Zenas BioPharma

Novel B-cell directed therapies

Roberta Manfroni, PharmD
Associate Director, Medical Scientific Liaison,
Zenas Biopharma

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5 Years Since Inception

~145 Employees

3 Pipeline programs focused on autoimmune diseases

3 Global presence; US, EU & Asia

1 **Vision: To be a global leader in bringing innovative immune-based medicines to patients in the US and around the world.**

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B cell targeting is validated for multiple autoimmune diseases therapies

Normal Immune Response:

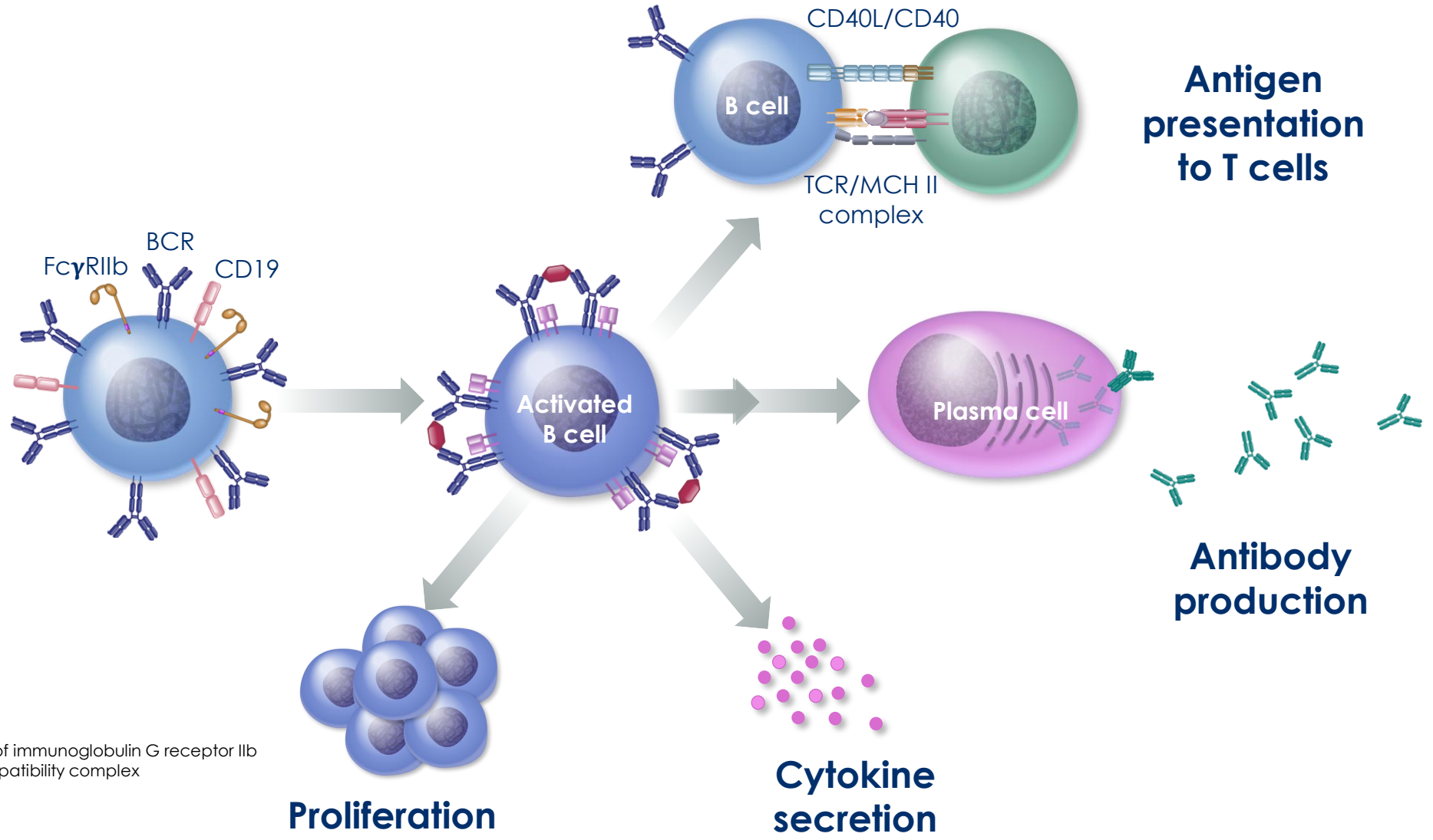
- B cells provide protective immunity against infectious agents through:
  - Antibody and cytokine production
  - Activation of T cells through antigen presentation and co-stimulation
- B cells evolve into plasma blasts and plasma cells, which produce large volumes of antibodies

Autoimmune Disease:

- B cells recognize self-antigens as foreign
  - Autoreactive B cells produce antibodies against healthy tissue resulting in inflammation, cell destruction, and tissue damage which can manifest as severe symptoms and lead to organ failure
  - Inflammation and cell destruction are further exacerbated by B cell-mediated T cell activation
- **Approved B cell therapies targeting CD20 or CD19 depend upon ADCC/CDC to kill/deplete B cells, which may be less efficient in tissue; dosing may not be optimal, and with the potential for an unfavorable safety profile**

ADCC/CDC= antibody-dependent cell-mediated cytotoxicity and complement dependent cytotoxicity

B Cell Responses Orchestrate Humoral Immunity



BCR = B-cell receptor
FcγRIIb = Fc fragment of immunoglobulin G receptor IIb
MHC = Major histocompatibility complex
TCR = T-cell receptor

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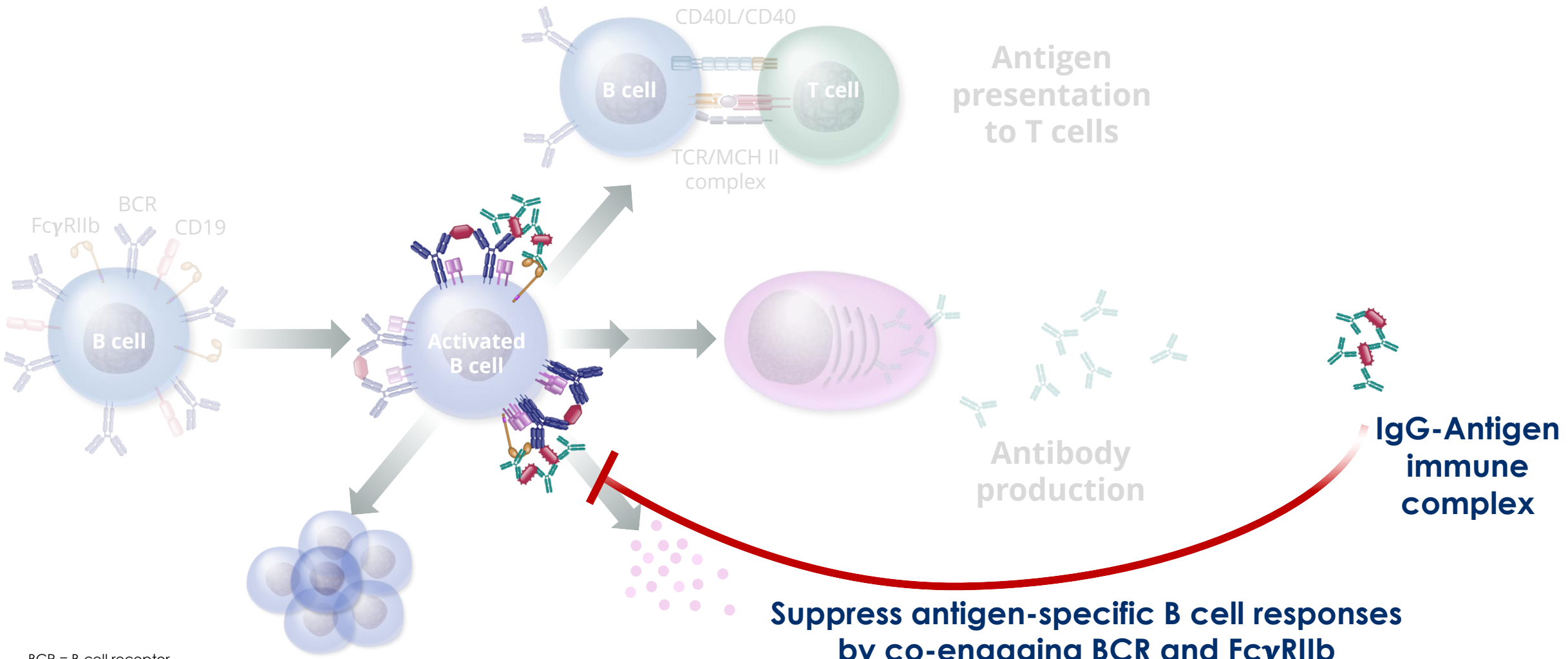
B Cell Responses are Naturally Downregulated by Immune Complexes Through FcγRIIb Binding



