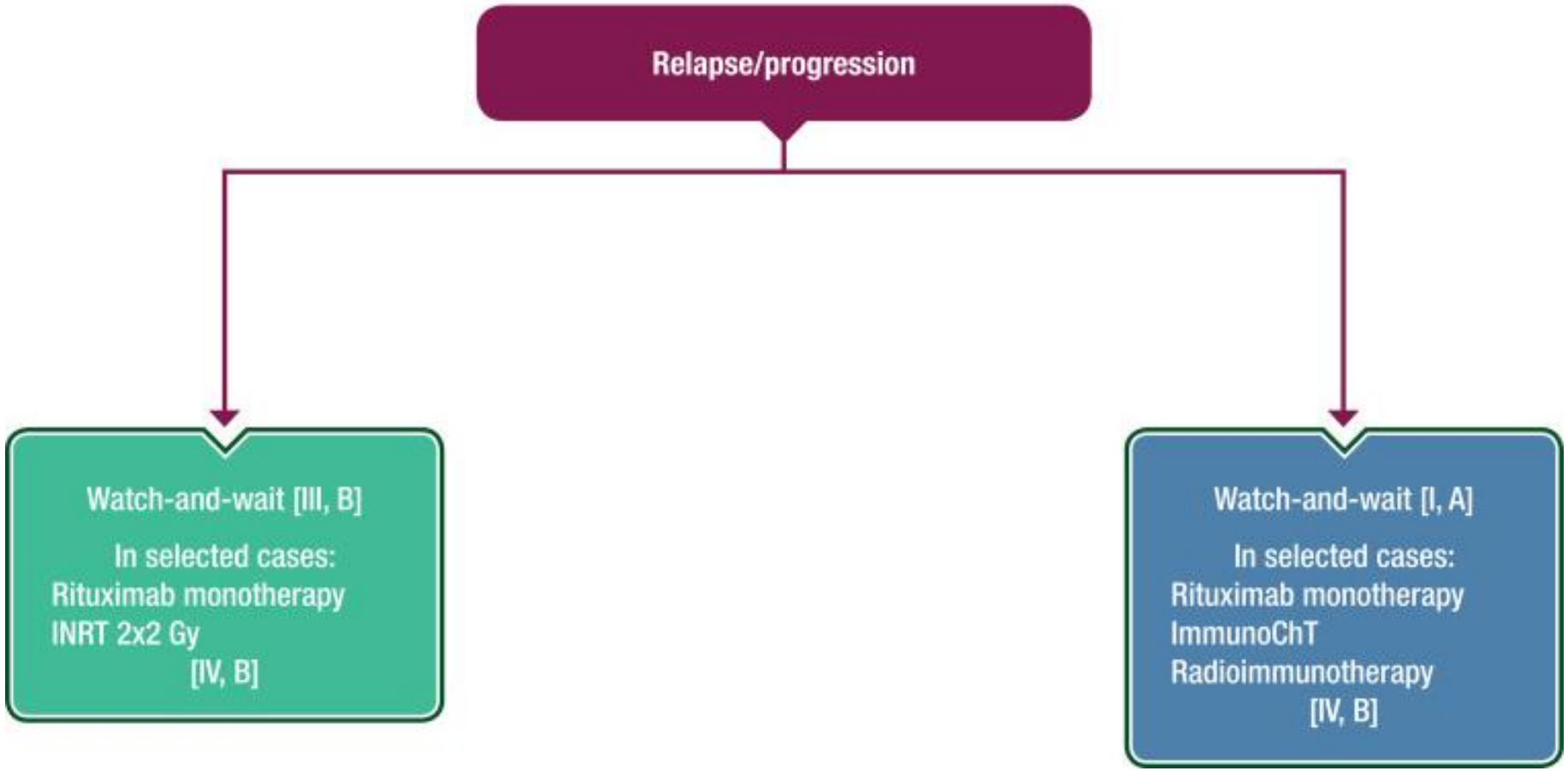
- Highly sensitive to anti-CD20 immunotherapies
- Highly radiosensitive
- Mostly nodal and bone marrow involvement
- Not curable

