AUTOIMMUNITY BioSolutions

Precision Genetically Driven Therapeutic Approach for Autoimmune Disease

ABS Company Overview

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ABS Background and Mission

BACKGROUND

- ABS has identified a **highly prevalent (50%) SNP** population predisposed to more severe autoimmune disease
- The risk allele of SNP leads to high levels of **soluble** IL7 receptor (**sIL7R**), which acts as an agonist elevating IL7
- The risk SNP and elevated sIL7R have been widely associated in multiple autoimmune diseases with poor response to therapy and more severe disease

MISSION

- Develop **therapeutics** and **biomarkers** to dramatically improve outcomes with genetically targeted precision therapies within the autoimmune space
  - ✓ **Therapeutics:** Our mAbs and ASOs reduce sIL7R in the risk population
  - ✓ **Biomarkers:** ABS biomarkers seek to identify responder populations for current or emerging standards of care

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ABS is Tackling the Biggest Unmet Need in Autoimmune Disease

30-50%

of patients with inadequate response to SOC

ABS Therapy

sIL7R mAb

Lowers soluble IL7R

ABS is targeting genetically elevated sIL7R likely to be the **root cause** of refractory disease

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A Portfolio of Therapies and Biomarkers

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Therapeutics:

Monoclonal antibody (mAb)

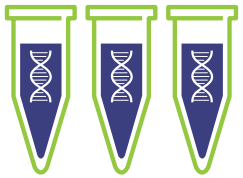
Reduces levels of the protein in circulation. Exclusive binding to sIL7R.

Lead program

Antisense oligonucleotide (ASO)

Prevents expression of sIL7R.

Biomarkers:



SNP multiplex genomics assay

Identifies patients with targeted SNPs.

ELISA assay

Measures the level of sIL7R in patients.

***Assays undergoing CLIA validation. Planned biomarker subsidiary.*

Therapies to reduce genetically elevated sIL7R and dramatically improve clinical outcomes

Biomarkers to identify non-responders to existing therapy due to genetically elevated sIL7R

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ABS identified a Prevalent SNP that Drives sIL7R Overexpression

The risk allele, **SNP rs6897932**, occurs in **~50%** of the population regardless of disease.

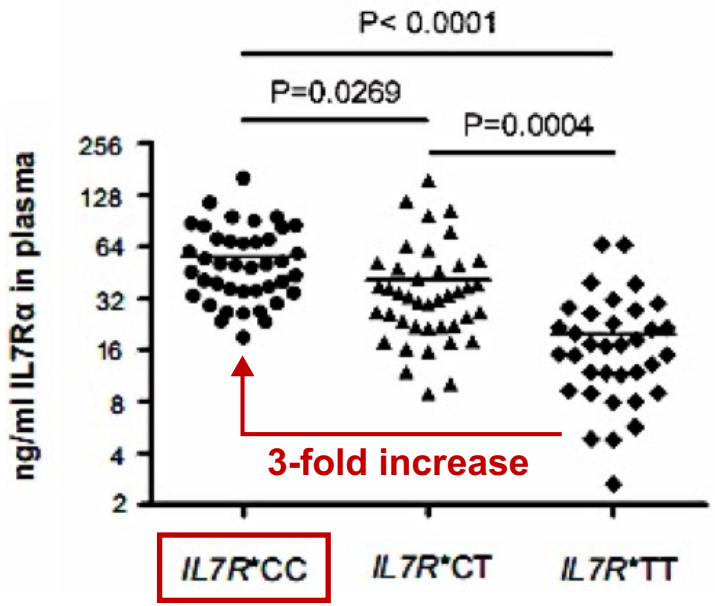
Risk Allele "CC"
- 52% controls
- 58% MS

Other Alleles "CT, TT"

Aggregate sample size (*n*):
Controls = 3657; MS patients = 2664

Data combined from:
Gregory et al., 2007 ***Nature Genetics*** *[PMID: 17660817]*
Traboulsee et al., 2014, ***Neurogenetics*** *[PMID: 24770783]*

Risk SNP **substantially upregulates sIL7R**



The **risk 'C' allele** of rs6897932 increases the expression of sIL7R by **3-fold.**

Lundstrom et al., ***Proceedings of the National Academy of Sciences (PNAS)*** *2013 [PMID: 23610432]*

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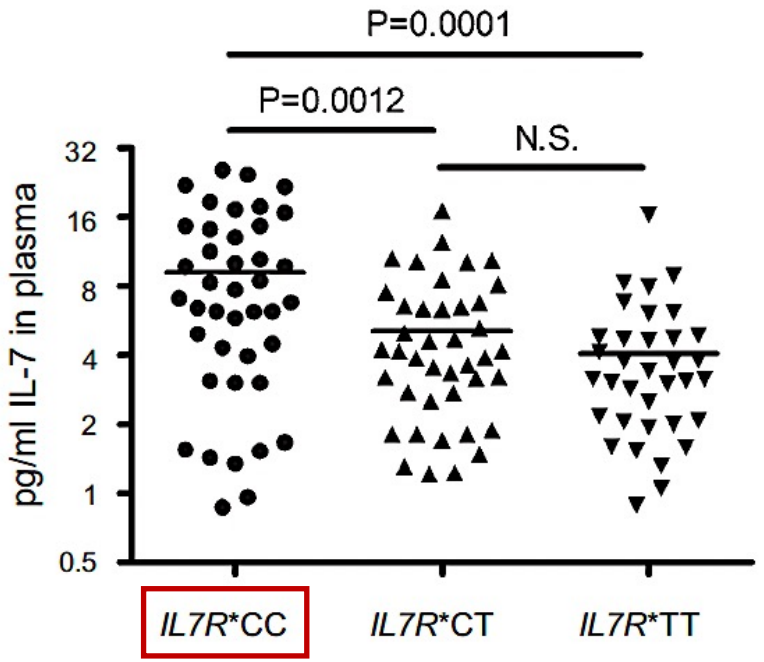
sIL7R Boosts IL7 More Than 2-fold

sIL7R is an **agonist** of IL7

- **sIL7R** enhances ligand availability & activity by preventing its degradation
- **sIL7R** potentiates the activity of **IL7** by stabilizing and maximizing its exposure to T cells, leading to overexpansion of T cells.
- **Other Examples of Soluble Receptors as Agonists**: sIL4R, sIL15Ra

