



# Targeted science, tailored solutions

*for people with autoimmune disease*



Corporate Presentation

February 2026



# Forward-looking statements

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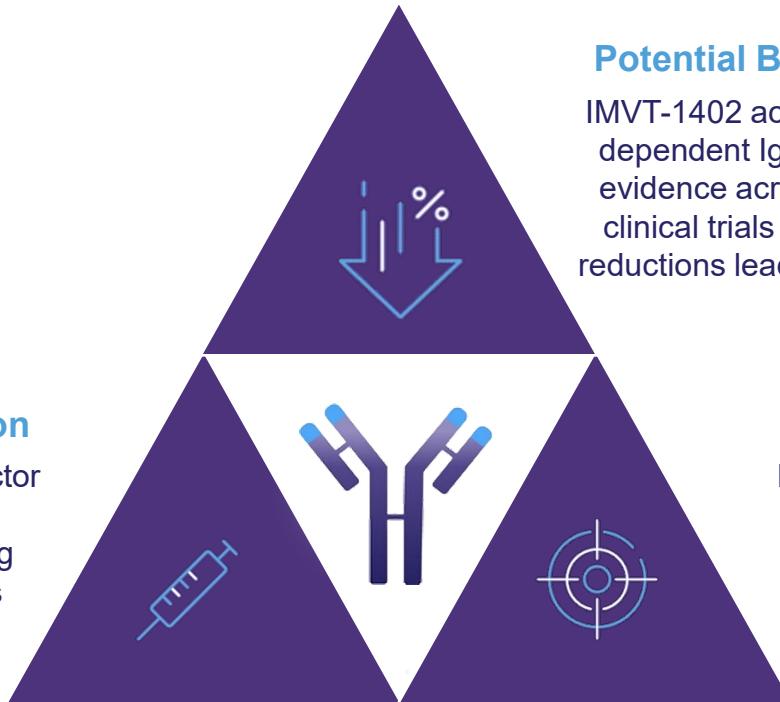
# Our Focus: Pursue a broad anti-FcRn strategy based on potential best-in-class profile of IMVT-1402 targeting autoantibody-driven diseases

Validated Target	IMVT-1402: Potential Best-in-Class Product Candidate	Significant Market Opportunity	Financial Strength
 <p>5 US regulatory approvals, 9 positive Phase 3 trials and 17 positive Phase 2 trials &gt;\$4.3 billion in global anti-FcRn sales in 2025<sup>1,2</sup></p>	 <p>Anti-FcRn with deepest, best-in-class IgG reduction delivered by simple autoinjector On track to be potential first-/best-in-class with potentially registrational trials in GD, MG, CIDP, SjD, ACPA+ D2T RA, &amp; proof-of-concept trial in CLE</p>	 <p>Large total addressable market with 20+ indications announced or in development across the anti-FcRn class<sup>3</sup> Current IMVT-1402 trials expected to potentially address &gt;600K patients in the US</p>	 <p>Cash balance of ~\$995 million as of December 31, 2025<sup>4</sup> Provides runway to Graves' disease commercial launch</p>

1. argenx Highlights 2026 Strategic Priorities
2. UCB HY 2025 Results Capital Markets Earnings Call
3. Indications announced or in development with anti-FcRn assets by Immunovant, argenx, Johnson & Johnson, and UCB
4. Includes cash and cash equivalents

Note: GD: Graves' disease; SjD: Sjogren's disease; ACPA+ D2T RA: anti-citrullinated protein antibody positive (ACPA+), difficult-to-treat rheumatoid arthritis; CIDP: Chronic inflammatory demyelinating polyneuropathy; MG: Myasthenia gravis; CLE: Cutaneous lupus erythematosus

# IMVT-1402 has the potential to be a first- and best-in-class therapy in autoantibody-driven disease



## Convenient Administration

Simple subcutaneous autoinjector with 5-10 second self-administration; currently being tested in all IMVT-1402 trials

## Potential Best-in-Class Efficacy

IMVT-1402 achieves deep, rapid, dose-dependent IgG reductions; consistent evidence across external and internal clinical trials validate that deeper IgG reductions lead to greater clinical benefit

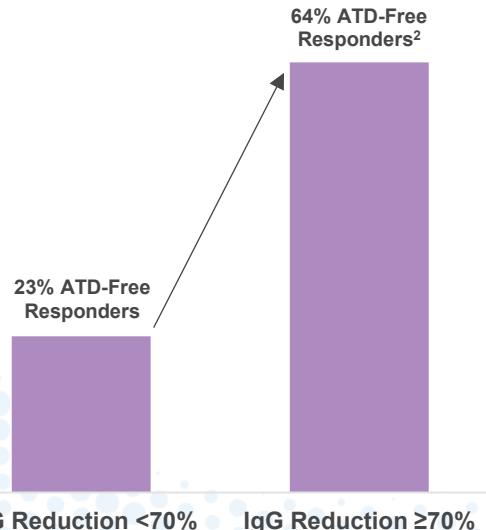
## Favorable Safety Profile

No significant expected safety issues based on data to-date

# First generation batoclimab clinical data across multiple indications shows that deeper IgG reduction leads to improved clinical outcomes

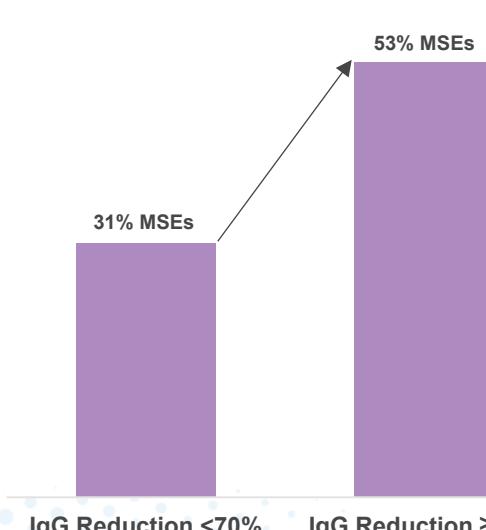
## Graves' Phase 2a<sup>1</sup>

**ATD-Free Response:** % of participants who achieve normal T3 and T4 or have T3 or T4 below LLN, and ceased all ATD medications