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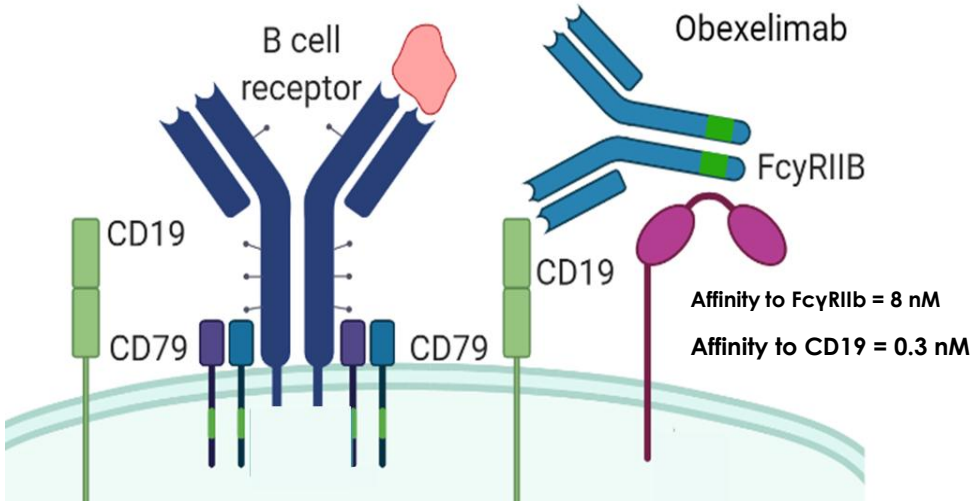
Obexelimab: A potentially differentiated B cell targeted therapy

Obexelimab **co-engagement** of CD19 and FcγRIIb results in an **inhibitory effect**, rather than direct depletion[1,2,3,4]

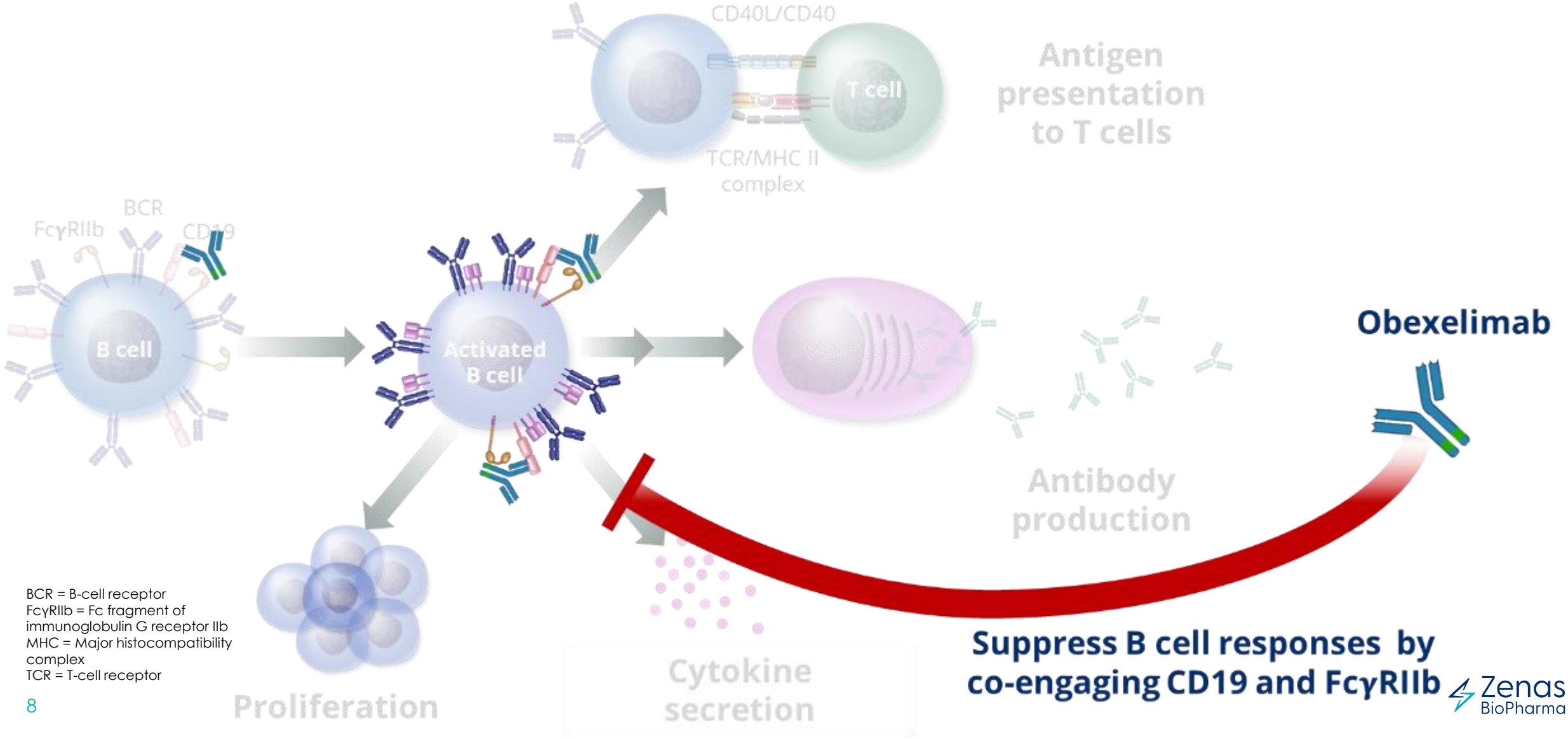
- FcγRIIb **mimics natural antigen-antibody** complex for potent inhibition of B cells
- Obexelimab binding affinity for human FcγRIIb increased approximately **230-fold relative to human native IgG1 due to Fc engineering**[2]
- Engineered to **avoid ADCC / CDC-mediated depletion**; non-reliance upon the presence of immune effector cells
- Impacts antibody production, proliferation, cytokine secretion, and antigen presentation to T cells
- Continuous exposure results in inhibitory activity within tissue



[1]Chu et al. *Molecular Immunology* 2008 & Zenas data on file
[2]Szili et al. *mAbs* 2014
[3]Chu et al. *Journal of Translational Autoimmunity* 2021
[4]Chu et al. *Arthritis & Rheumatology* 2014

Source: Zenas BioPharma

Bi-functional Antibody that acts as a Pharmacological Mimic of Immune Complexes to Inhibit B Cell Activity



BCR = B-cell receptor
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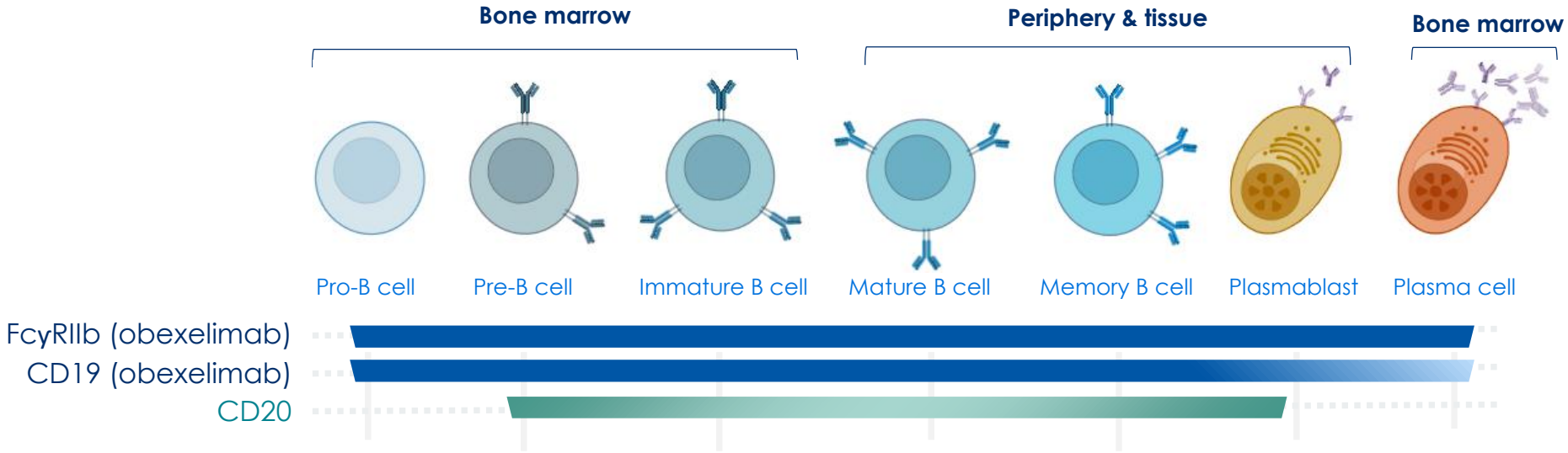
Targeting CD19 and FcγRIIb provides broad coverage of B cell lineage[1]



- CD19 and FcγRIIb broadly **expressed across B cell lineage**, including pro-B cells, pre-B cells, B cells, plasmablasts and select plasma cells[1]

[1]Abeles et al. *Annual Review of Immunology* 2024; Verbeek *et al. Front. Immunol* 2019