Kefaloyianni, 2022, ***FEBS Letters*** *596, 589-606. PMID: 35113454*

Elevated **sIL7R** due to risk SNP leads to enhanced **IL7** in MS patients



The **risk 'C' allele** of rs6897932 correlates with elevated levels of **IL7** in MS patients.

Lundstrom et al., 2013, ***PNAS*** *110, E1761-1770. PMID: 23610432*

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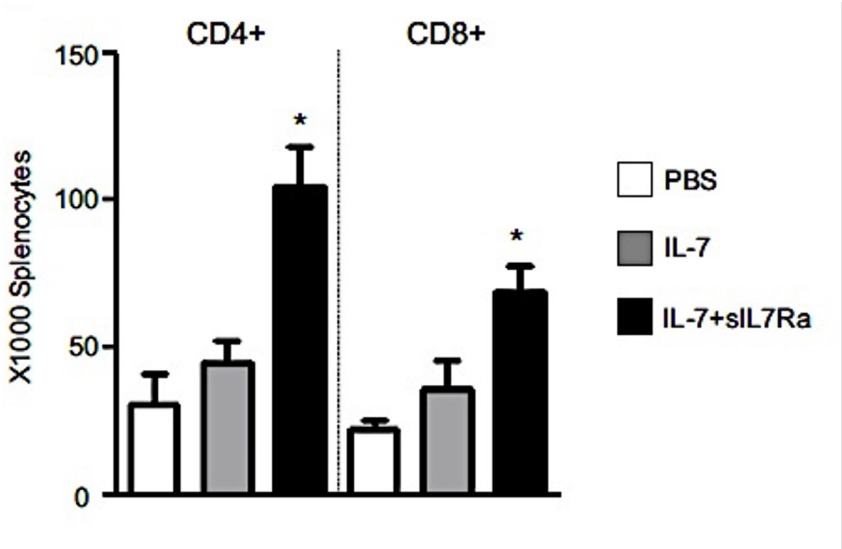
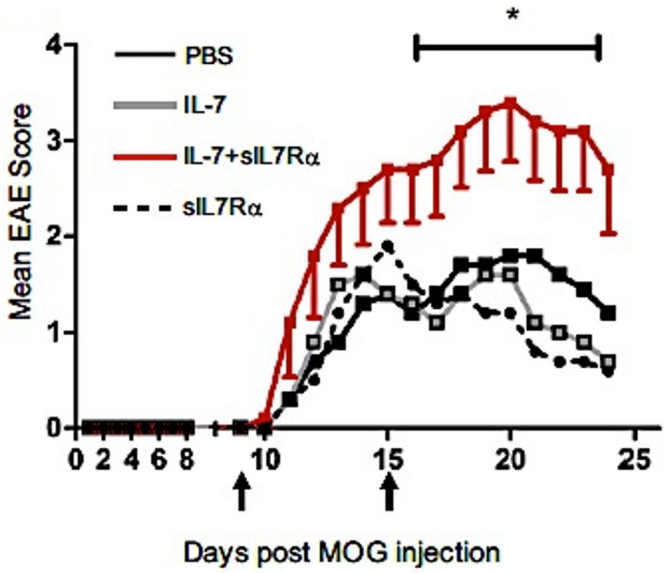
sIL7R Drives T Cell Expansion and Disease Severity in MS Model

Injection of sIL7R protein in IL7 knockout mice **enhances expansion of T cells**



sIL7R has been shown to enhance expansion of T cells both *in vitro* and in mice.

Injection of sIL7R in EAE mouse model of Progressive MS **enhances disease severity**



sIL7R enhances disease severity in EAE mouse model of Progressive MS.

**Animal model to be used to establish initial proof of concept of top mAbs.*

*Lundstrom et al., 2013, **PNAS** 110, E1761-1770. PMID: 23610432*

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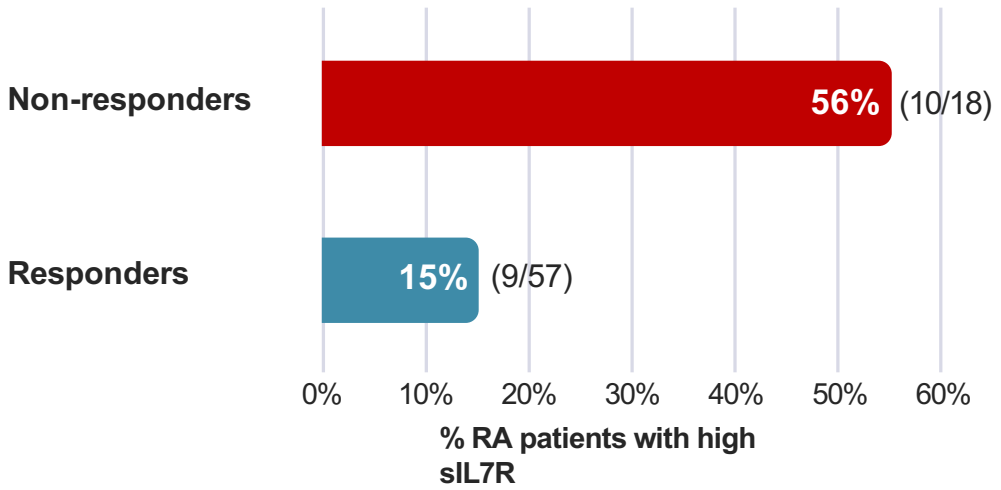
High sIL7R Confers a 3-fold Higher Risk of Anti-TNF Failure in RA

High sIL7R strongly correlated with **poor response to infliximab**, whereas low sIL7R strongly correlated with adequate response.