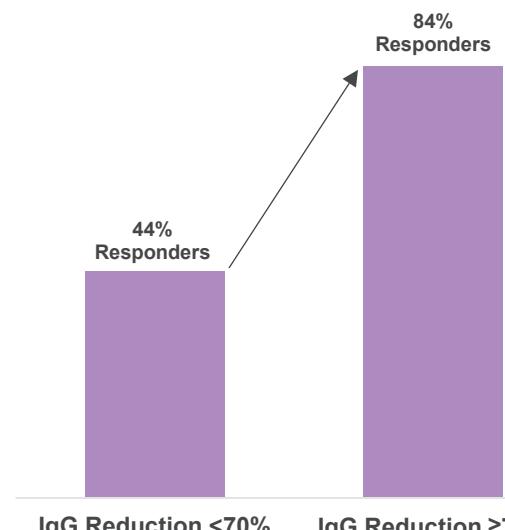
## MG Phase 3<sup>1</sup>

**Minimal Symptom Expression:** % of participants who achieve MG-ADL score of 0 or 1 at Week 12



## CIDP Phase 2b<sup>1</sup>

**alNCAT Response:** % of participants who achieve alNCAT improvement ≥1 at Week 12



Reflects data from multiple clinical trials in multiple indications. Differences exist between trial designs and participant characteristics and caution should be exercised when comparing data across trials.

Notes: MG data presented for acetylcholine receptor antibody-positive patients; ATD: Antithyroid drug; alNCAT: Adjusted Inflammatory Neuropathy Cause and Treatment; IgG: Immunoglobulin G; MSE: Minimal Symptom Expression; LLN: Lower limit of normal. The data referenced here includes data from the ongoing batoclimab Phase 2 study in CIDP and is based on a preliminary analysis of key efficacy and safety data, and such data may change following completion of the clinical trial and may not accurately reflect the complete results of the study. 1. Batoclimab clinical data. 2. Includes N=1 additional responder vs. September 2024 disclosure. Patient discontinued prior to Week 12 and was counted as a non-responder per protocol but was included by the PI in the ATA 2025 poster presentation, given they were a responder at time of discontinuation and continued through 6 month off-treatment follow-up period.

# Best-in-class IgG reductions position Immunovant to drive best-in-class efficacy

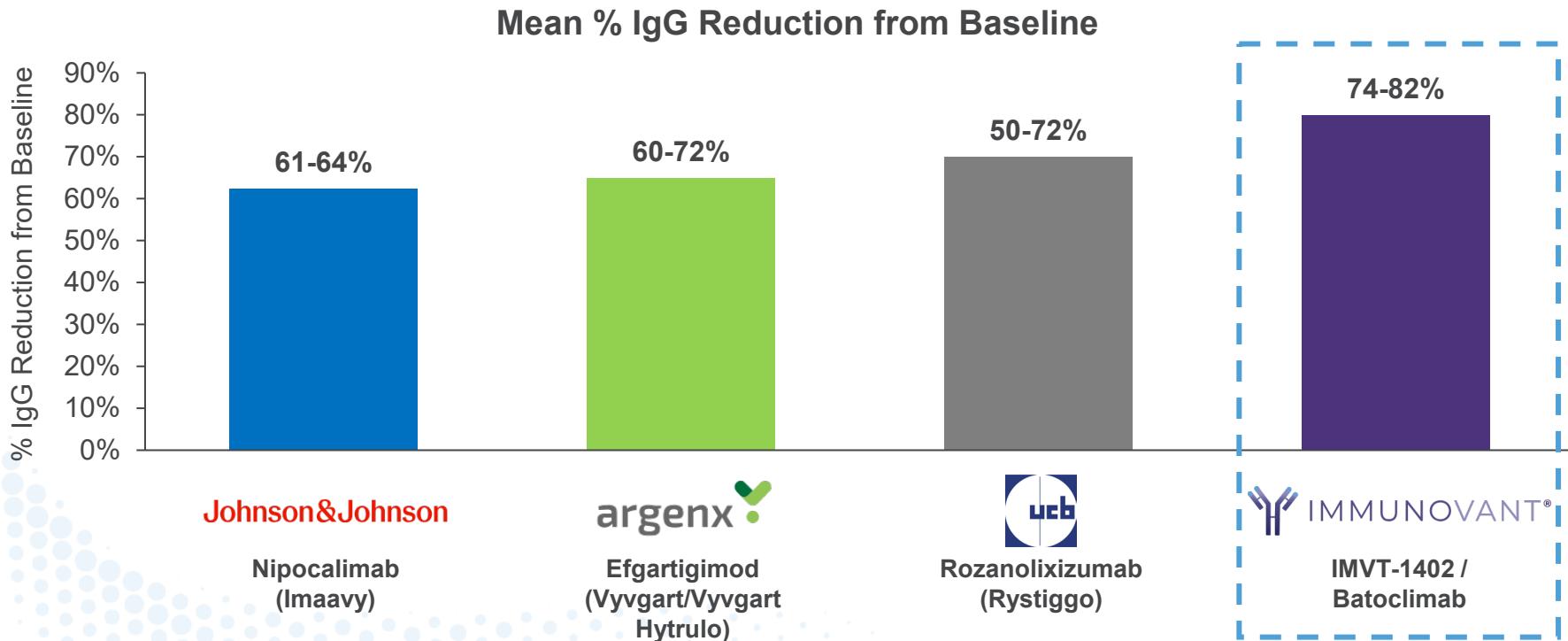


Figure reflects cross-trial comparisons and not data from head-to-head studies.