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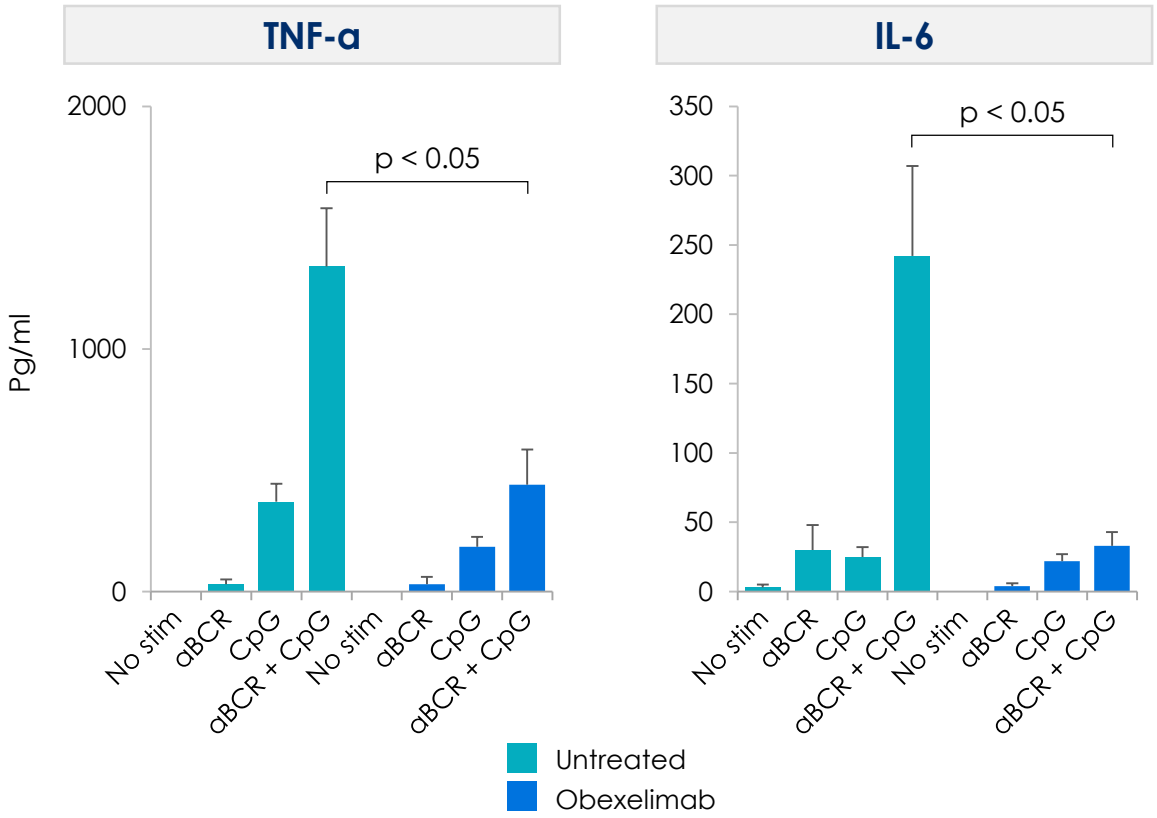
Obexelimab inhibits B cell cytokine production, and B cell activation in tissue without depletion

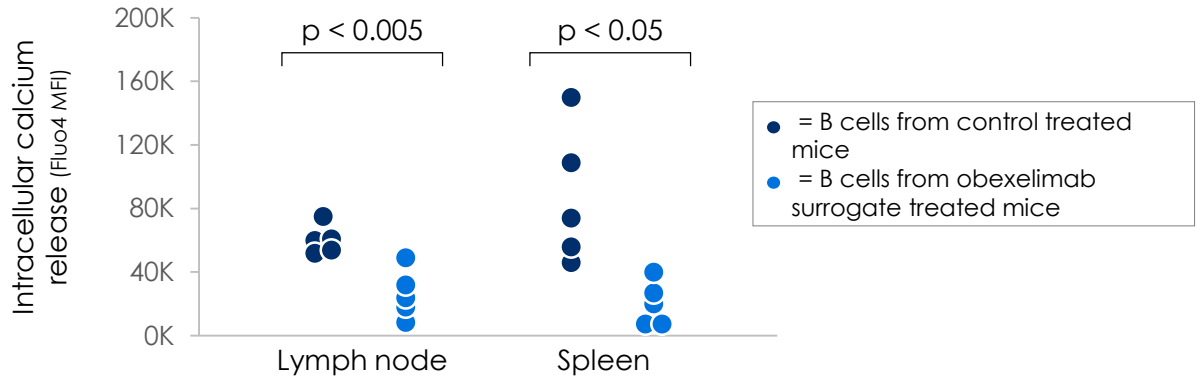
Obexelimab reduction of cytokine production from human B cells



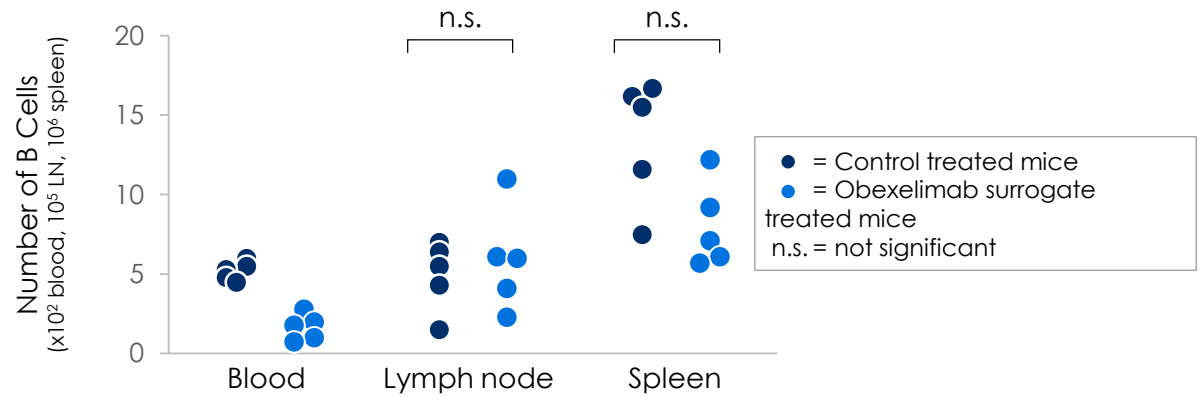
Modified from Szili et al. (2014) *mAbs* 6 (4): 991–99

BCR = B cell receptor; aBCR = anti-BCR stimulation; CpG = unmethylated cytosine-guanine; IL = interleukin; stim = stimulation; TNF = tumor necrosis factor;

Inhibition of tissue B cell activation by obexelimab surrogate



Non-depletion of tissue B cells by obexelimab surrogate



Mice were treated with XENP8206 (obexelimab surrogate mAb) for 7 days after which blood LN and spleen B cells evaluated by flow cytometry; B cells were harvested from mice treated with XENP8206 and stimulated with IgM. B cell activation was evaluated using calcium mobilization assays (average of 5 experiments shown); Adapted from Chu et al. *Journal of Translational Autoimmunity* 2021.

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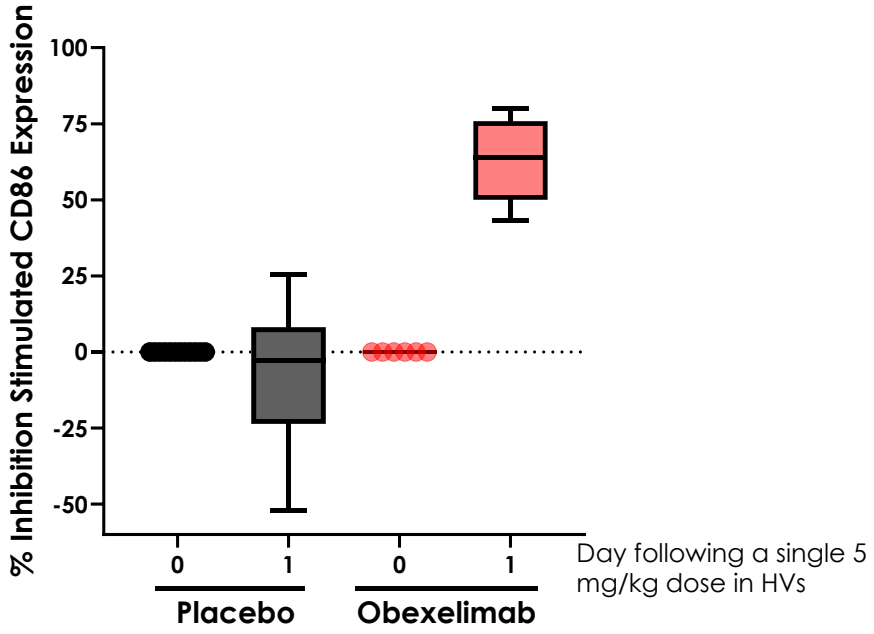
Rapid and broad inhibition of B cell response after obexelimab administration in clinical trials

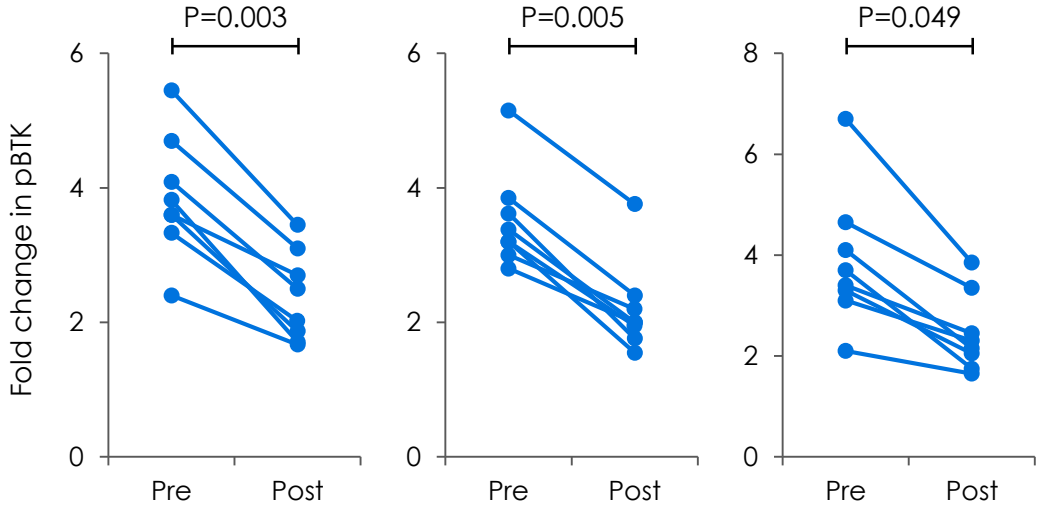
Rapid inhibition following a single obexelimab dose