Percentage of RA patients with high levels of sIL7R among responders & non-responders to treatment



Journal of Cellular and Molecular Medicine

Rheumatoid arthritis synovial fibroblasts produce a soluble form of the interleukin-7 receptor in response to pro-inflammatory cytokines.

V. Badot, 2011

sIL7R is an accurate predictor of response to infliximab therapy in DMARD-resistant RA patients:

- ✓ **Low levels of sIL7R:**
  87% probability of being **responders**.
- ✓ **High levels of sIL7R:**
  29% probability of being responders.

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sIL7R-Linked Proteinuria Likely Impairs Belimumab Efficacy in LN

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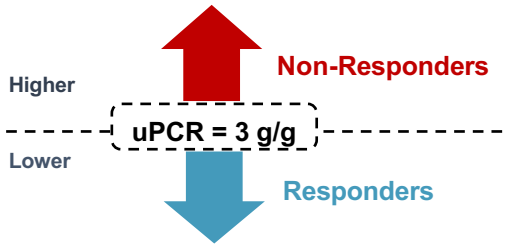
High Proteinuria (uPCR) Correlates with Reduced Response to Belimumab (Benlysta):



Kidney International

A secondary analysis of the Belimumab International Study in Lupus Nephritis trial examined effects of belimumab on kidney outcomes and preservation of kidney function in patients with lupus nephritis.

Rovin et al, 2022

2

Elevated sIL7R correlates with greater 24h proteinuria and uPCR

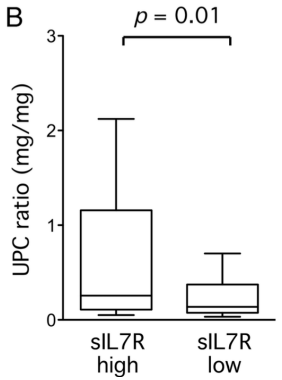


Figure B. Serum soluble form of the interleukin-7 receptor (sIL7R) concentrations vs urinary protein to creatinine (UPC) ratio in a longitudinal cohort of SLE nephritis patients

Lupus Science and Medicine

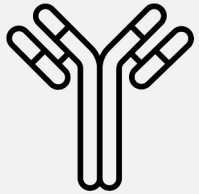
sIL7R concentrations in the serum reflect disease activity in the lupus kidney

B Lauwerys et al, 2017

This implies **sIL7R could drive this lack of response**

Therapeutic Opportunity

ABS Therapy



Lowering **sIL7R** in high-proteinuria LN patients could reduce proteinuria, restore eGFR, and potentially restore responsiveness to existing therapies

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Elevated sIL7R Linked to Poor Outcomes Across Autoimmune Diseases

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The Science

- SNP elevates sIL7R expression by **3-fold**.
- Elevated sIL7R acts as an **agonist**, extending and expanding the impact of IL7 on T cells.
- **Greater activation** of autoreactive T cells and conversion to pathogenic memory T cells.
- Growing pool of **autoreactive effector and memory T cells** amplifies disease severity.

Disease Impact

Poor Response to Therapy

More Severe Disease

Greater Risk of Progression

Examples

Rheumatoid Arthritis (RA)

RA patients with highest sIL7R levels have a **3-fold higher** likelihood to be non-responders to anti-TNF therapy.

Lupus Nephritis (LN)

LN patients with highest sIL7R levels have an **8-fold higher** incidence of severe flares (48% vs 6%).

Progressive MS (PMS)

MS patients with the SNP and elevated sIL7R have a **37% higher** risk of developing Progressive MS.