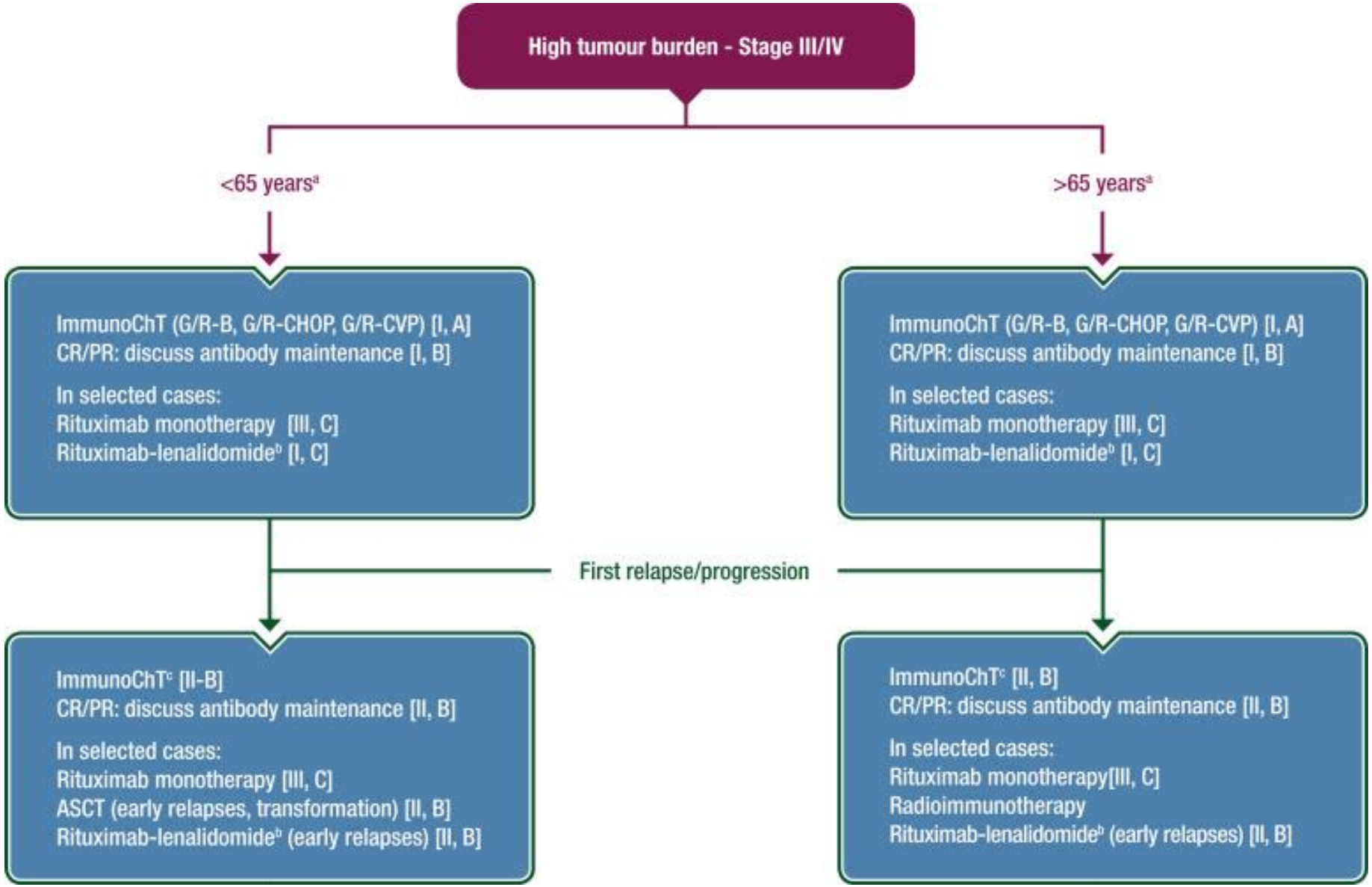
Differences

- MCL more often clinically aggressive
- Active novel agents in MCL
  - BTK inhibitors
  - BCL2 inhibitors
- Active novel agents in FL
  - PI3K inhibitors