Ex Vivo Stimulated CD86 Expression



Source: Wang, X. American College of Rheumatology 2022 poster presentation

Potent inhibition across multiple B cell subtypes



Source: Perugino et al. (2023) *Lancet Rheumatol* 5: e442 Supplement
pBTK = phosphorylated Burton's tyrosine kinase
Fold-change in the induction of pBTK with anti-IgG/IgM treatment before and after treatment with obexelimab

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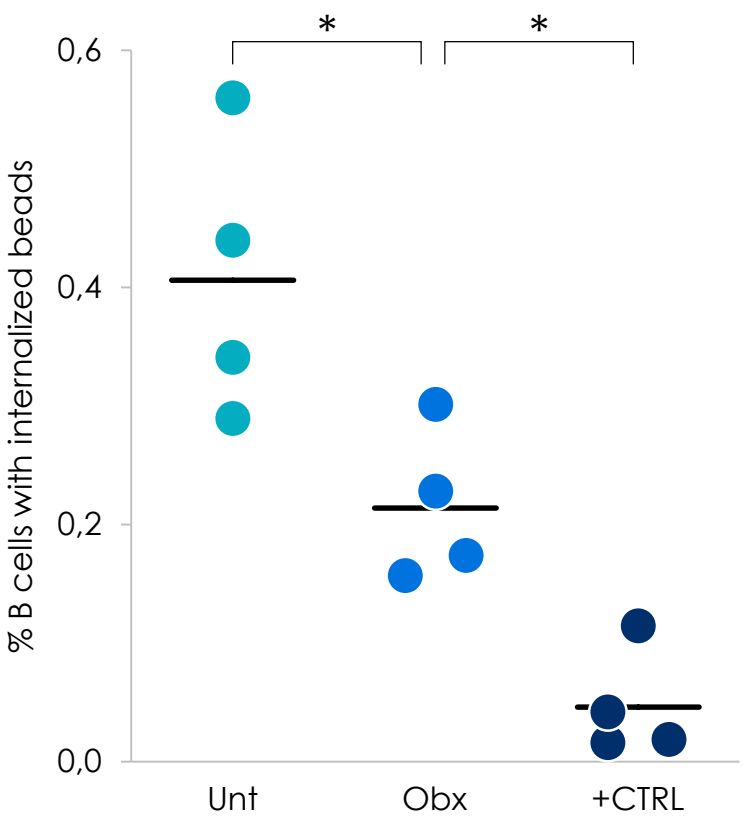
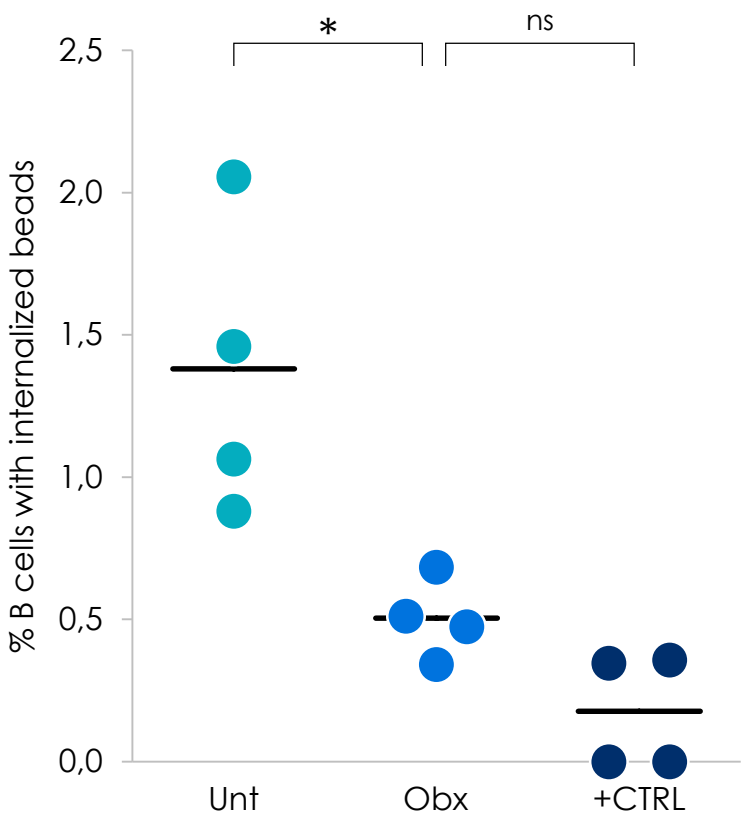
Obexelimab reduces antigen uptake by human B cells

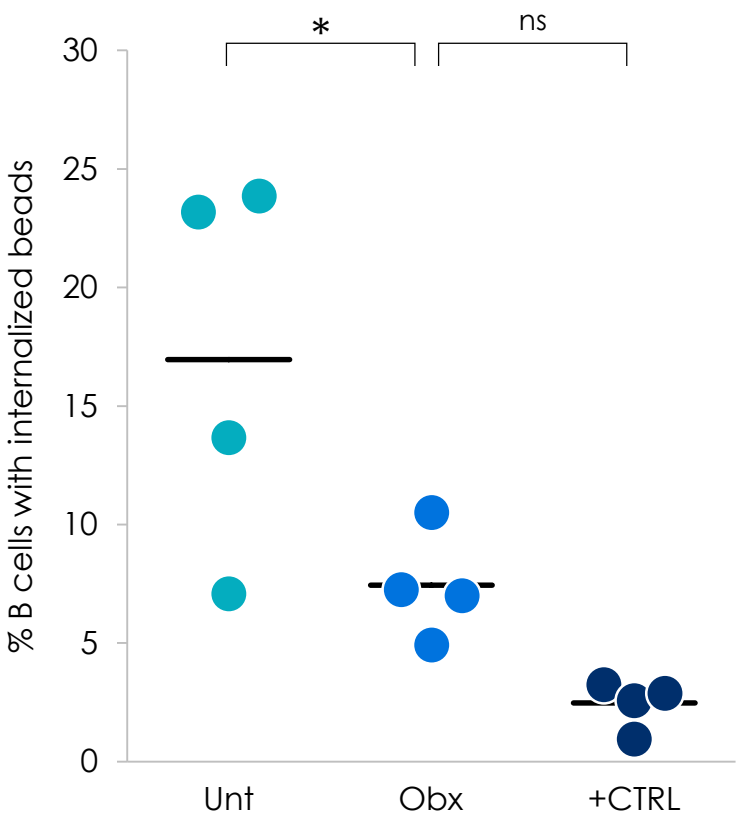
Follicular B cells



Marginal Zone B cells



B1 B cells



+ CTRL = positive control (cytochalasian D); Obx = obexelimab; Unt = untreated
Source: Zenas and Kerfoot Lab collaboration, unpublished

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Obexelimab's B cell *inhibition* has the potential to achieve optimum disease control for autoimmune diseases

Maintain effective disease control through potent inhibition of broad B cell lineage in tissue

Obexelimab

Once-weekly, self-administered, subcutaneous injection

Potentially favorable safety profile related to infections and response to vaccination

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Obexelimab demonstrated clinical activity in multiple, completed clinical trials

Trial Stage	Description	Outcome
Phase 1[1]	SAD HV, safety and PK	• Demonstrated proof-of-mechanism
Phase 1b/2a[2]	*MAD* **Rheumatoid Arthritis (RA)**	• Proof-of-mechanism and clinical activity established • Day 85 (all dose levels): **ACR20: 78%, ACR50: 33%, ACR70: 14%**[3]
Phase 2[4]	*Pilot Study* **IgG4-Related Disease**	• Clinical activity established; **rapid disease response (mean of 21 days), and sustained response achieved in 93% of patients**
Phase 2[5]	Randomized Controlled **Systemic Lupus Erythematosus (SLE)**	• Clinical activity established • Primary endpoint effect size of 17% for ITT population; **35% effect size for population with optimal exposure level (C_{trough})** • Biomarkers potentially predictive of obexelimab response identified
Phase 1[6]	*Bioequivalence* HV, Subcutaneous (SC) versus Intravenous (IV) dosing	• Established subcutaneous formulation with improved tolerability, and potential for optimized drug exposure (C_{trough})

SAD = Single Ascending Dose, HV = Healthy Volunteers, PK = Pharmacokinetics, MAD = Multiple Ascending Dose

[1]Wang, X. American College of Rheumatology 2022 poster presentation

[2]Wang, X. American College of Rheumatology 2023 poster presentation

[3]Jaraczewska-Baumann et al EULAR 2015 poster presentation (obexelimab efficacy at all dose levels)

[4]Perugino, C. et al. *Nature Reviews Rheumatology*. 16, 702–714 (2020)

[5]Merrill, J. et al. *Arthritis and Rheumatology*. Vol. 75, 2185-2194 (2023)