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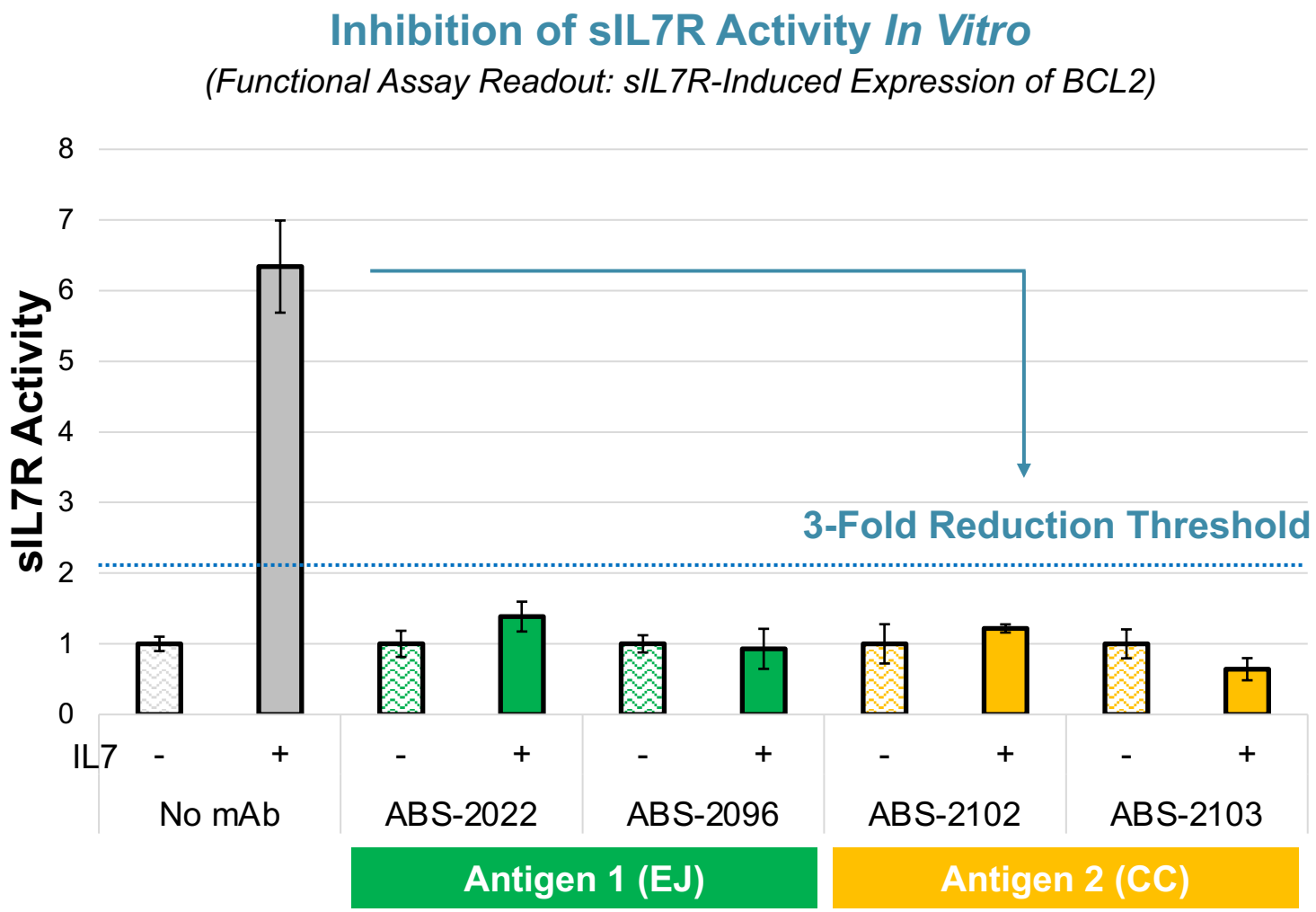
Anti-sIL7R mAbs Achieve Robust Inhibition of sIL7R Activity *In Vitro* *Assay Using Human Primary T cells from Individuals with the Risk SNP*



Relevance of *in vitro* T cell functional assay:

- T cells derived from donors carrying the risk SNP.
- sIL7R is endogenously expressed and active in these T cells, as it is in patients.
- Anti-sIL7R antibodies suppress IL7 hyperactivity by blocking sIL7R.
- This *in vitro* inhibition reflects our intended therapeutic effect in patients.

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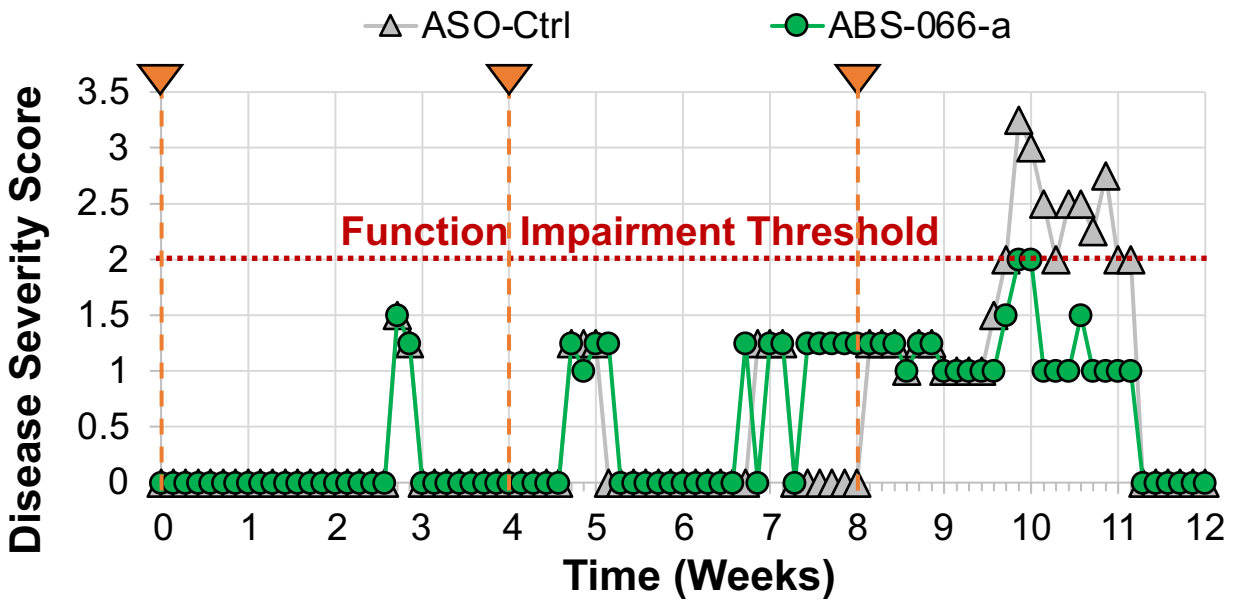
Pilot NHP Study: ABS ASOs Diminish Impairment in EAE Model

Disease Severity (Impairment)