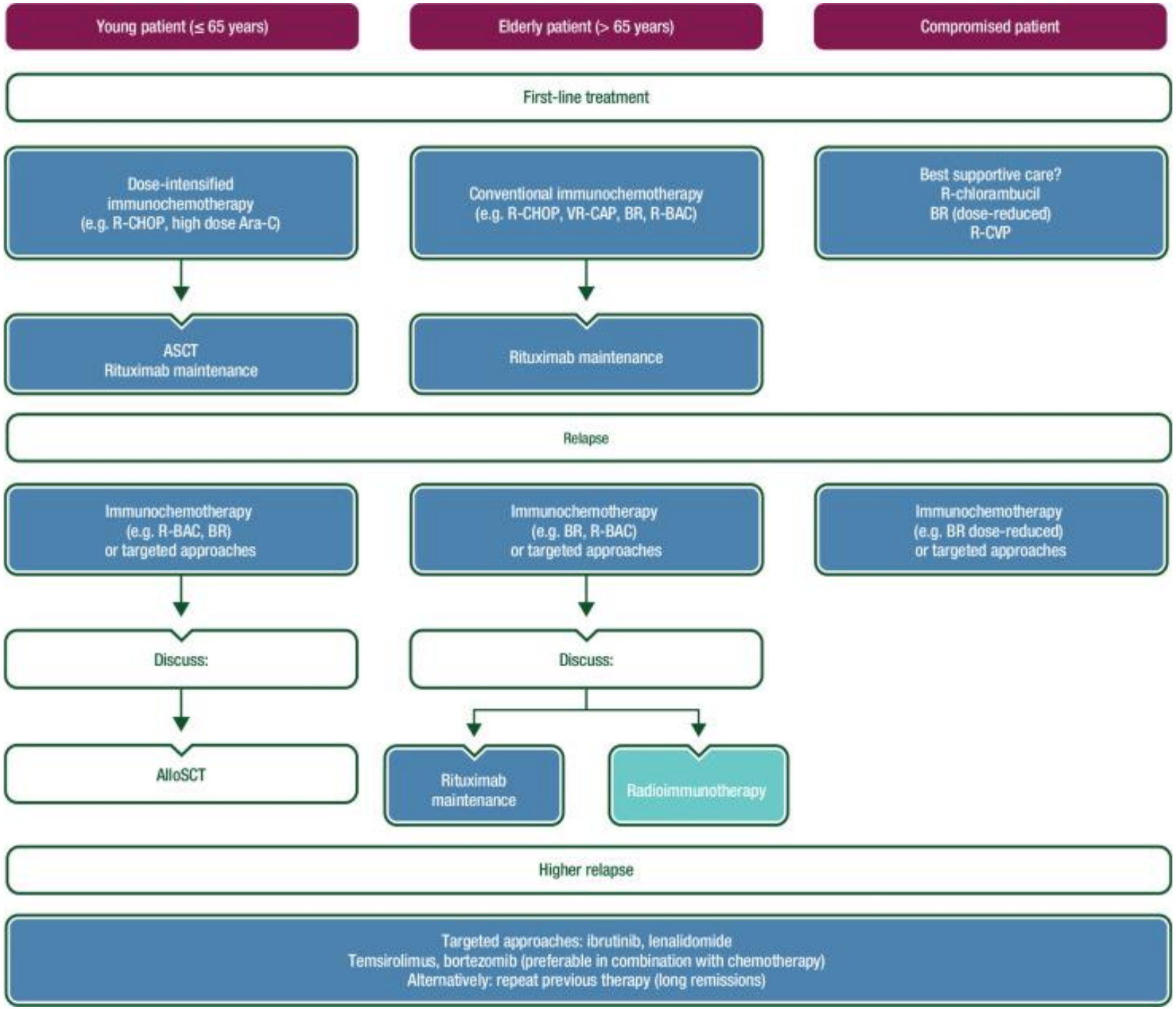
ESMO Guidelines FL 2020




Relapse/progression
Watch-and-wait [III, B]
In selected cases:
Rituximab monotherapy
INRT 2x2 Gy
[IV, B]
Watch-and-wait [I, A]
In selected cases:
Rituximab monotherapy
ImmunoChT
Radioimmunotherapy
[IV, B]


High tumour burden - Stage III/IV
<65 years[a]
>65 years[a]
ImmunoChT (G/R-B, G/R-CHOP, G/R-CVP) [I, A]
CR/PR: discuss antibody maintenance [I, B]
In selected cases:
Rituximab monotherapy [III, C]
Rituximab-lenalidomide[b] [I, C]
ImmunoChT (G/R-B, G/R-CHOP, G/R-CVP) [I, A]
CR/PR: discuss antibody maintenance [I, B]
In selected cases:
Rituximab monotherapy [III, C]
Rituximab-lenalidomide[b] [I, C]
First relapse/progression
ImmunoChT[c] [II-B]
CR/PR: discuss antibody maintenance [II, B]
In selected cases:
Rituximab monotherapy [III, C]
ASCT (early relapses, transformation) [II, B]
Rituximab-lenalidomide[b] (early relapses) [II, B]
ImmunoChT[c] [II, B]
CR/PR: discuss antibody maintenance [II, B]
In selected cases:
Rituximab monotherapy[III, C]
Radioimmunotherapy
Rituximab-lenalidomide[b] (early relapses) [II, B]