[6]Wang, X. Japan College of Rheumatology 2023 oral presentation

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Obexelimab: Multiple upcoming Phase 2 and Phase 3 data readouts

Program	Indication	Trial/Status	Next Milestone	
Obexelimab[1] CD19 x FcγRIIb Bifunctional mAb	IgG4-RD (Immunoglobulin G4-Related Disease)	Phase 3 INDIGO trial enrolled[2,3]	**Phase 3 Topline Results**	Expected around year end 2025
	RMS (Relapsing Multiple Sclerosis)	Phase 2 MoonStone trial enrolling[3]	**Primary endpoint (12-week) data**	Expected early Q4 2025
	SLE (Systemic Lupus Erythematosus)	Phase 2 SunStone trial enrolling[3]	**Primary endpoint (24-week) data**	Expected mid-2026

[1]Zenas acquired exclusive worldwide rights to obexelimab from Xencor, Inc.
[2]Bristol Myers Squibb & Co. holds exclusive development and commercialization rights in JPN, SK, TWN, HK, SGP, AUS
[3]Randomized versus placebo

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Obexelimab: IgG4-RD

IgG4-RD: A debilitating chronic fibro-inflammatory disease affecting multiple organ systems[1]

Disease Overview:

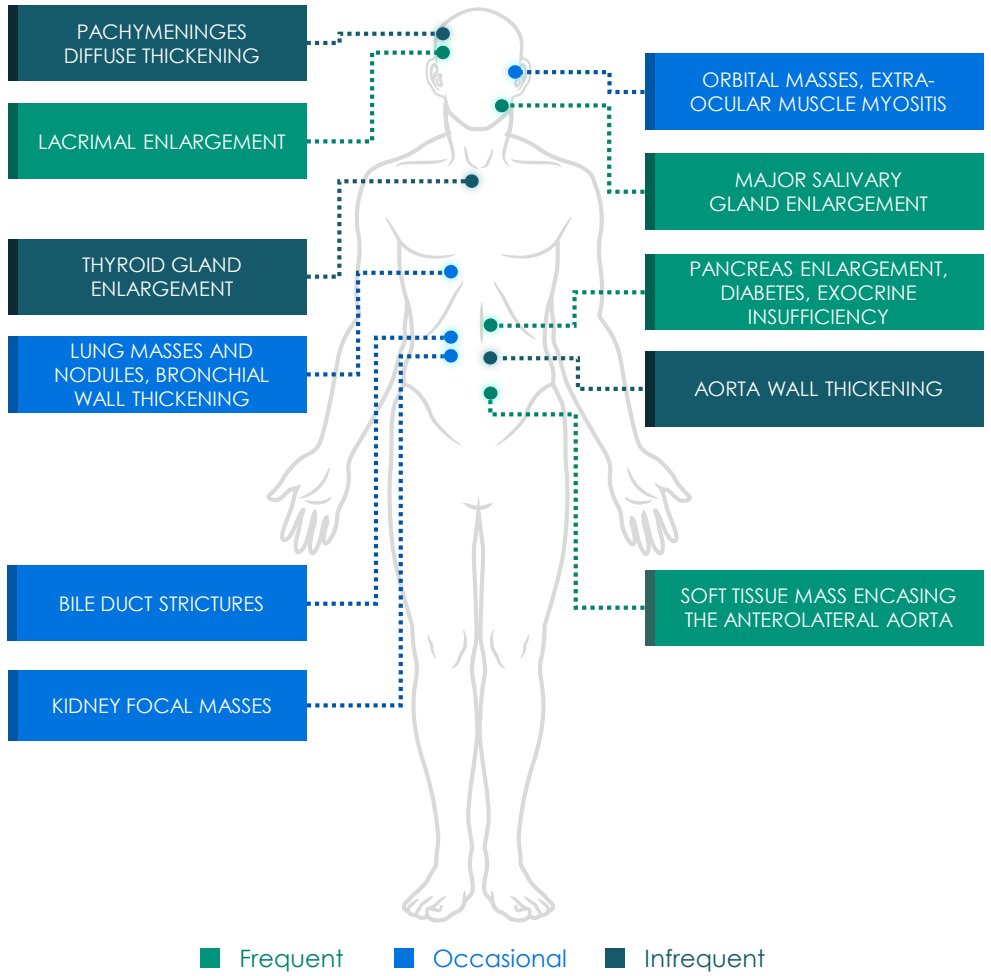
- Presents with single or multi-organ involvement
- As disease progresses patients experience new or worsening symptoms (*e.g.*, flare)
- Early inflammatory disease state moves to a fibrotic stage, which can lead to major irreversible tissue damage and organ failure

Pathophysiology:

- Expansion of CD19+ and IgG4+ B cells and plasmablasts with tissue infiltration
- These cells produce IgG4 and inflammatory cytokines, and activate T cells through antigen presentation exacerbating inflammation & fibrosis

Patient Population:

- We estimate the prevalence of IgG4-RD patients in the U.S. is approximately 20,000 to 40,000, and approximately 20,000 to 40,000 collectively in the UK, Germany, France, Italy, and Spain alone[2]



[1]Perugino, C. *et al. Nature Reviews Rheumatology*. 16, 702–714 (2020); Zhang, W & Stone, *J. Lancet Rheumatology*. 1(1), E55-E65 (2019); Mattoo et al *J Allergy Clin Immunol*. 2014; UpToDate
[2]Wallace et al 2023 and Zenas BioPharma research

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Current treatments are suboptimal due to relapse and long-term toxicities

Patients with asymptomatic and symptomatic disease require treatment to reduce flares and prevent irreversible organ damage and complications

First-line agent for remission induction

Glucocorticoids (GCs, e.g., prednisone) for 2–4 weeks followed by taper

Treatment of flares

Additional cycles of GCs ± steroid-sparing agents including conventional drugs and rituximab[10]

Obexelimab Opportunity

Use of GCs and rituximab off-label are suboptimal due to:

- High relapse rate for first line therapy; **40–50%** will fail to completely remit or relapse within a year[1-6]
- **30–40%** experience relapse following rituximab[7,8]
- Rituximab and GC toxicities including infection, and metabolic/endocrine complications[1-3]
- Reimbursement hurdles; no randomized controlled studies conducted with rituximab[9]

[1]Khosroshahi A, et al. *Arthritis Rheumatol*. 2015;67(7):1688-1699. [2]Chen Y et al. *Chin Med J* (Engl). 2022;135(4):381-392. [3]Masaki Y et al. *J Clin Exp Hematop*. 2014;54(2):95-101. [4]Perugino CA et al. *Nat Rev Rheumatol*. 2020 Dec;16(12):702-714. [5]Yunyun F et al. *Sci Rep*. 2017;7(1):6195. [6]Yunyun F et al. *Rheumatology* (Oxford). 2019;58(1):52-60. [7]Wallace et al. Rheumatology. 2016. [8] Ebbo et al. *PLOS ONE 2017*. [9]Orozco-Galvez, et al. *Autoimmun Rev*. 2023:22(3):103273 and Zenas market research. [10]Conventional drugs include cyclophosphamide, mycophenolate mofetil, azathioprine, mercaptopurine, methotrexate

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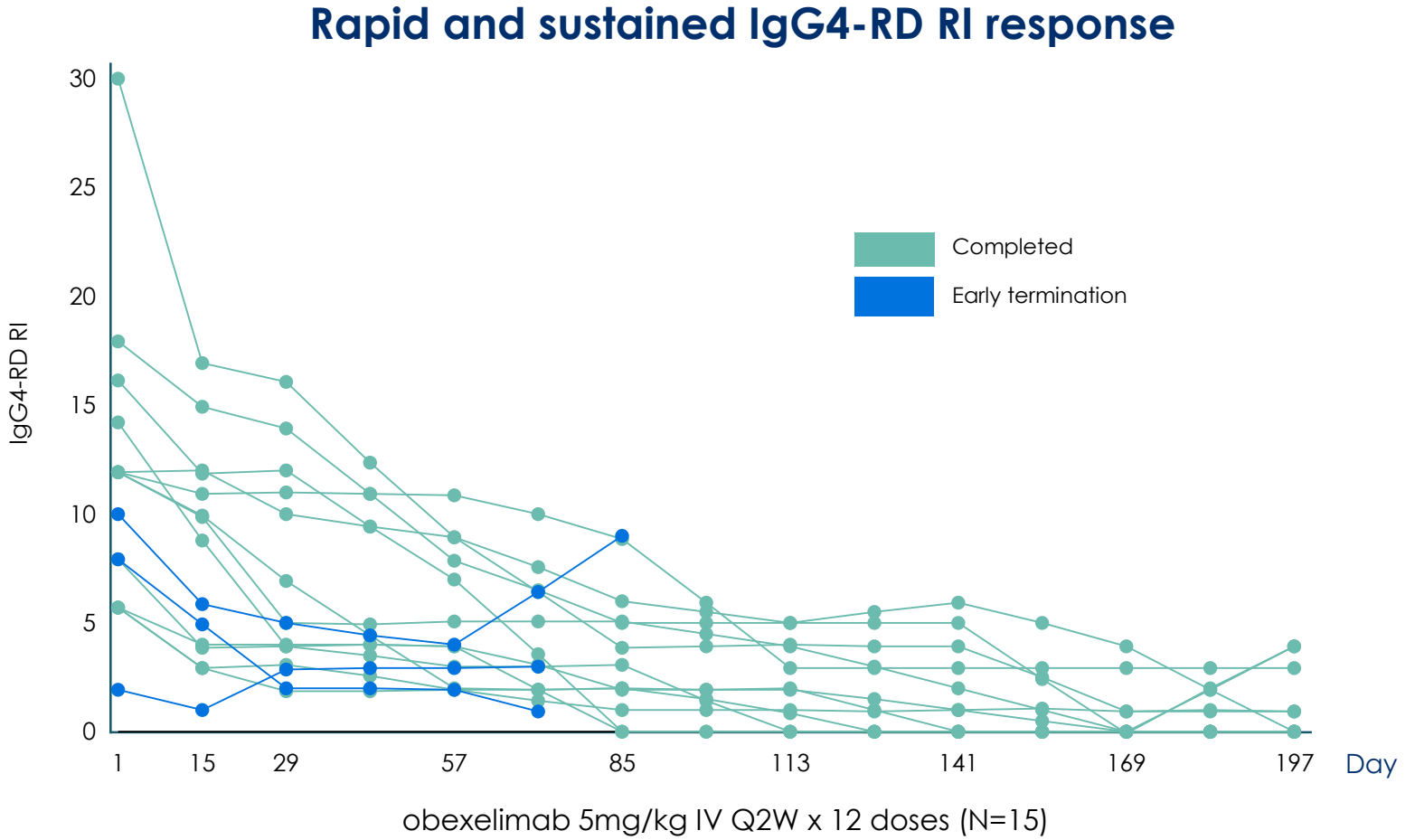
Obexelimab: Phase 2 IgG4-RD results demonstrated rapid, robust, and sustained reduction in IgG4-RD disease activity[1]