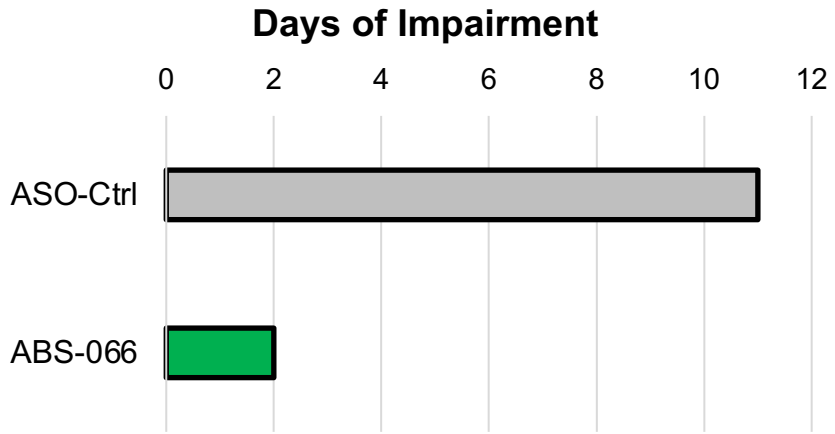


ASO-Ctrl = Control animal developed **more severe disease**

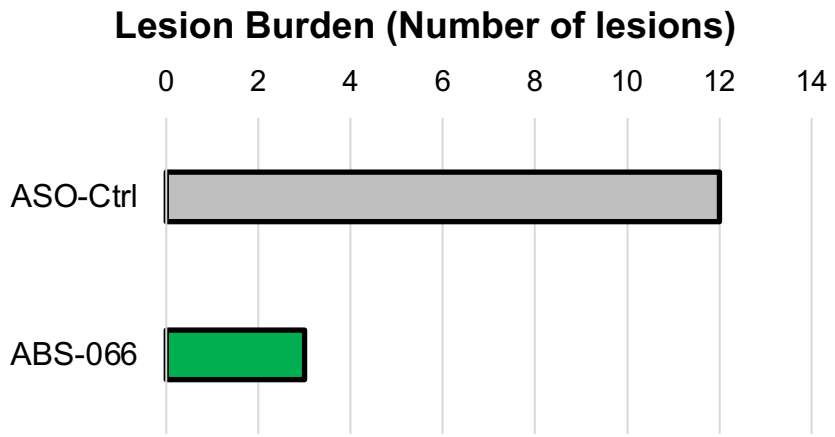
ABS-066-a = Experimental animal developed **ameliorated disease**

Injection of **auto-antigen** (human MOG protein)

Number of Days Animals were Impaired



Assessment of Brain Lesions by MRI



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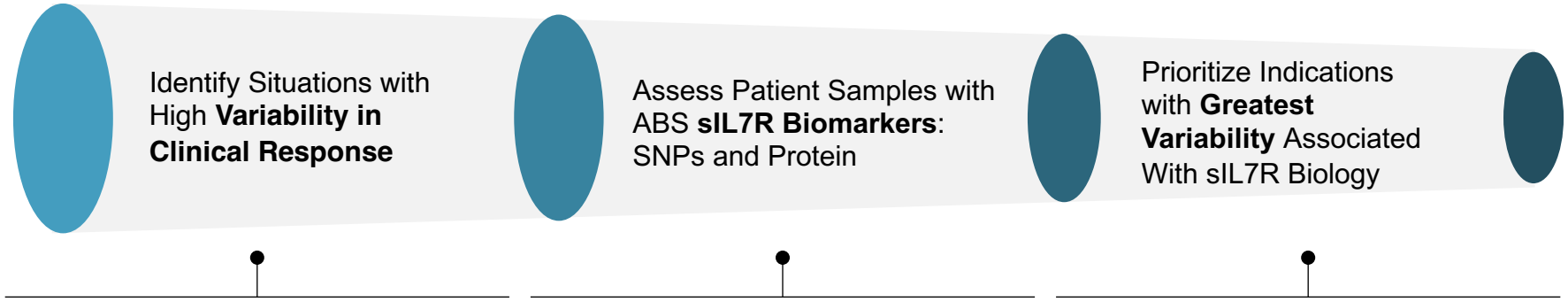
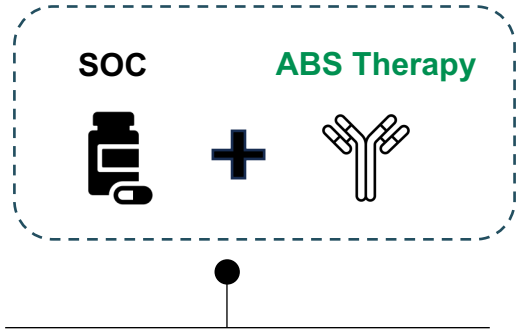
ABS Strategy for Indication Selection: Clinical Response and Biomarker Data

Highly Derisked Initial Clinical Proof of Concept





Initial Selection

- *Existing Standards of Care*
- *Late Stage Clinical Development Programs*

Patient Biosample Assessment

- *Correlate sIL7R biology with clinical response or non-response*

Indication Prioritization

Derisked PoC Strategy

- Treat the **low-responder** SNP/ high sIL7R population
- **ABS + SOC Combination** Treatment
- Use SOC monotherapy as active control arm – **known poor response**