Differences exist between trial designs and participant characteristics and caution should be exercised when comparing data across trials.

# Our market: Autoimmune diseases driven by harmful IgG autoantibodies

Anti-FcRn mechanism potentially the leading therapeutic class with 20+ indications announced or in development<sup>1</sup>



## NEUROLOGY

Chronic inflammatory demyelinating polyneuropathy (CIDP)

Generalized myasthenia gravis (MG)

Myelin oligodendrocyte glycoprotein antibody disorders (MOG-antibody disorder)

Ocular MG



## ENDOCRINOLOGY

Graves' disease (GD)

Thyroid eye disease (TED)



## HEMATOLOGY

Fetal neonatal alloimmune thrombocytopenia (FNAIT)

Hemolytic disease of the fetus and newborn (HDFN)

Idiopathic thrombocytopenic purpura

Warm autoimmune hemolytic anemia (WAIHA)



## RHEUMATOLOGY

Rheumatoid arthritis (RA)

Sjögren's disease (SjD)

Myositis

Severe fibromyalgia syndrome

Systemic lupus erythematosus



## DERMATOLOGY

Cutaneous lupus erythematosus (CLE)

Bullous pemphigoid

Pemphigus foliaceus/Pemphigus vulgaris

Systemic sclerosis



## RENAL

Antibody-mediated rejection

Lupus nephritis

Membranous nephropathy

# Indication Strategy: Development strategy designed to maximize commercial potential, with IMVT-1402's potentially best-in-class profile

<b>First-in-Class Best-in-Class</b>	<ul style="list-style-type: none"><li>• Expanding use of FcRn blockers to benefit greater number of patients with several new indications, with a potential efficacy advantage driven by deeper IgG reduction</li><li>• Example – GD, D2T RA, CLE</li></ul>
<b>Nearly-First Best-in-Class</b>	<ul style="list-style-type: none"><li>• Close from a timing perspective to in-class competition, while maintaining potential for a differentiated clinical profile driven by best-in-class IgG reductions</li><li>• Example – SjD</li></ul>
<b>Best-in-Class</b>	<ul style="list-style-type: none"><li>• Well-established markets with multiple competitors; potential to differentiate on efficacy and convenience</li><li>• Example – MG and CIDP</li></ul>

**IMVT-1402's potentially differentiated product profile offers wide range of development opportunities**

# Broad development program for IMVT-1402 with trials underway, expected to potentially address >600K patient population

	Graves' Disease	Difficult-to-Treat Rheumatoid Arthritis	Cutaneous Lupus Erythematosus	Sjögren's Disease	Myasthenia Gravis	Chronic Inflammatory Demyelinating Polyneuropathy
<b>Expected US Addressable Population<sup>1</sup></b>	~330K	~70K	~75K	~90K	~20-35K	~16-58K
<b>Autoantibody Driven Pathology</b>	Driven by autoantibodies to the thyroid-stimulating hormone receptor (TSHR-Ab)	Autoantibodies such as RF and ACPA are present in ~75% of RA patients	IgG autoantibodies (Ro/SSA, La/SSB) observed in majority of CLE patients	Autoantibodies detected in ~50-70% of patients with primary SjD	Driven by AChR autoantibodies disrupting signal transmission in nerve and muscle fibers	Driven by autoantibodies that demyelinate peripheral nerves and nerve roots
<b>In-Class Data</b>	Batoclimab data showed deeper IgG reduction correlated with improved clinical response	Response rate higher for patients with high baseline ACPA & deep IgG reduction	Proof of principle IMVT-1402 case study showed meaningful clinical response	Response rate higher for patients with deeper IgG reduction <sup>2</sup>	Batoclimab data showed deeper IgG reduction correlated with improved clinical response	Batoclimab data showed deeper IgG reduction correlated with improved clinical response
<b>Stage of Development</b>	Two Potentially Registrational Trials Enrolling	Potentially Registrational Trial Fully Enrolled	Proof of Concept Enrolling	Potentially Registrational Trial Enrolling	Potentially Registrational Trial Enrolling	Potentially Registrational Trial Enrolling
<b>Potential Best-in-Class</b>	✓	✓	✓	✓	✓	✓
<b>Potential First-in-Class<sup>3</sup></b>	✓	✓	✓	✓		

# Clear focus on execution to unlock value both near and long term

Indication	Study	Data Catalyst	2026		2027	2028
			1H	2H		
TED	Potentially Registrational	Top Line Results*	<span style="background-color: #4a86e8; border: 1px solid black; display: inline-block; width: 15px; height: 15px;"></span>			
ACPA+ D2T RA	Potentially Registrational	Top Line Results		<span style="background-color: #1a237e; border: 1px solid black; display: inline-block; width: 15px; height: 15px;"></span>		
CLE	POC	Top Line Results		<span style="background-color: #1a237e; border: 1px solid black; display: inline-block; width: 15px; height: 15px;"></span>		
GD	Potentially Registrational	Top Line Results			<span style="background-color: #1a237e; border: 1px solid black; display: inline-block; width: 15px; height: 15px;"></span>	
MG	Potentially Registrational	Top Line Results			<span style="background-color: #1a237e; border: 1px solid black; display: inline-block; width: 15px; height: 15px;"></span>	
SjD	Potentially Registrational	Top Line Results				<span style="background-color: #1a237e; border: 1px solid black; display: inline-block; width: 15px; height: 15px;"></span>
CIDP	Potentially Registrational	Top Line Results				<span style="background-color: #1a237e; border: 1px solid black; display: inline-block; width: 15px; height: 15px;"></span>

IMVT-1402

Batoclimab

# IMVT-1402: Potentially first anti-FcRn to launch with simple autoinjector device

All current IMVT-1402 trials are being conducted with the YpsоМate® autoinjector – the intended commercial presentation