- Induction and Maintenance
- **100%** of patients who completed trial met primary endpoint[2]
  - No flares or steroid use after Day 57
- **93%** with ongoing response at end of trial
- **80%** with prior rituximab achieved complete remission
- Well tolerated; most frequent AEs were IV infusion-related gastrointestinal events; three SAEs were not considered to be related to obexelimab



[1]Perugino et al. *Lancet Rheumatology* 2023. Open-label, single-arm Phase 2 PoC trial in 15 obexelimab-treated patients with moderate to severe disease as induction and maintenance, one or more organ systems involved and an IgG4-RD Responder Index (RI) of ≥ 3

[2]Primary endpoint: proportion of patients on Day 169 with a decrease in IgG4-RD RI ≥ 2 points

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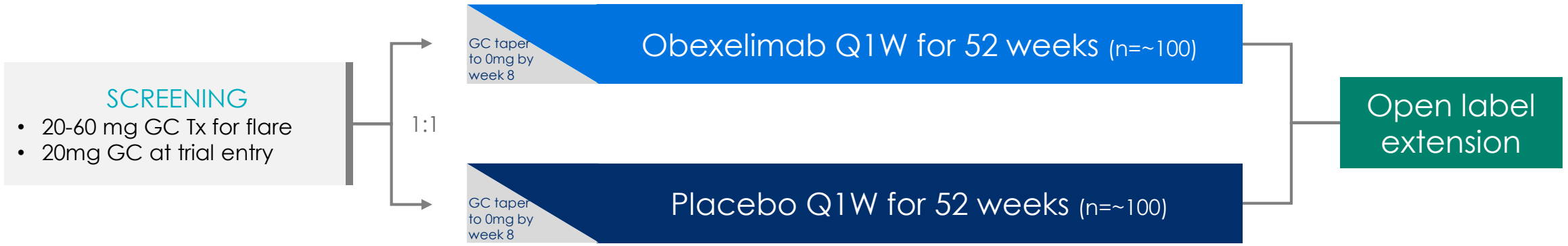
Phase 3 INDIGO IgG4-RD trial enrollment complete

Trial of over 190 patients, the largest ever conducted, with topline results expected around year-end 2025



INDIGO Trial Summary:

- Design: Randomized, double-blind, placebo controlled
- Treatment: weekly obexelimab 250 mg subcutaneous or placebo control; GC taper to 0 mg by week 8
- **Primary endpoint: Time to disease flare through week 52**
- Secondary endpoints include: 52-week flare rate, Achievement of complete remission, Use and quantity of rescue medication, Change in GC-associated toxicity as measured by the Glucocorticoid Toxicity Index (GTI)

GC = glucocorticoid

Obexelimab potential differentiation in the evolving IgG4-RD treatment landscape

Obexelimab potential attributes support its differentiation in the IgG4-RD treatment landscape

- Potential to achieve higher complete remission rates
- Possibility for fewer rates of severe/opportunistic infections and ability to vaccinate/treat serious infections
- Anticipate no premedication required/no risk of infusion-related reactions
- Patient preference for at home, subcutaneous injection

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Obexelimab: Multiple Sclerosis

Multiple Sclerosis: A debilitating chronic neuroinflammatory disease characterized by flares and disability progression

Disease Overview:

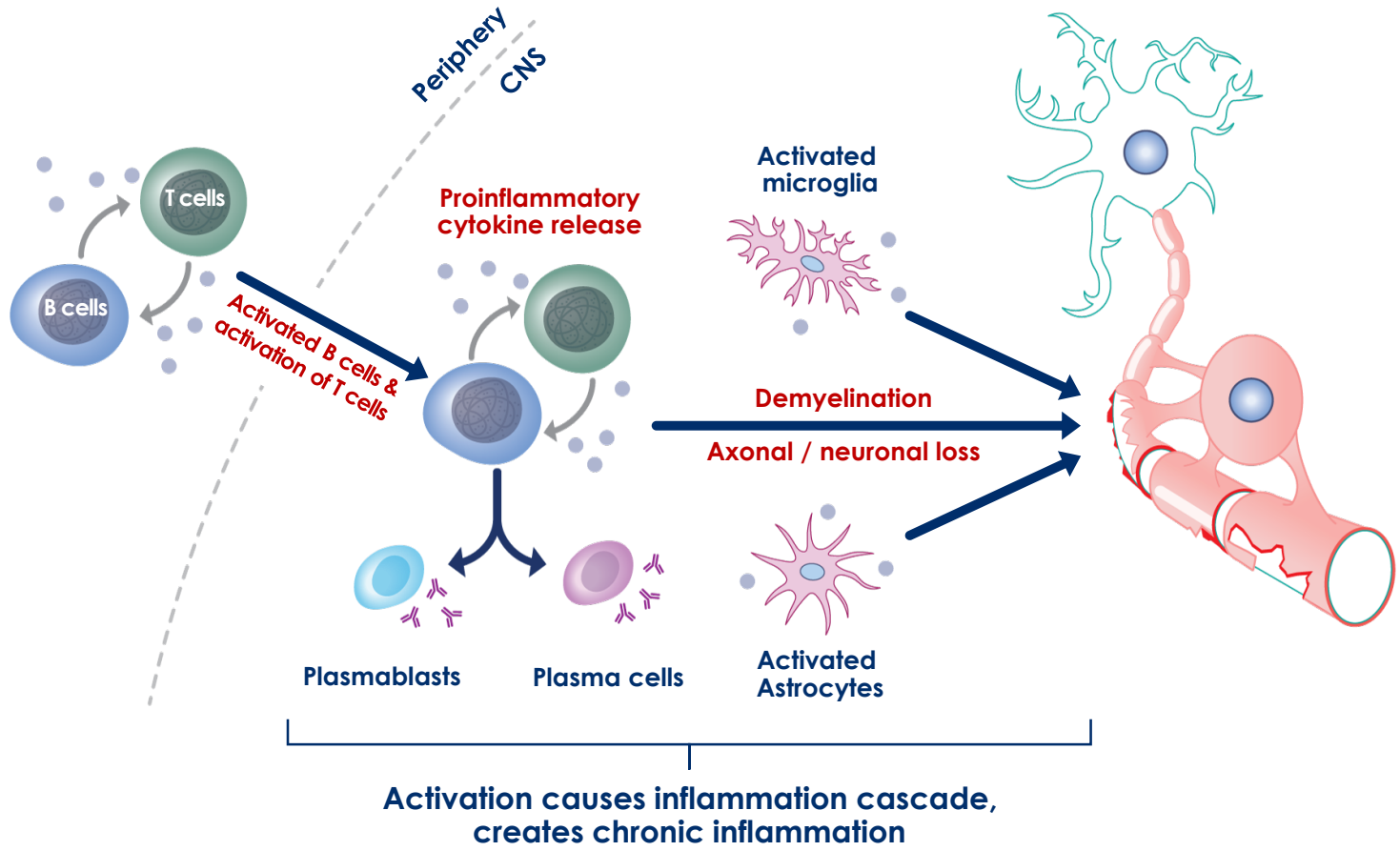
- Characterized by demyelinating lesions of the CNS. Symptoms include sensory and visual disturbances, coordination impairment and spasticity, fatigue, pain, weakness, and cognitive deficits
- Three major forms: relapsing MS (**RMS**), secondary progressive (**SPMS**), and primary progressive (**PPMS**). RMS is characterized by episodes of neurological dysfunction (relapses) followed by complete or incomplete recovery
  - ➢ **Disability progression can occur independently of relapse activity**; referred to as "smoldering" disease and can be measured clinically **(PIRA)**

Pathophysiology:

- B cells, including plasmablasts and plasma cells, represent the predominant cell type in meningeal inflammation

Patient Population

- ~650K diagnosed prevalent patients in the U.S. and ~670K diagnosed prevalent patients in major EU countries



PIRA = Progression Independent of Relapse Activity

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Obexelimab's attributes for potential success in RMS