ESMO Guidelines MCL 2017


Young patient (≤ 65 years)
Elderly patient (> 65 years)
Compromised patient
First-line treatment
Dose-intensified immunochemotherapy (e.g. R-CHOP, high dose Ara-C)
Conventional immunochemotherapy (e.g. R-CHOP, VR-CAP, BR, R-BAC)
Best supportive care?
R-chlorambucil
BR (dose-reduced)
R-CVP
ASCT
Rituximab maintenance
Rituximab maintenance
Relapse
Immunochemotherapy (e.g. R-BAC, BR) or targeted approaches
Immunochemotherapy (e.g. BR, R-BAC) or targeted approaches
Immunochemotherapy (e.g. BR dose-reduced) or targeted approaches
Discuss:
Discuss:
AlloSCT
Rituximab maintenance
Radioimmunotherapy
Higher relapse
Targeted approaches: ibrutinib, lenalidomide
Temsirolimus, bortezomib (preferable in combination with chemotherapy)
Alternatively: repeat previous therapy (long remissions)

Potential role of BI-1206

- Sensitizer of rituximab, more specific than lenalidomide?
- Component in ’chemo free’ regimens
  - Low tumor burden FL
  - Elderly patients with MCL
- In low tumor burden FL - with rituximab as single agent?
- In MCL – combination with rituximab as maintenance?

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BioInvent – CASI Strategic Partnership
BI-1206 for China

Jan 28, 2021

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BI-1206 : Targeting FcγRIIB, the First Checkpoint Inhibitor Directed Towards Monoclonal Antibody Receptor Interaction

- BI-1206 is a first-in-class monoclonal antibody that targets FcγRIIB - the only inhibitory Fcγ receptor that acts as a "brake" on the innate immune system
- BI-1206 acts like a Checkpoint Inhibitor, blocking the mAb-checkpoint FcγRIIB interaction to unleash antibody-mediated reactivation of the immune response against cancer
- By removing the checkpoint FcγRIIB, BI-1206 allows better and prolonged mAb anti-tumor activity
- BI-1206 has broad clinical potential, much like the PD-1 checkpoint's, in many relapsed/refractory and first-line settings by blocking FcγRIIB interaction

CASI – BioInvent Partnership

Strategic partners for developing and commercializing BI-1206 using a China development model

- Leverage CASI's expertise and resources to accelerate development and commercialization of BI-1206 in China
- Generate clinical data on BI-1206 rapidly in China to support the global development program and reach value inflection points quickly
- Complements CASI's clinical/medical teams and our established relationships with hematology KOLs, hospitals, medical centers and pharmacies
- **CASI has exclusive China development and commercialization rights**

BI-1206: Multiple Opportunities for Clinical Development and Commercialization in China

- **Lead Indication**: **NHL**
  - BI-1206 in Combination with Rituximab (or biosimilar) in Relapsed/Refractory Subjects With Indolent B-Cell Non-Hodgkin Lymphoma

- **Other Potential Indications (selection will be data driven)**:

Combination with PD-1

- Lung Cancer - NSCLC
- Hepatocellular Cancer

Combination with Anti-CD38 (CID-103)