**Established, user-friendly autoinjector with multiple approved products**

- Automated, simple, subcutaneous injection
- Hidden needle shield
- Provides both visual and audio feedback
- <10 second at home self-administration or HCP administration

# Graves' Disease

## First-in-Class Opportunity



# IMVT-1402: Potentially first- and best-in-class in Graves' disease (GD)

## High Unmet Need

~25-30% of Graves' disease patients are challenging to manage on ATD therapy; these patients are either unable to complete initial treatment or unable to stay euthyroid despite treatment

## Autoantibody Pathology

Role of TSH-R IgG autoantibodies well-recognized in Graves' disease; anti-FcRn directly targets the underlying disease pathophysiology, while ATDs do not

## Lower is Better

Batoclimab POC demonstrated strong correlation between deep IgG lowering, normalization of thyroid hormone levels and reduced dependence on background ATD therapy

## Optimized Study Design

IMVT-1402 trial designed to demonstrate thyroid hormone normalization and independence from ATD therapy at rates previously unattainable for challenging-to-manage Graves' patients

## Potentially Registrational Trials Initiated

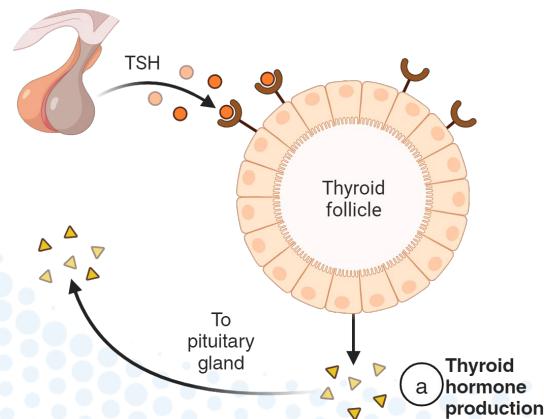
Two potentially registrational trials are actively enrolling, both with self-administration via market-proven autoinjector

Graves' disease is a classic autoimmune condition driven by the presence of autoantibodies to the thyroid stimulating hormone receptor

### Graves' Disease: Autoantibody-Driven Pathogenesis

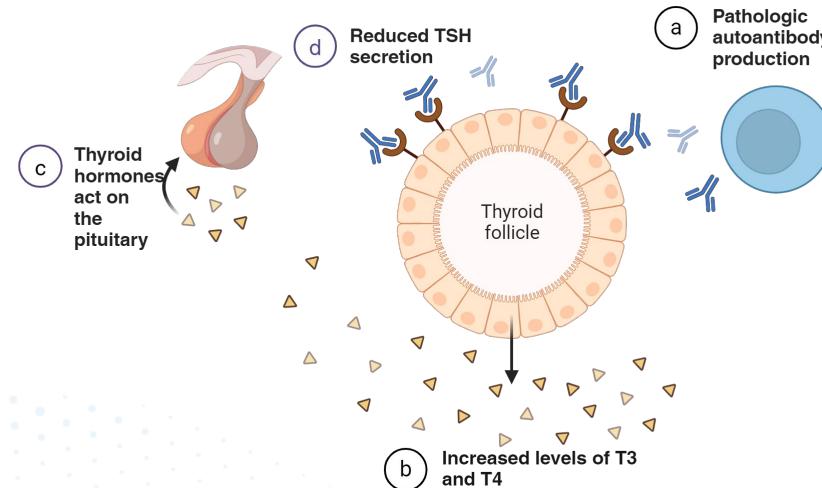
#### Normal Function

TSH produced by the pituitary gland stimulates the thyroid gland to produce and release thyroid hormones (T3 & T4)



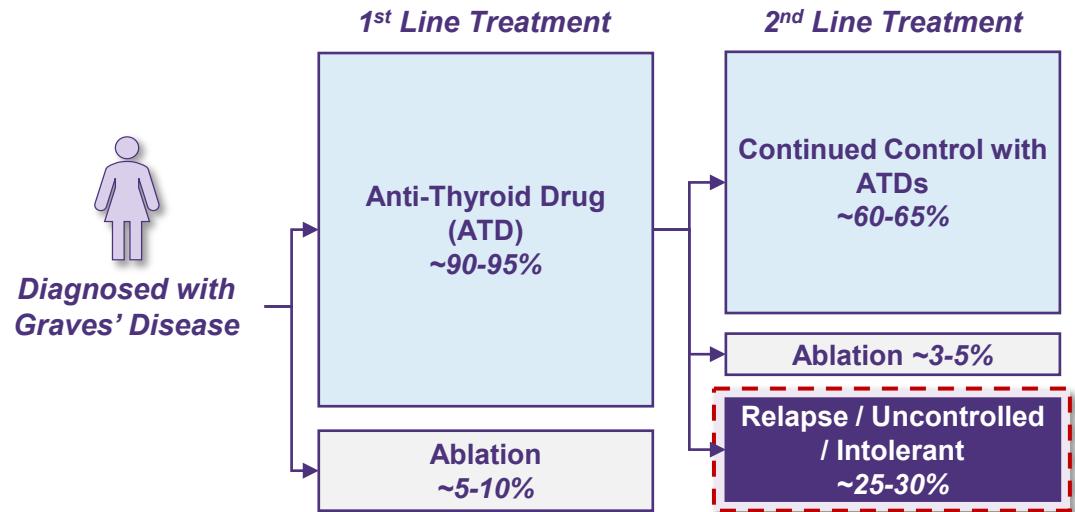
#### Graves' Disease

Autoantibodies to the thyroid stimulating hormone receptor (TSHR) stimulate thyroid hormone production and lead to excess thyroid hormone production (increased T3, T4)



Shift away from ablation and lack of new medical therapies leaves 25-30% of patients who are relapsed, uncontrolled on, or intolerant to ATDs