Obexelimab potential attributes support its differentiation in the MS treatment landscape

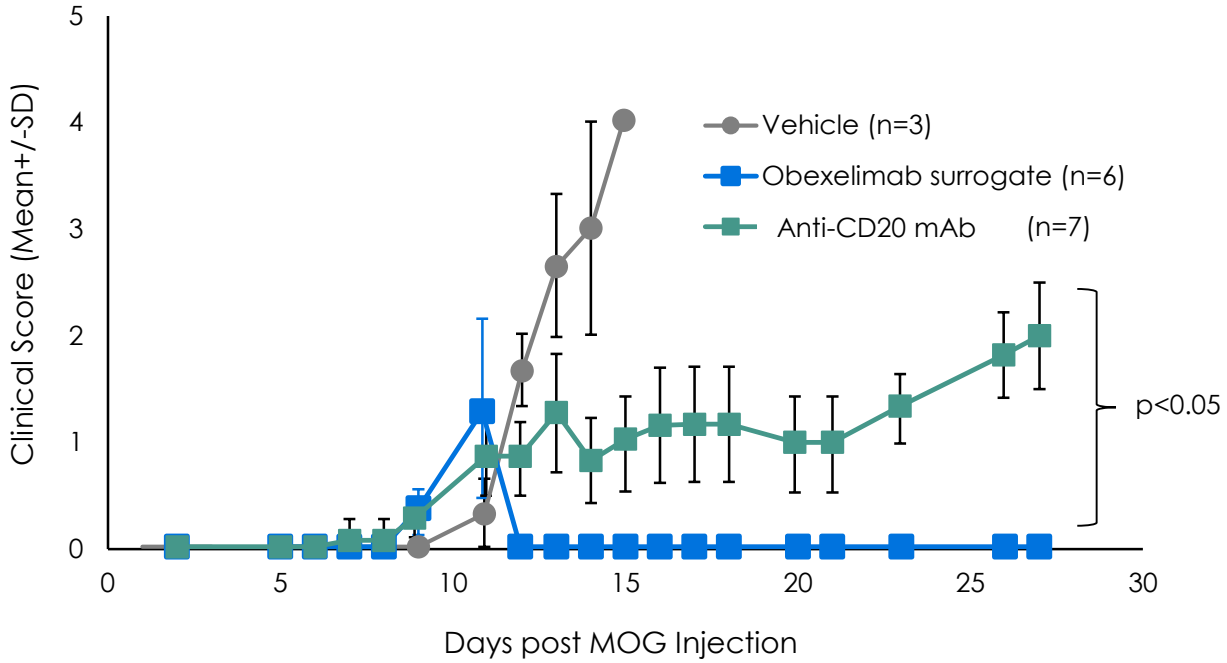
- CD20 are high efficacy (approved) in RMS
- Plasmablasts and plasma cells (not targeted by CD20-directed therapies) are implicated in MS pathogenesis[1]
  - Co-engagement of CD19 and FcγRIIb targets plasmablasts and subset of plasma cells, and has the potential to directly target innate cells
- Superior activity of obexelimab in a preclinical MS model vs. depletion comparator

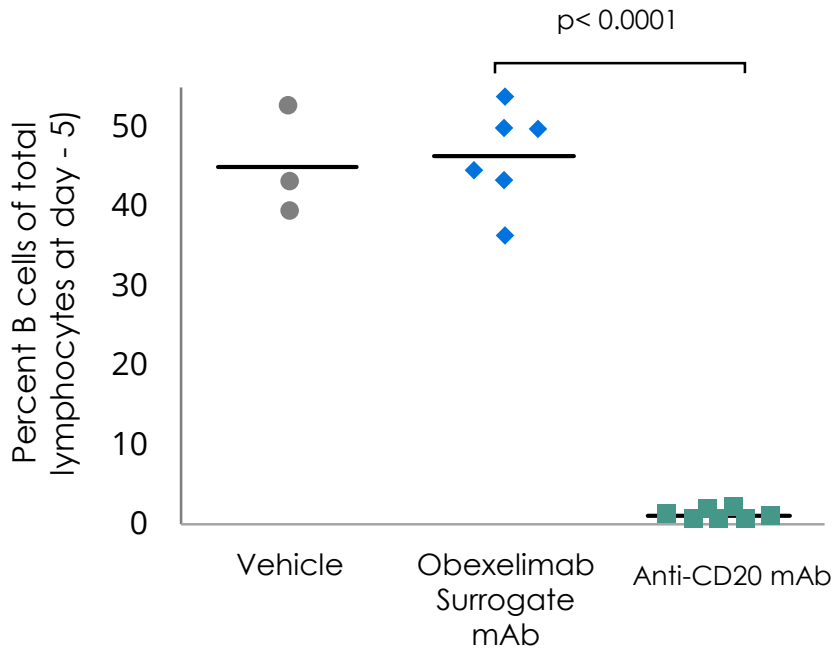
[1]Chen, et al. *J Immunol*, 15 February 2016;196(4): 1541-1549

PIRA = progression Independent of Relapse Activity

Obexelimab surrogate mAb suppressed disease activity in EAE model without B cell depletion vs. an anti-CD20 depleting mAb

EAE: a gold-standard nonclinical model for assessing autoimmune-mediated CNS disease





EAE = Experimental Autoimmune Encephalomyelitis

huFcγRIIb transgenic mice (human FcγRIIb knock-in). Obexelimab and anti-CD20 mAb dosed 10 mg/kg intraperitoneally 2x per week beginning day -7 continuing through day 24. Whole blood Immunophenotyping performed at day -5 by flow cytometry to measure percent B cells. Disease induction: Human MOG protein in Complete Freund's Adjuvant administered on day 0 followed by pertussis toxin at days 0 and 3. Daily clinical scores measured from day 2 through day 27; mice sacrificed at clinical score of 4

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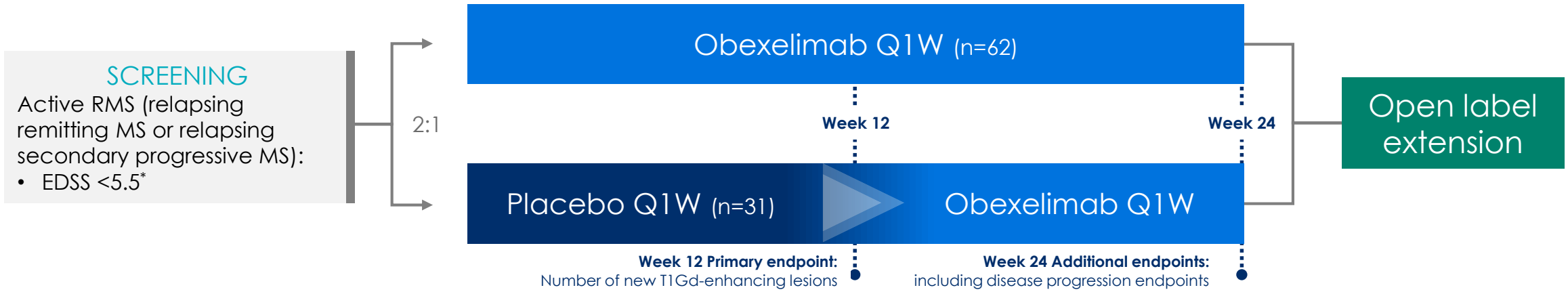
Phase 2 MoonStone RMS trial enrolling

Gold-standard design with MRI measurements; highly predictive of successful outcome in large randomized trials



MoonStone Trial Summary:

- Design: Double-blind, randomized, placebo controlled with placebo crossover at week 12
- Treatment: obexelimab 250mg SC weekly vs. placebo control (first 12 weeks)
- **Primary endpoint: Number of new T1 Gd-enhancing lesions at week 12**
- Secondary endpoints: Utilizing standardized assessments, imaging and biomarkers to evaluate impact on disease progression/silent progression
- 90% power to detect 90% reduction in T1-Gd lesions vs. placebo at week 12

*EDSS 5.5 = disability severe enough to preclude full daily activities. Able to walk without aid or rest for 100m

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Obexelimab: Systemic Lupus Erythematosus

System Lupus Erythematous (SLE): A debilitating chronic autoimmune disease that attacks healthy tissue

Disease Overview:

- SLE is a complex, chronic autoimmune disease characterized by unpredictable flares in joints, skin, kidneys and other vital organs that cause progressive organ damage. Comorbidities, such as infections, malignancies, hypertension, lipid disorders and diabetes increase risk of patient disability and death

Pathophysiology:

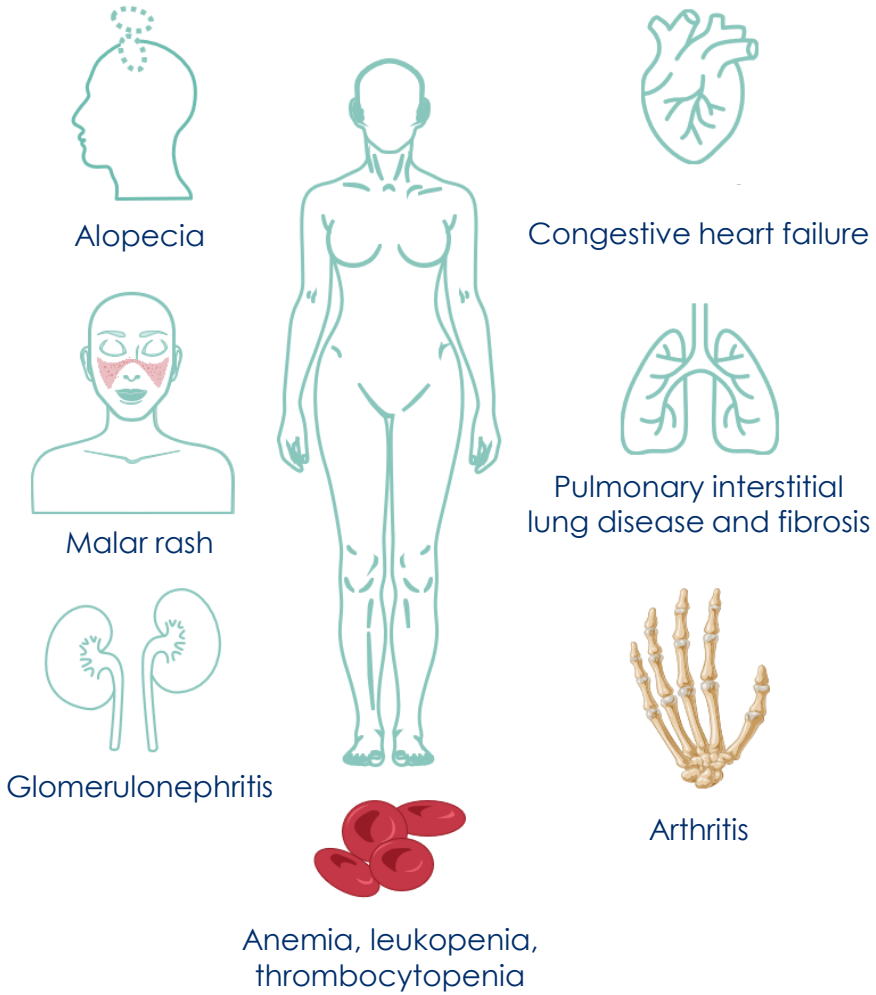
- B cell dysfunction resulting in abnormal regulation of immune responses and the production of autoantibodies toward cellular and nuclear components results in tissue inflammation and multi-organ damage

Therapeutic Opportunity

- GC and immunosuppressants are the mainstay of treatment, only two moderqtely effective therapies are approved for moderate-to-severe disease
- Long-term GC use and irreversible organ damage has been reported to be a predictor of morbidity and mortality in SLE[2]

Patient Population

- ~150K patients in the U.S. and ~170K patients in major EU countries



[1]BENLYSTA® and SAPHNELO®

[2]Pawlak-Buś, K. Current treatment of systemic lupus erythematosus: a clinician's perspective. *Rheumatology Int*. 2023

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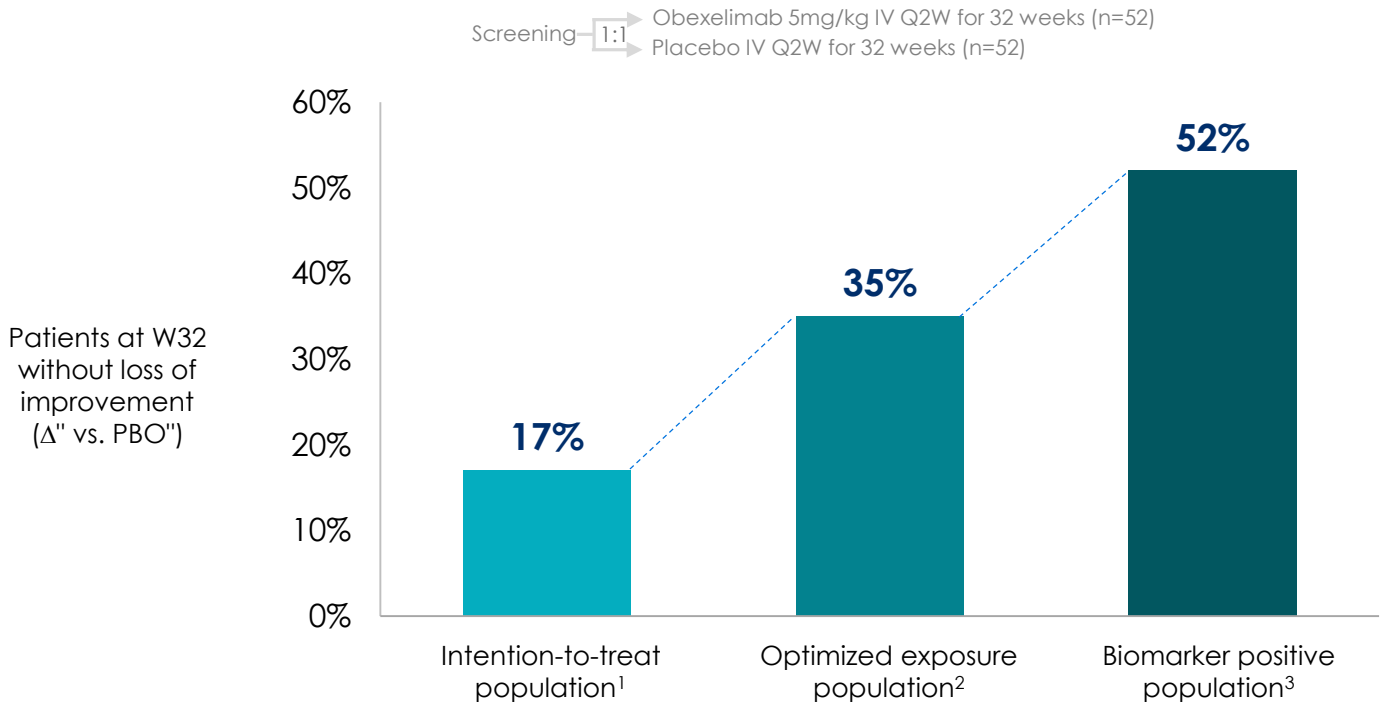
Potential for improved clinical activity with an optimized obexelimab dosing regimen

Higher **clinical** activity observed with obexelimab in a Phase 2 trial with optimized exposure, and in biomarker positive population



- Current approved therapies demonstrate modest effect sizes of 12–17% over placebo on SRI-4/BICLA assessments

Source: Merrill et al. *Arthritis Rheumatol*. 2023

[1]Defined as all randomized patients receiving at least one dose of study medication

[2]C_{trough} Quartiles 3 & 4 in efficacy evaluable analysis

[3]Biomarker positive defined as patients in predefined lupus phenotypic gene expression clusters 3 & 6 (~38% of evaluated population)

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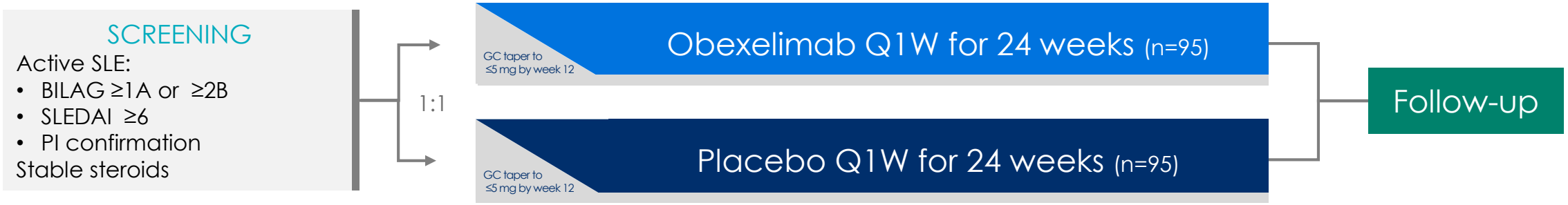
Phase 2 SunStone SLE trial[1] enrolling

Designed to confirm obexelimab activity in all-comer and biomarker populations

Incorporates learnings from previous Phase 2 trial to increase POS

- SC dosing to improve PK (steady state C_{trough} above Phase 2 top (4^{th}) quartile for all patients)
- Powered on appropriate placebo response and effect size assumptions
- Strict adjudication for eligibility and assessment (moderate/severe patients only); strict corticosteroid tapering rules to reduce placebo responses



Primary Endpoint: Reduction of SLE disease activity at week 24 by BILAG-Based Composite Lupus Assessment (BICLA)

[1]Double-blind, randomized, placebo-controlled

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Conclusion (1/2)

- Obexelimab is a bi-functional monoclonal antibody that binds CD19 and FcγRIIb to inhibit B cell responses in circulation and tissues
- Targeting CD19 inhibits a broader range of B cells, including memory B cells and CD19+ plasma cells
- Engineering a molecule with higher affinity to FcγRIIb may lead to inhibition of cells that express FcγRIIb but not CD19, such as innate cells and CD19- plasma cells
- Obexelimab treatment causes a partial decrease in circulating B cells, but B cells recovered quickly (approximately 80% of mean baseline levels within 6 weeks)
- Suppressing B cell activity with obexelimab provides a unique MoA and therapeutic profile for treating several autoimmune diseases

Conclusion (2/2)

- Obexelimab has been well tolerated across 5 completed clinical studies
- Overall tolerable safety profile:
  - Most common AEs with IV formulation: GI-related symptoms (primarily vomiting, nausea, and/or diarrhea)
  - Most common AEs with SC formulation: mild injection site reactions characterized by erythema, pain, and induration that resolved within 24 hours
  - No clear difference in serious infections or infections in general between Obexelimab and placebo but exposures are limited

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Thank you