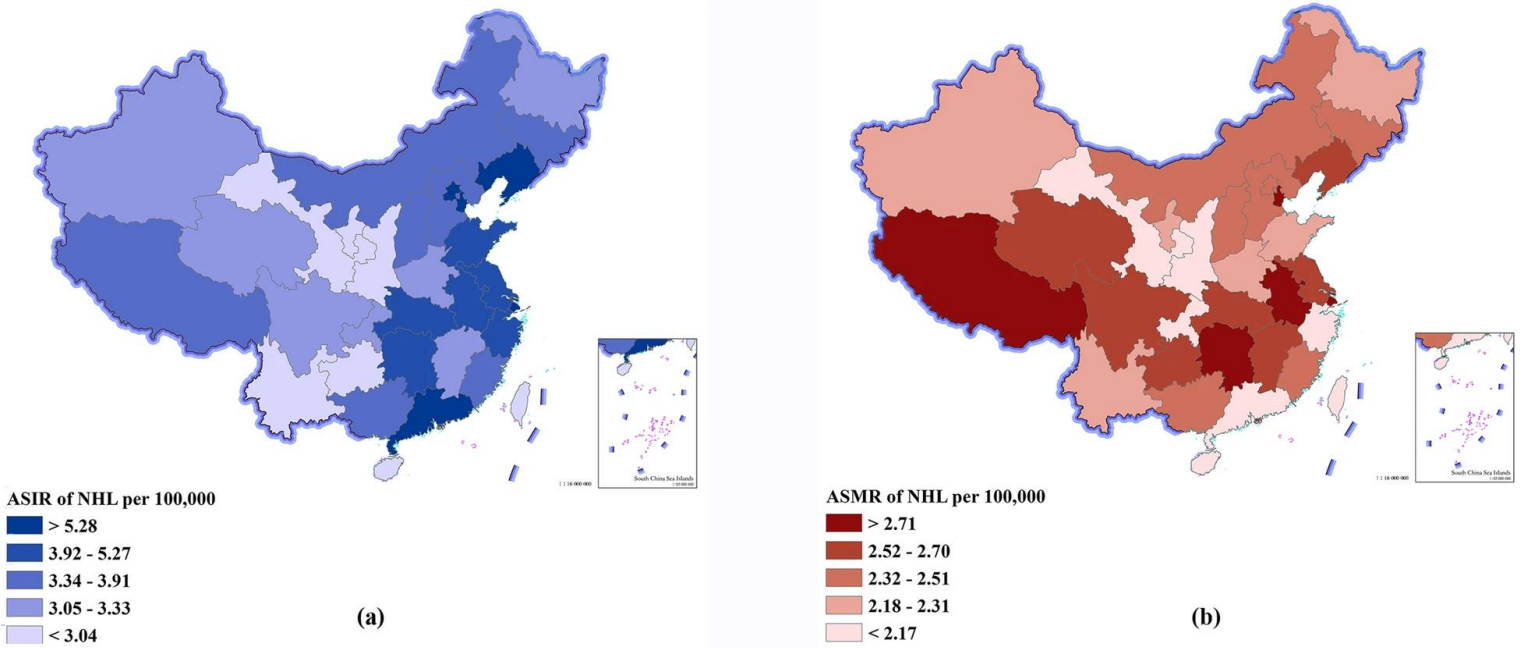
- Multiple Myeloma

BI-1206 for NHL – Complements CASI's Hem-Onc Focus

- Synergistic with CASI's clinical expertise and commercial/medical teams
- Leverage our established relationships with hematology-oncology Opinion Leaders and top cancer hospitals/medical centers
- CASI China can contribute up to 50% of the patients to accelerate the recruitment of the global pivotal study
- For an Innovative Product BLA filing in China, a local phase I (PK/PD) study plus the global pivotal trial are required for approval

Non-Hodgkin's Lymphoma – A Large Pool of Patients in China

- The disease burden of lymphoid neoplasms has been rising in China over the last decade
- Estimated 88,000 new cases/year and a 5 year prevalence of 227,600
- 48,000 deaths from NHL annually



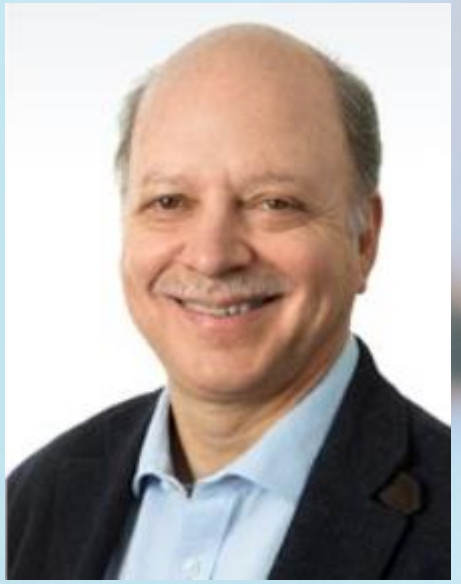
Age-standardized incidence rates (ASIRs) and age-standardized mortality rates (ASMRs) of non-Hodgkin's lymphoma (NHL) by province of China, 2016. a ASIR of NHL. b ASMR of NHL

Sources: Liu et al. Journal of Hematology & Oncology (2019) 12:115; Globocan 2018; CA CANCER J CLIN 2020;70:7–30.