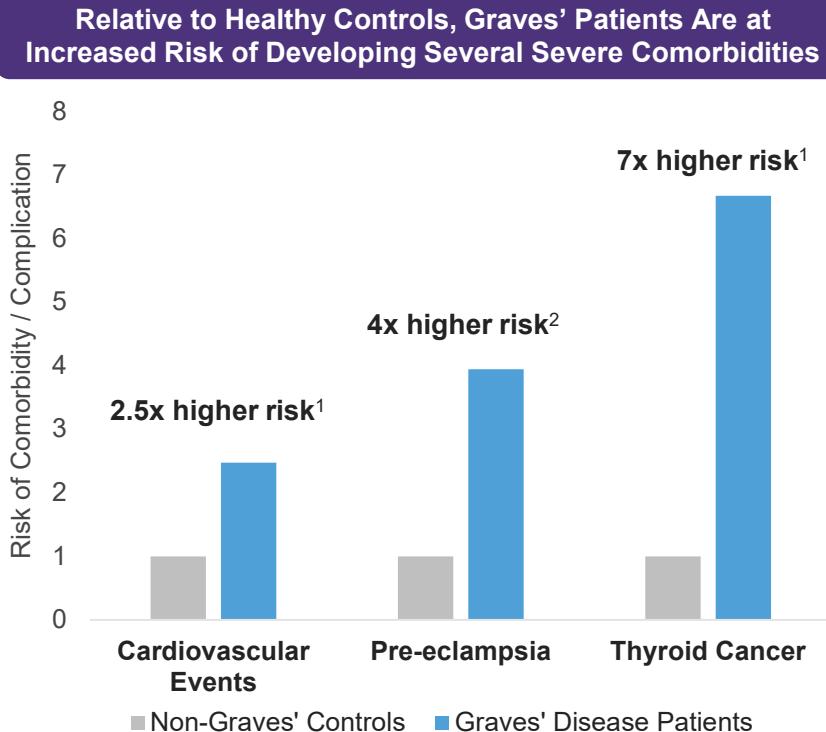
### Graves' Disease Patient Journey:



### Unmet Need

- 25-30% of patients are relapsed, uncontrolled on or intolerant to ATDs
- US data on ablation rates indicate that patients with ATD-refractory disease are choosing not to undergo ablation
- Patients and healthcare providers seek therapeutic options that address underlying disease pathology

# Scientific literature indicates that Graves' disease patients are at a higher risk of a sequelae of severe comorbidities



## Untreated Or Insufficiently Treated Graves' Patients Experience Substantial Morbidity And Loss Of Quality Of Life

### Thyroid Eye Disease (TED)

- TED affects ~40% of patients diagnosed with Graves' Disease<sup>3</sup>
  - Up to 8% of TED patients experience dysthyroid optic neuropathy (impairment of visual function, leading to permanent sight loss)<sup>4</sup>

### Other Significant Complications

- In patients hospitalized for Graves' Disease, ~16% are diagnosed with thyroid storm<sup>5</sup>, which has a ~20% mortality rate<sup>6</sup>
- Graves' Disease patients who develop thyroid cancer are at a >3x risk of recurrent disease / progressive distant metastases relative to euthyroid controls<sup>7</sup>

# Graves' patients uncontrolled on ATDs experience significant disease burden and risk of adverse events with limited treatment options



**RAI and surgery** are associated with **significant complications** including increased risk of death from solid cancers; patients are often hypothyroid and require **lifelong thyroid hormone replacement**

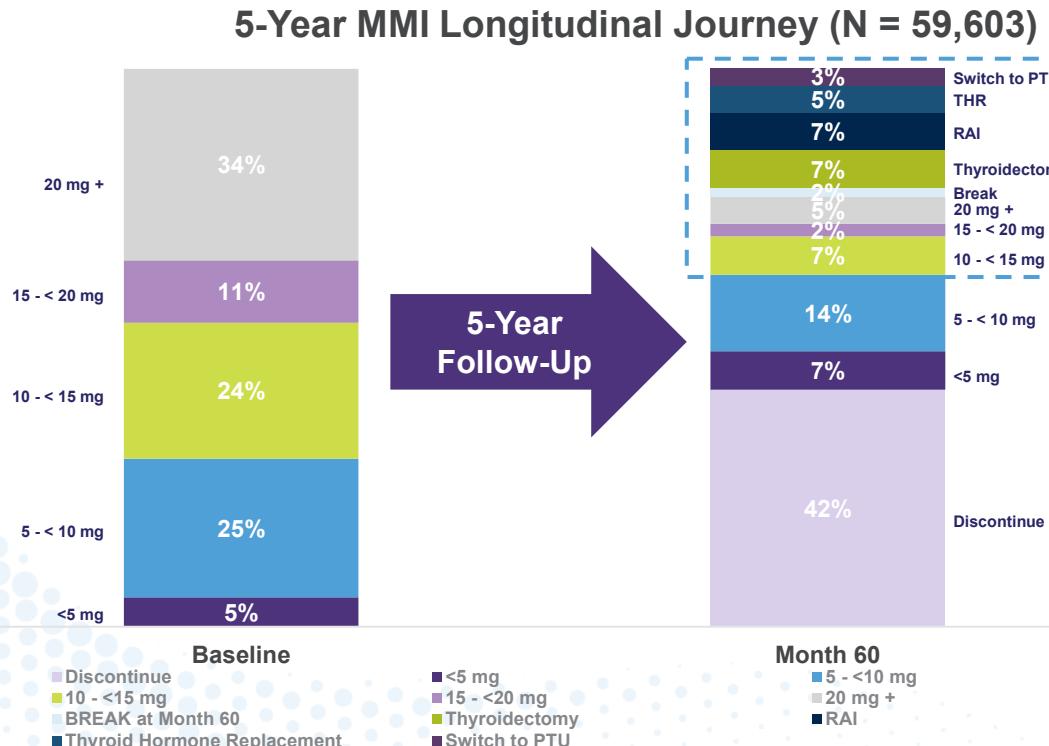


**Chronic ATD use** can be associated with risk of severe adverse events, such as **hepatotoxicity**, **pancreatitis**, and **agranulocytosis** (loss of white blood cells)