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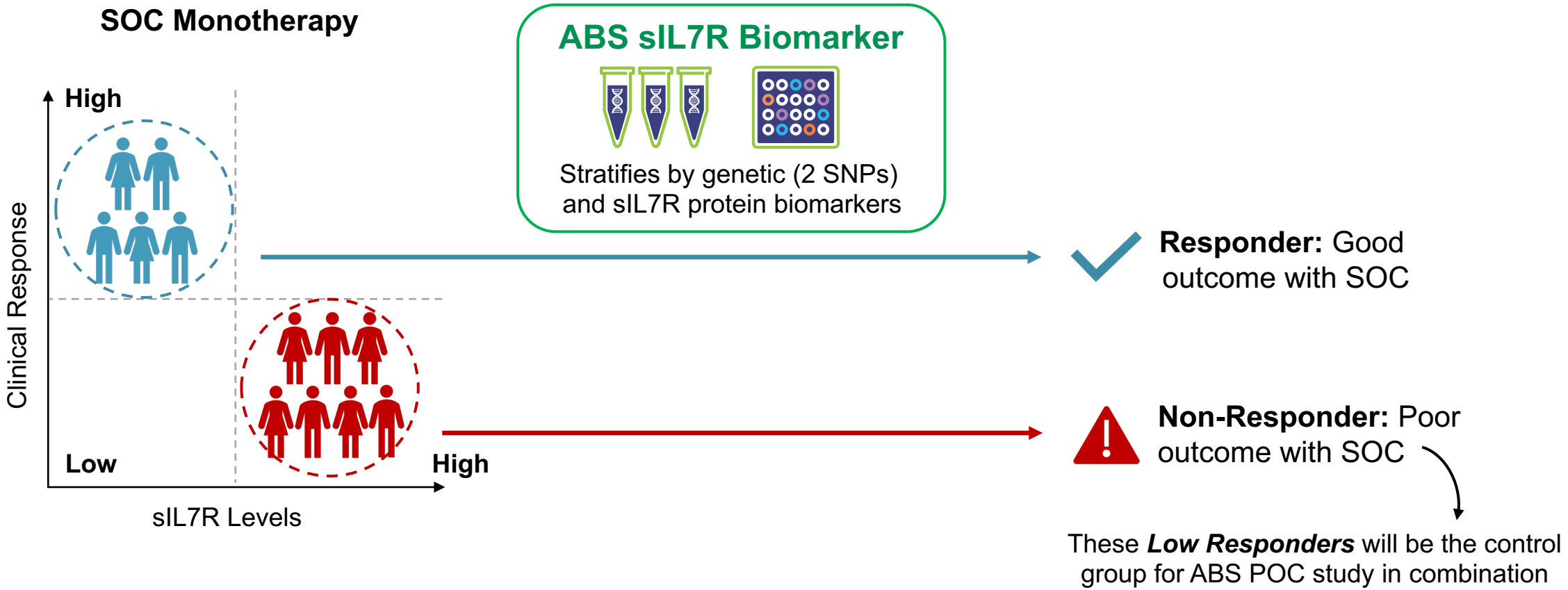
ABS Commercial / Clinical Strategy

Stage 1: Use ABS biomarker assays to identify a **non-responder** population to SOC



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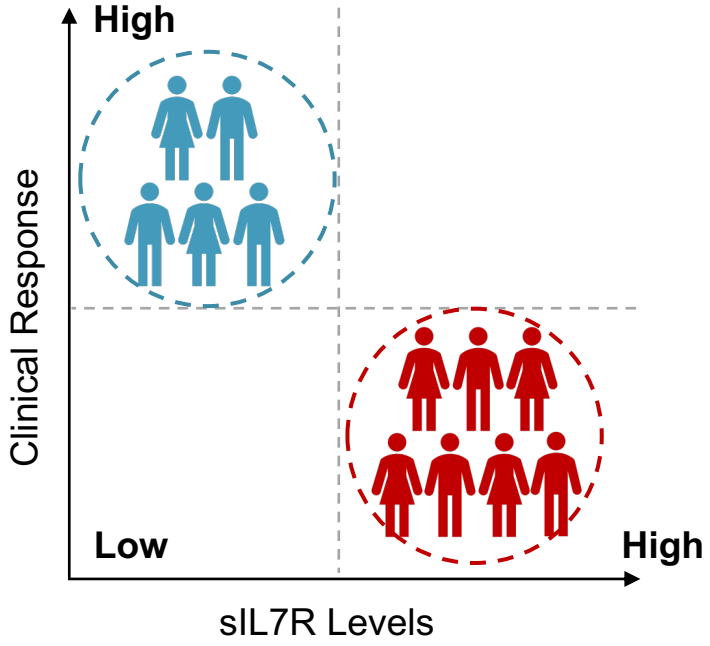
ABS Commercial / Clinical Strategy