Exciting Clinical Data from BioInvent's Phase I/IIA Study of BI-1206 in Non-Hodgkin's Lymphoma: 2 CRs and 4 PRs in 9 Patients Evaluated

- Of the 11 patients who have completed induction cycle
  - **Two complete responses** (one at 30mg, one at 70mg)
    - Both complete responses continue today, 12-24 months out
  - **Four partial responses** (one at 30mg, three at 70mg)
  - One MCL patient with blastic form who achieved *complete depletion* of peripheral tumor cells, and achieved a PR
  - Two patients (100 mg) not evaluated for response yet

Mats Jerkeman, MD



Andres McAllister, CMO BINV

Wei-Wu He, Chair & CEO CASI

Martin Welschof, CEO BINV

Q&A SESSION

BioInvent

BACKUP SLIDES

CASI Pharmaceuticals, Inc. (NASDAQ: CASI) - Highlights

- Driving sales growth for EVOMELA®, our first commercial product in China
- Growing pipeline of innovative therapeutics with focus on hematological malignancies
- Active BD to pursue further pipeline expansion, including solid tumor therapeutics
- Over 100 employees led by global management team with deep knowledge of US and China global drug development, regulatory, tech transfer, & commercial
- State-of-the-art GMP manufacturing facility currently in design stage
- Strong cash position – first quarter at $53.8 million
- US NASDAQ-listed company backed by long-term fundamental investors

CASI's Business Model

A strategic partner for developing and commercializing innovative products in China, the U.S. and globally

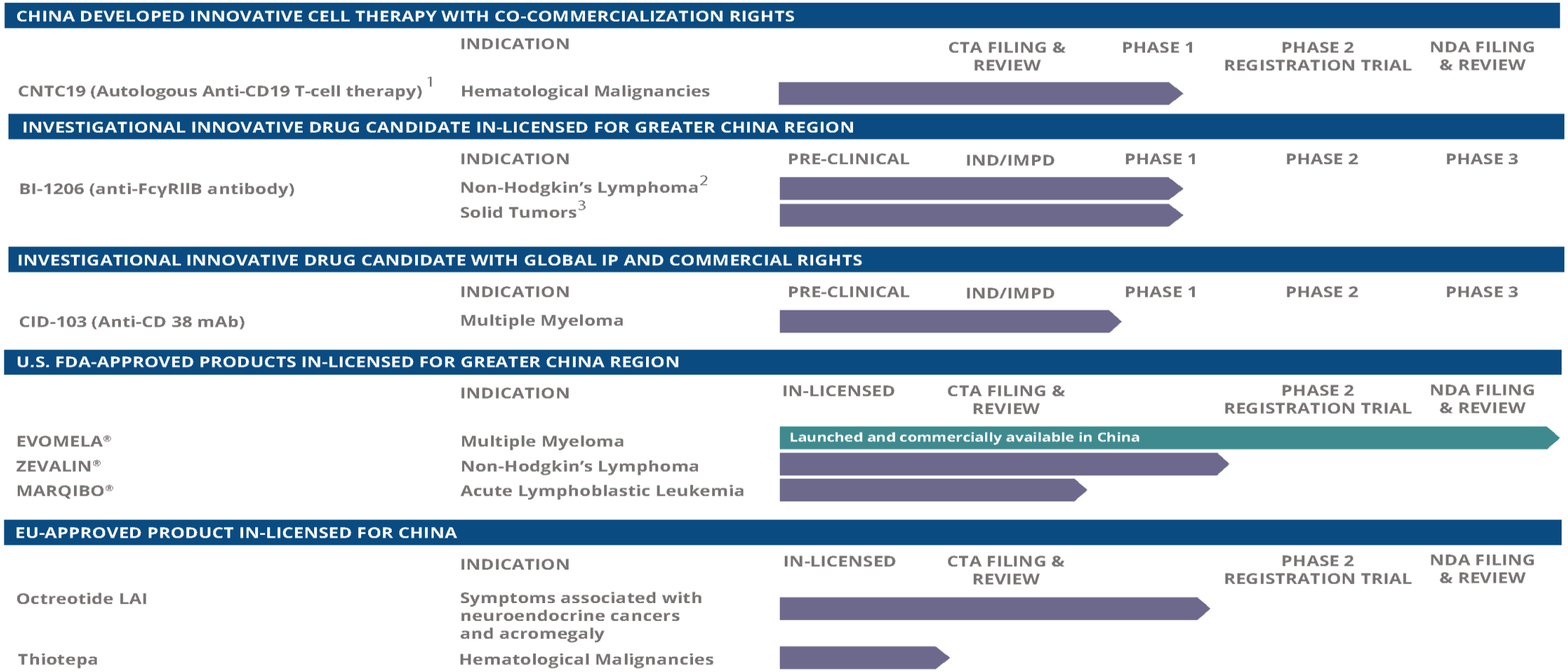
- Leverage CASI Pharmaceutical's expertise and resources to accelerate development and commercialization of innovative products into the China and U.S./global markets
- Reach value inflection points quickly to support global development programs
- Dedicated clinical and commercial team of experienced pharmaceutical professionals
- Bringing innovative medicines to 1.4 billion people in Greater China while addressing the U.S. and global markets efficiently