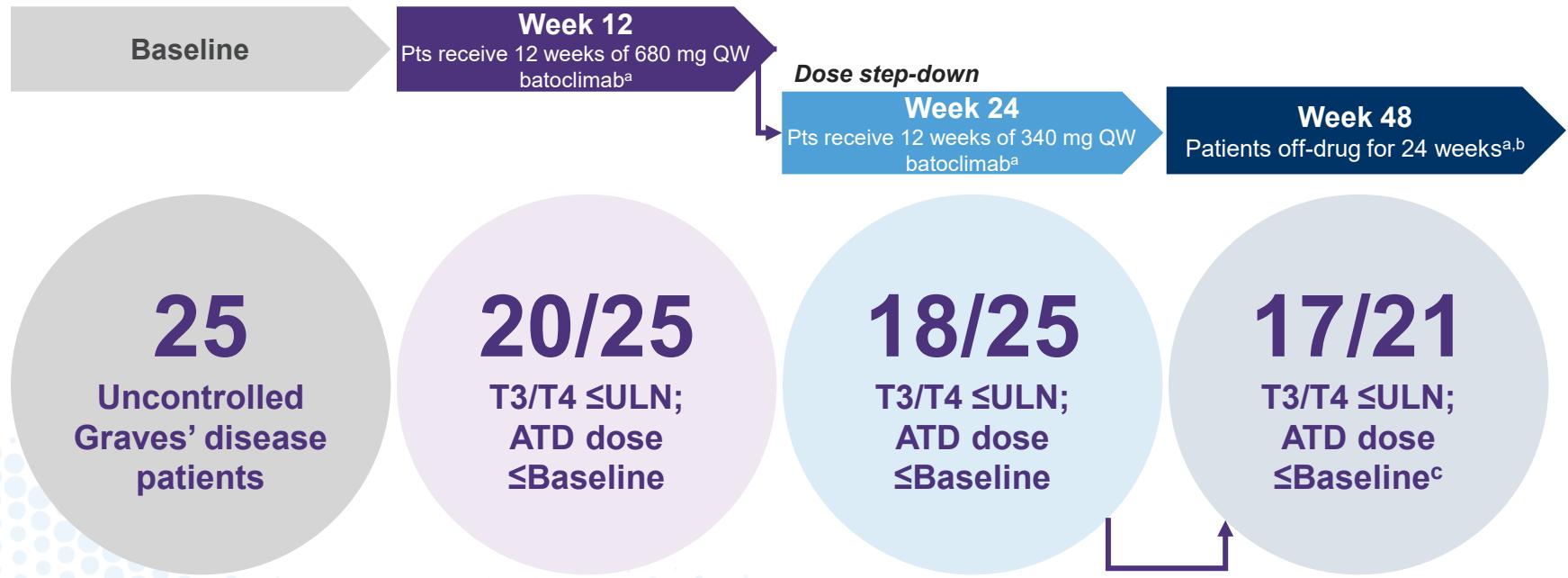
Uncontrolled Graves' patients are at risk for a sequelae of **severe comorbidities** (e.g., **cardiovascular events**, **thyroid cancer**) and experience significant **anxiety** and **impact to quality of life**

# Follow-up of Graves' disease patient methimazole dosing shows significant percent of patients remaining on ATDs after 5-years



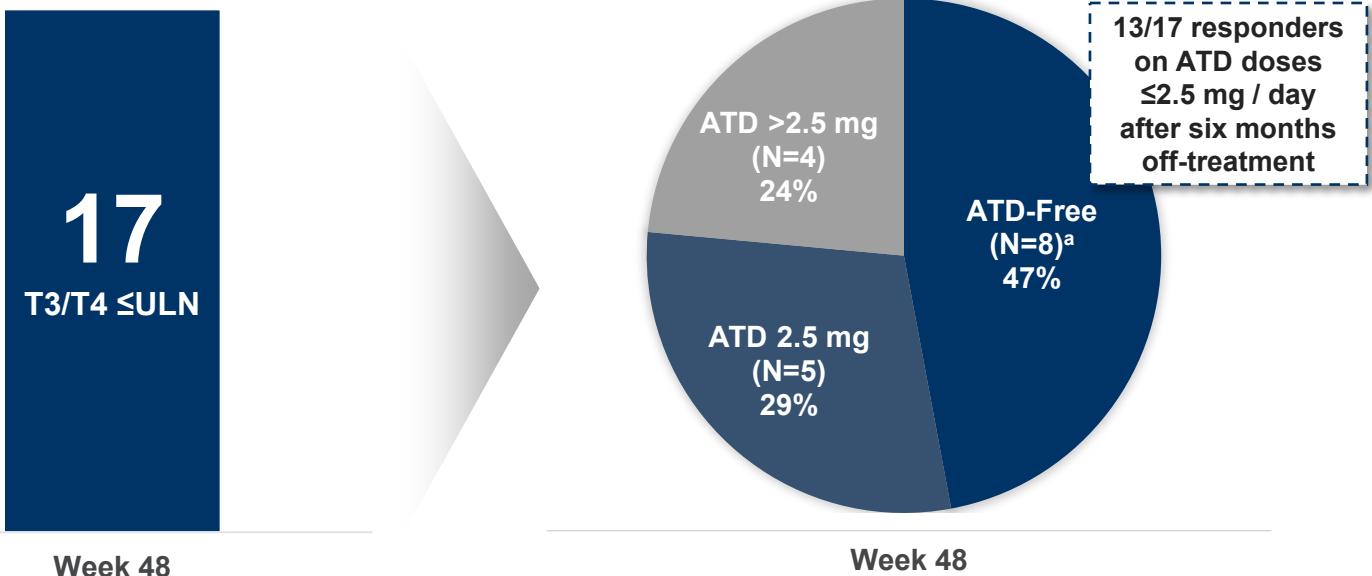
- In a 5-year follow-up period, only 42% of patients were controlled on ATDs alone
- ~37% of patients were on  $\geq 10$  mg MMIs, break, switched to PTU, received thyroid hormone replacement or ablation