Stage 2: In the **non-responder** population, show benefit of ABS combo therapy

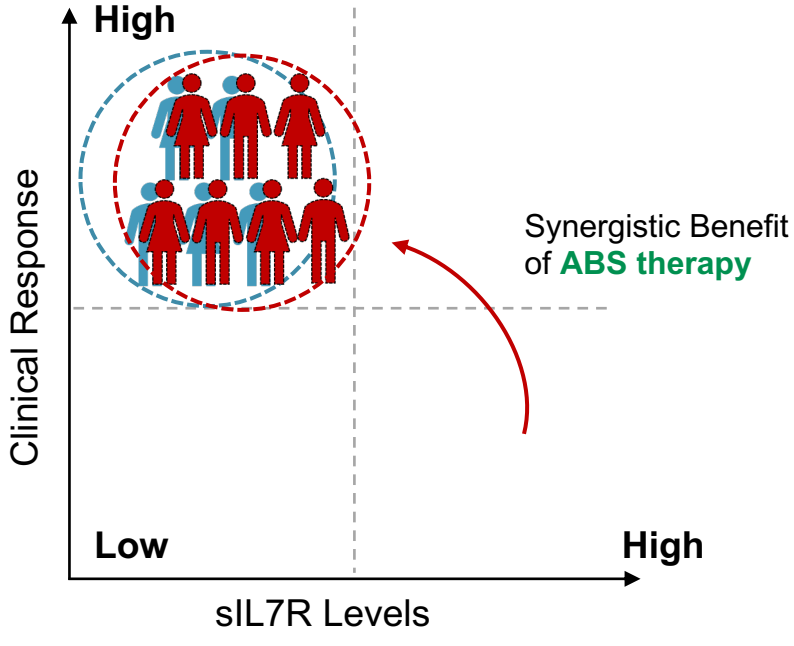
SOC Monotherapy



ABS Therapy

sIL7R mAb
Lowers sIL7R

SOC + ABS Therapy



Goal: Large Pharma Collaborations to identify 2 indications for PoC

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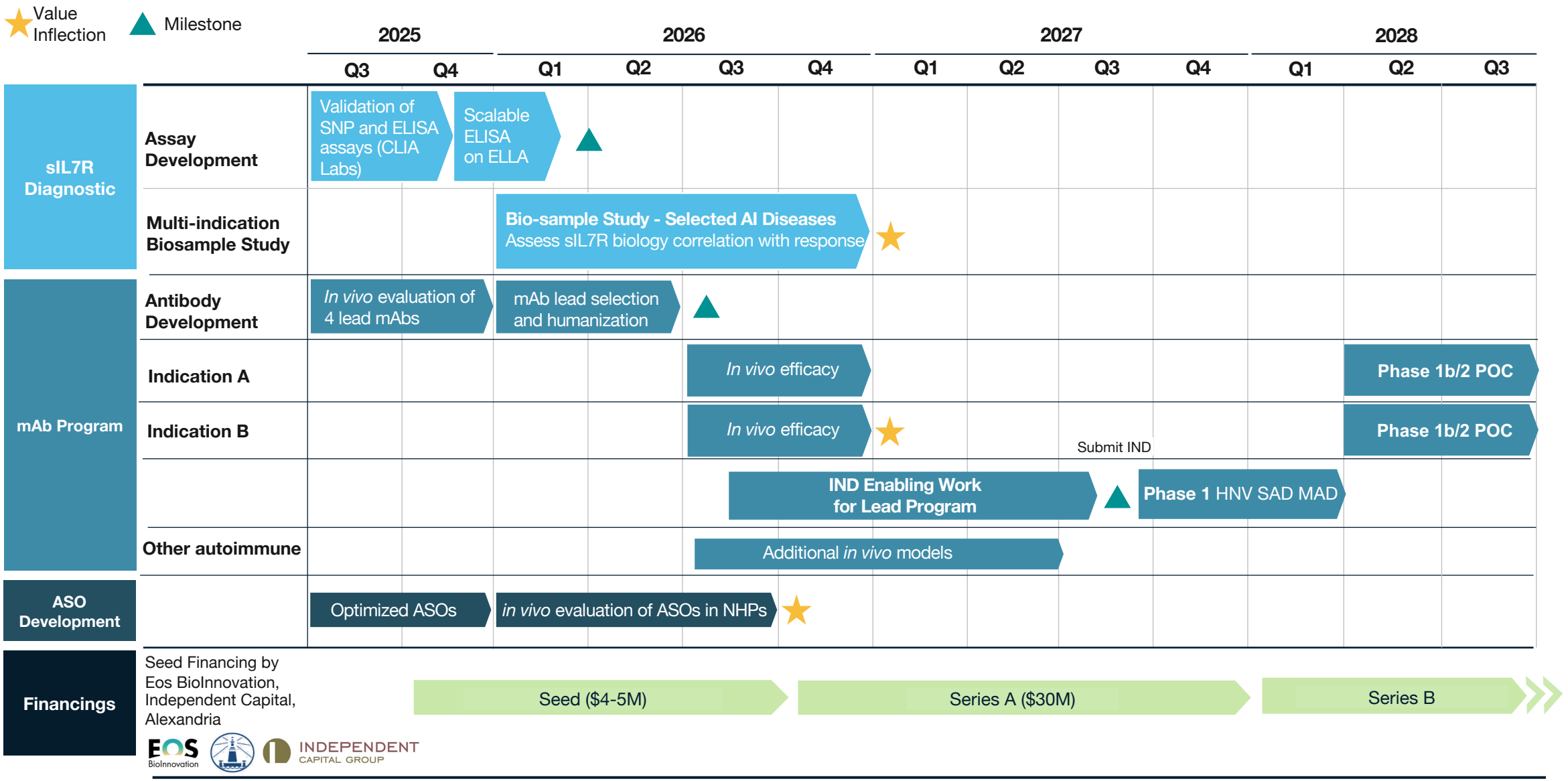
Development Plan



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ABS mAb: Target Product Profile

Parameter	Minimum Acceptable	Ideal	Comments
Indication	Treatment of Lupus Nephritis (or other AI disease) patients with the SNP	All patients with diagnosed autoimmune disease and the SNP	Regulatory procedures (FDA Type C Meeting, EMA Scientific Advice) to explore basis for broad label
Target Population	SNP population of approved autoimmune disease indications	All patients with diagnosed autoimmune disease and the SNP	TAM of ideal label is 25MM US, 60MM global markets
Treatment Duration	Chronic	Chronic	ABS mAbs may enable episodic use of immunosuppressives
Delivery Mechanism	IV	Subcutaneous	Well established Sub Cu platforms – likely
Dosing	Frequency: parallel to standard of care (for example, in LN: Every week for the first four weeks, every other week thereafter).	Twice a month subcutaneous	
Efficacy	25% improvement in efficacy of SOC treatments (BAFF, CD-20, anti-TNF, IL-23, etc.) in SNP population	2-3 fold improvement in efficacy of SOC treatments (BAFF, CD-20, anti-TNF, IL-23, etc.) in SNP population	Possible to target a population (SNPs and sIL7R) to achieve highly differentiated efficacy
Side Effects	Similar to immuno-suppressives	No significant Adverse Events	