EVOMELA® for Multiple Myeloma

- Successfully launched in China mid-August 2019
- HDT + ASCT is 1st line treatment for multiple myeloma
- Provides best choice of preparative regimen:
  - Lack of propylene glycol solvent (related to certain adverse events)
  - Captisol® enabled formulation is stable when reconstituted and substantially improves handling for pharmacists/nurses/physicians for patient administration

- The **only** form of melphalan commercially available in China
  - Despite COVID-19, EVOMELA has proven to be an essential drug with strong orders and demand
- Post-marketing study will complete accrual started in 2020

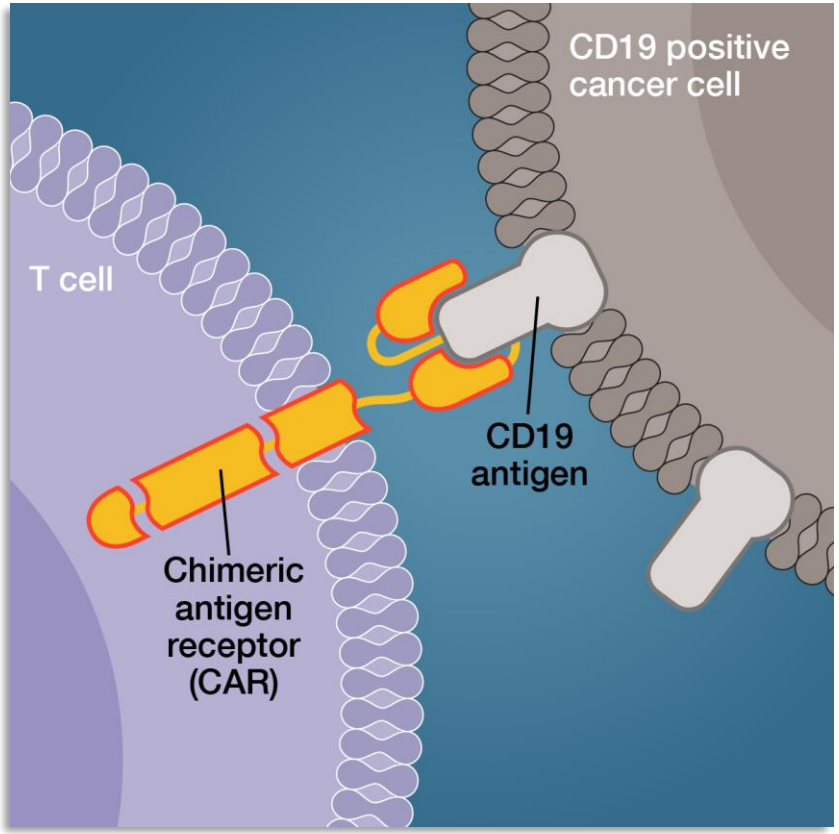
Pipeline



(1) Clinical development is the responsibility of Juventas Cell Therapy Ltd.
(2) In combination with rituximab. Trial conducted by BioInvent.
(3) In combination with pembrolizumab. Trial conducted by BioInvent.