# Potential for disease modification with batoclimab responders demonstrating strong durability of response through six months off-treatment at end of follow-up



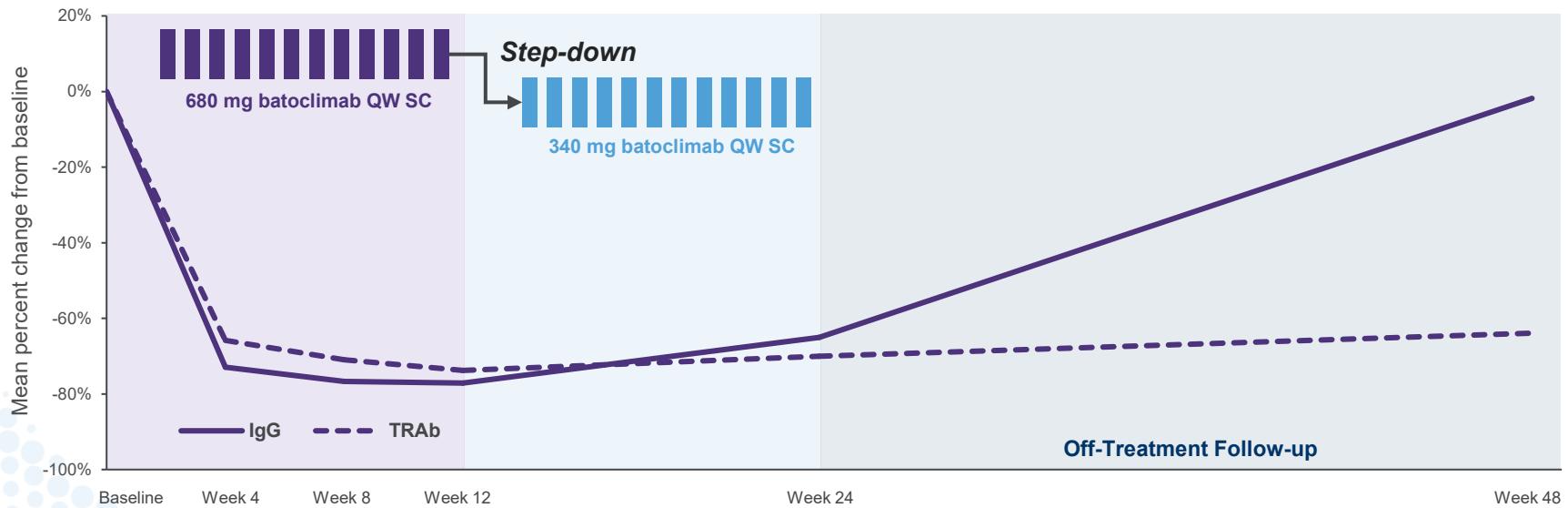
Notes: Responders: Patients who have T3 and T4 values ≤ULN and no increase in ATD dose from baseline. Pts: Patients; T3: Triiodothyronine; T4: Thyroxine; ULN: Upper limit of normal; ATD: Anti-thyroid drug. a. Includes N=1 patient who discontinued prior to Week 12 but remained in off-drug follow-up. b. Includes N=21 patients who entered follow-up period and could be assessed for remission. c. N=1 patient had T3/T4 ≤ULN, and one day following Week 48 visit had ATD dose equivalent to baseline.

~50% of responders at Week 48 achieved ATD-free remission, demonstrating strong potential for disease modification by a high-dose FcRn



8 of 17 patients with normal T3/T4 at Week 48 were in ATD-free remission

# Sustained TRAb reductions post-batoclimab treatment further demonstrate the potential for disease modification



# IMVT-1402 could potentially be the first-in-class disease-modifying therapy in Graves' disease

01

**Remarkable effect seen in uncontrolled Graves' disease patients: 18 of 25 patients treated with batoclimab were responders\* at Week 24**

02

**Durable off-drug response observed: Of the 21 patients who entered the off-drug follow-up period, 17 remained responders\* six months following batoclimab treatment**

03

**First-ever observed ATD-free remission in uncontrolled patients: 8 of 17 responders\* remained off all medications six months following batoclimab treatment demonstrating potential for disease modification**