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Maximizing Patient Benefit and Commercial Potential

Phase 2

Derisked Initial PoC

- **Identify subpopulations** with significant differences in treatment response driven by sIL7R biology
- Therapeutic reduction of excessive **sIL7R** in defined population leads to **significant clinical benefit**

Phase 3

Pivotal Trials

Pivotal Trial(s) in POC Indications

Real World Data:

Poor response to SOC in numerous autoimmune diseases – SNP population

BROAD LABEL

Phase 4

Expansion of Treatment Regimen

- **Monotherapy** maintenance
- **Combination induction** upon initial diagnosis followed by sIL7R monotherapy
- **Reduce dose of immunosuppressives**
- Other

Total Addressable Market
~25MM US; **~60MM** Global

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Experienced Management Team

Eugene Williams
CEO

Senior Life Science Executive & Serial Entrepreneur

Significant Experience in R&D management, commercialization, deal making, in biotech and pharma.

Chair & Co-Founder, ProMIS Neurosciences.

Former SVP & General Manager, Genzyme (Immune Mediated Diseases)

Gaddiel Galarza-Munoz
Co-Founder & CSO

Experienced Scientist in Neurobiology and Immunology

PhD, Neurobiology, University of Puerto Rico

Postdoc, Duke University and UTMB

Discovered foundational sIL7R biology underlying ABS therapy

Dick Polisson
CMO

Translational Medicine & Clinical Development Physician

MD Medicine, Duke University

Associate Professor, Rheumatology, Massachusetts General Hospital

Former Head of Translational Medicine and Early Development, Sanofi-Genzyme

Jen Beachell
CBO

Life Science Executive & Startup Company Operator

Former founding COO of Upstream Bio.

VP of AutoAntibody Disease Area, Global Commercial Strategy at J&J and Momenta

Alidad Mireskandari
Scientific Advisor, Diagnostics

Life Science Executive & Molecular Diagnostics Expert

CEO, DiamiR Biosciences
Former CEO JS Genetics

Former CDO of Interpace Biosciences
Former Managing Partner at Miresco Investment Services

Robert McBurney
Director of Personalized Medicine Strategy

Expert In Patient-centered Research & Clinical Outcomes

CEO, Optimal Healthcare Outcomes

Former CEO and CRO of Accelerated Cure Project for MS
Former Founder and Director, Optimal Medicine

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ABS Scientific Advisory Board

Mariano A. Garcia-Blanco, MD, PhD
Co-founder, SAB Chair & Board Director

Chair & Professor, Microbiology, Immunology & Cancer Biology, University of Virginia

Founder of 5 companies
Member of American Academy of Arts & Science
190+ peer-reviewed publications

George Hutton, MD

Vice Chair, Neurology, Baylor College of Medicine

Led 30+ clinical trials in MS and neuroimmunology
Founding director, Maxine Mesinger MS Center

Johanne Kaplan, PhD

Chief Development Officer, ProMIS Neurosciences

Former CSO of Shepherd Therapeutics
Former VP of Neuroimmunology, Genzyme

Sir Richard Roberts, PhD

Nobel Laureate & CSO, New England Biolabs

Discovered RNA splicing (1993 Nobel Prize)
Knighted for contributions to molecular biology

Chandra Mohan, MBBS, PhD

Cullen Distinguished Professor, University of Houston

Leading LN expert; 250+ publications
Discovered urine biomarkers for early LN detection

Shikha Wadhwani, MD, MS

Associate Professor & Vice Chair, UTMB Nephrology

Glomerular disease specialist and trialist
Leads nephrology clinical research at UTMB

Harv Rinder, MD

Professor of Lab Medicine & Hematology, Yale University

Expert in diagnostics and hematologic assays
Former ASCP President

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Broad and Growing Intellectual Property Portfolio

19

filed patent applications

Patent coverage: exclusive license from University of Texas (UT) covers:

- Various drug modalities (mAbs and ASOs).
- Numerous indications in autoimmune disease and cancer.
- U.S. and International rights, with other applications. In drafting.

8

issued patents

Patents issued / allowed: 2 families

- ASOs for autoimmune diseases;
- Companion diagnostic.

5

patent families

- mAbs for autoimmune diseases (composition of matter, and methods).
- ASOs for autoimmune diseases (composition of matter, and methods).
- ASOs for cancer (composition of matter, and methods).
- Diagnostic utilizing multiplex genomic assay for risk assessment.
- Diagnostic utilizing mAbs for specific quantification of sIL7R.

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ABS Investment Thesis: Summary

- The SNP leads to **3-fold** higher sIL7R leading to greater risk of autoimmune disease and greater disease severity.
  - **SNP role discovered by ABS Scientific Founders.**
- Highly prevalent SNP – over **50%** of Autoimmune Disease patients.
  - Addressable market of **~25M** cases in the U.S., **~60M** cases Global
- Potential to address area of great unmet need in **Autoimmune Indications:**
  - Elevated sIL7R leads to worse disease outcomes, poor response to existing therapy.
  - Goal of ABS antibody therapy – normalize sIL7R, improve response to SOC therapy .
  - High unmet need, potential for efficient clinical POC and rapid route to approval.
- Clinical indications will be driven by bio-sample insights from autoimmune patient populations—prioritizing settings with clear biomarker-defined segments leading to dramatic differences in clinical response, highly risk reduced initial clinical POC
- Phase 4 expansion potential into monotherapy maintenance, initial treatment, other treatment regimen innovation
- Proprietary **biomarkers** (SNP and sIL7R levels) enable patient stratification and support a precision medicine approach.
- **Combined biomarker-therapeutic strategy** supports blockbuster commercial potential, with large pharma very actively looking to acquire next generation autoimmune disease therapies

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