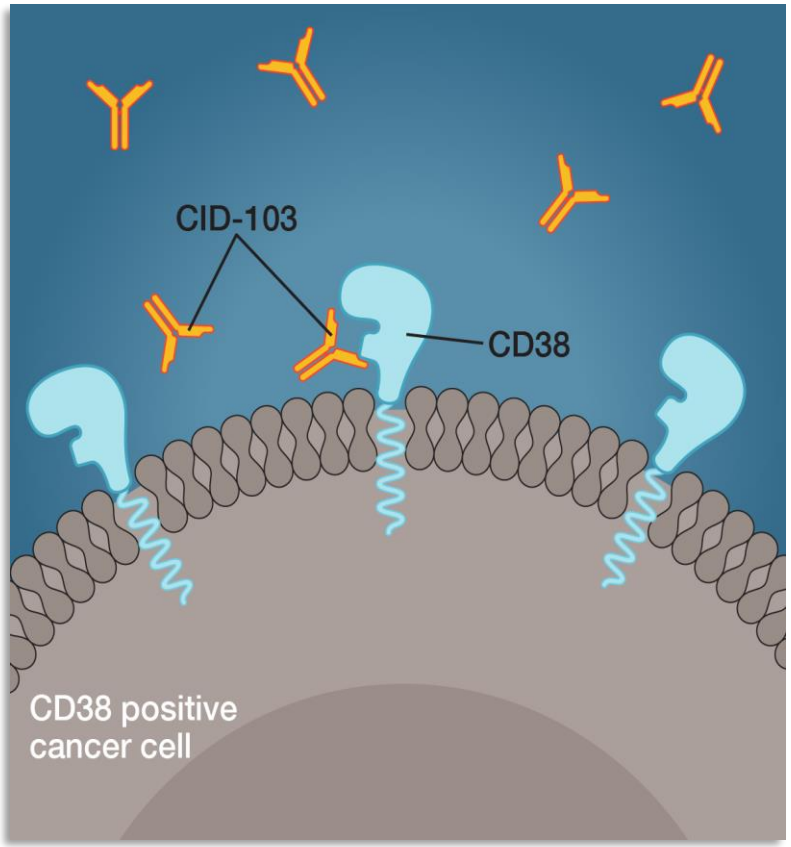
CASI Pharmaceuticals

CNCT-19: CD19 CAR-T Cell Therapy – A Validated Target



- Targets CD19, a B-cell surface protein widely expressed during all phases of B-cell development and validated target for B-cell derived hematological malignancies
- CD19-targeted CAR have demonstrated consistently high antitumor efficacy in children and adults with relapsed B-cell acute lymphoblastic leukemia (B-ALL), chronic lymphocytic leukemia (CLL), and B-cell non-Hodgkin lymphoma (B-NHL)
- **Interim Phase 1 data presented at ASH: total CR/CRi rate in 20 r/r B-ALL patients was 90% on day 28, in which MRD negative CR/CRi rate was 70%**
- CASI has exclusive China and worldwide commercial rights
- **Synergistic with current EVOMELA commercial team already trained and established with hematology KOLs, hospitals, medical centers and pharmacies**

CID-103: Potential Best in Class Anti-CD38 mAb for Multiple Myeloma



- **Exclusive global rights**
- **Phase I study targeted for 1Q2021**
- Fully human IgG1 anti-CD38 monoclonal antibody recognizing a unique epitope; selected to have strong ADCC activity against CD38 malignant cells and to reduce CDC activity with a potential reduction of infusion reactions with observed with existing anti-CD38 treatments
- Encouraging preclinical efficacy & safety profile compared to other anti-CD38 mAbs
- Demonstrates greater ADCC activity over Daratumumab and other anti-CD38 mAbs
- In vivo activity outperforms Daratumumab and other anti-CD38 mAbs
- Survival improvement observed in Daudi, Ramos and Raji Xenograft models

Other Assets

Octreotide Long Acting Injectable (LAI)

- **Exclusive China rights**
- Octreotide LAI formulations considered a standard of care for the treatment of acromegaly and the control of symptoms associated with certain neuroendocrine tumors
- Approved in various European countries

ZEVALIN®

- **Exclusive greater China rights**
- CD20-directed radiotherapeutic antibody for treatment of patients with R/R, low-grade or follicular B-cell non-Hodgkin's lymphoma (FNHL) and patients with previously untreated follicular non-Hodgkin's Lymphoma (FNHL)
- Approved and commercialized in the U.S.

Thiotepa

- **Exclusive China rights**
- Conditioning treatment for allogeneic haemopoietic stem cell transplants (EMA)

China Market Opportunity

- In China, therapeutic oncology treatments grew by 23.6% to **$6.3 billion** in 2018 and spending has more than doubled since 2013
- New medicines launched since 2013 generated **$218 million** in spending in 2018
- Drugs are increasingly reaching the market **faster** in China as a result of expedited reviews and **35 approvals (~73%)** following review and approval acceleration policies in 2018
- In 2018, Chinese Health Authority approved **14 new oncology drugs**, on track with the US and other **developed markets**

**Source—IQVIA Global Oncology Trends 2019*

CASI Corporate Offices

- CASI Pharmaceuticals, Inc. (NASDAQ: CASI)
  - 9620 Medical Center Drive, Suite 300; Rockville, MD 20850 USA
  - 425 Eccles Ave, South San Francisco, CA 94080, USA
- CASI Pharmaceuticals (China) Co., Ltd.
  - 1701-1703 Tower 1,China Central Place, No. 81 Jianguo Street, Chaoyang district, Beijing, 100025, China

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