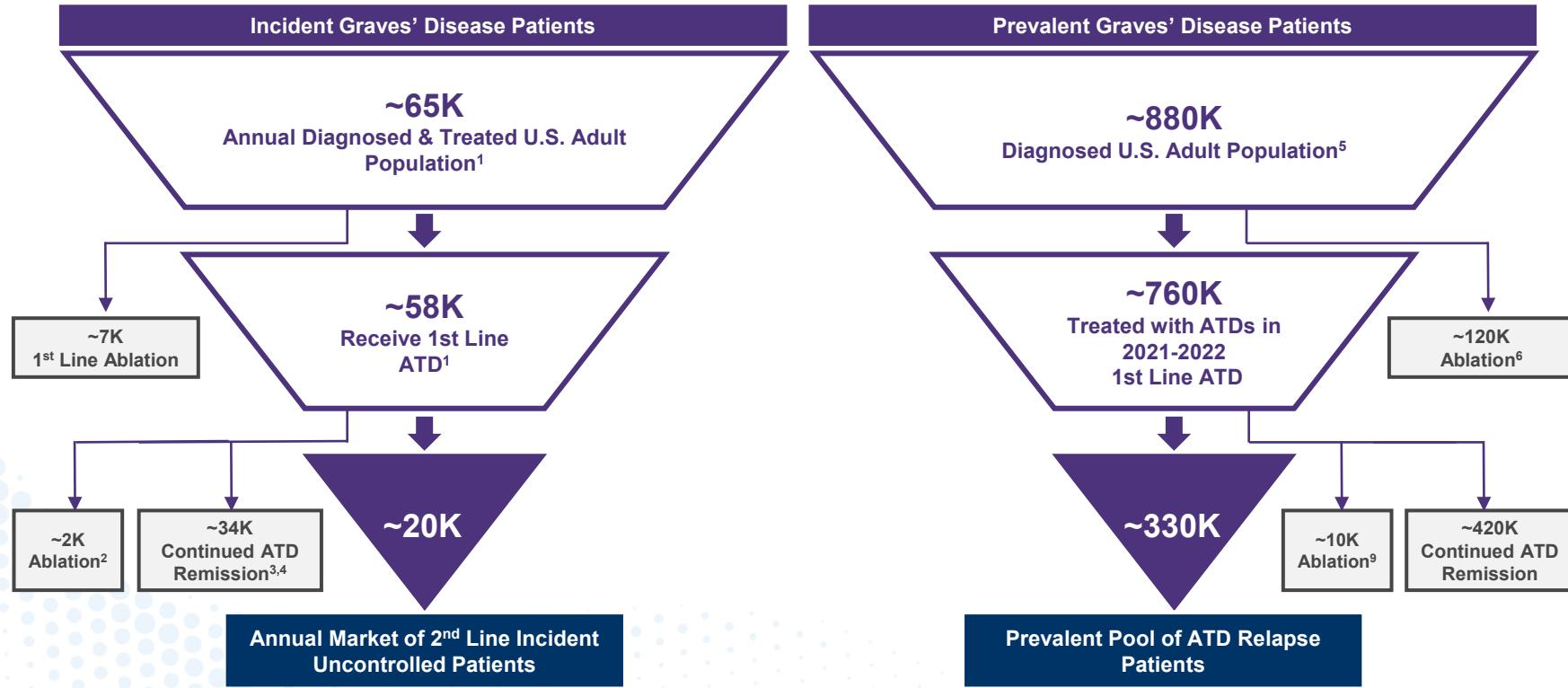
04

**IMVT-1402 pivotal trial design could potentially generate improved efficacy data due to continuous 600 mg QW dosing vs. batoclimab's step-down dosing design**

05

**Two potentially registrational trials for IMVT-1402 in Graves' disease are currently enrolling**

# Graves' disease market opportunity includes annual incident opportunity and a significant untapped prevalent patient pool



# Myasthenia Gravis

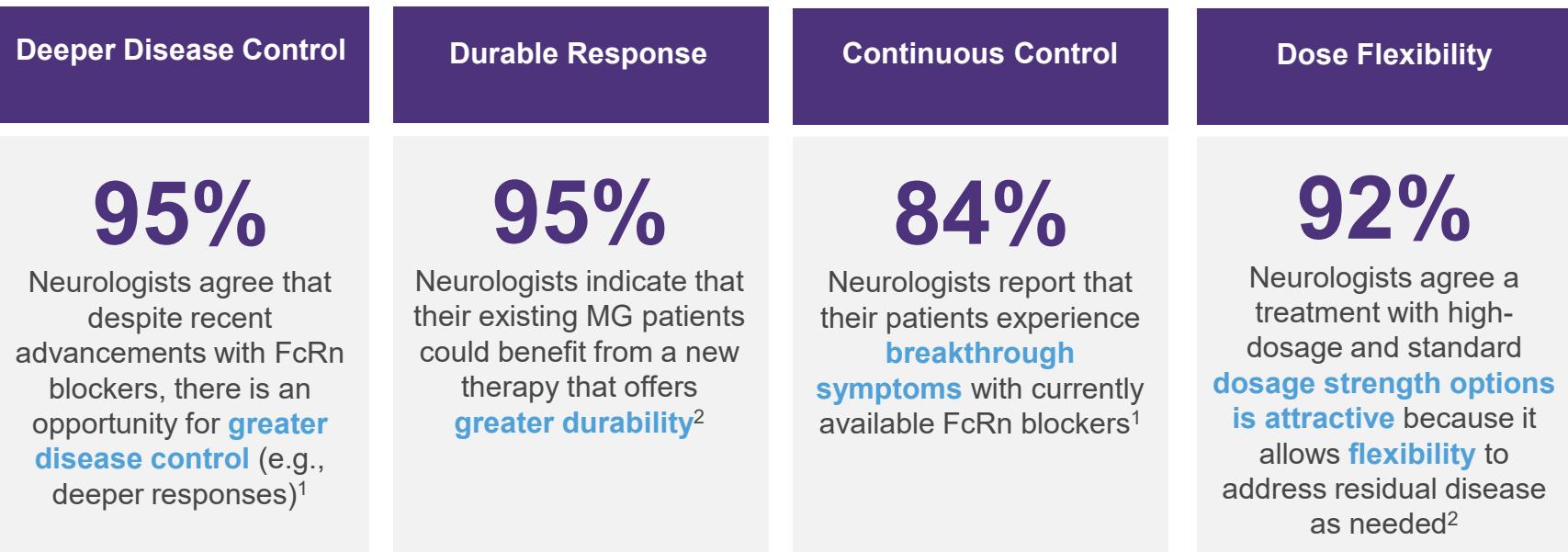
Best-in-Class Opportunity



# IMVT-1402 has the potential to improve Myasthenia Gravis treatment outcomes as a best-in-class therapy, leveraging batoclimab learnings

<b>High Unmet Need</b>	95% of Neurologists agree there is an opportunity for greater disease control (e.g., deeper responses) <sup>1</sup>
<b>Autoantibody Pathology</b>	Classic IgG mediated disease, with proven anti-FcRn mechanistic response <sup>2</sup>
<b>Lower is Better</b>	First-gen anti-FcRn batcolimab demonstrated deeper IgG suppression is consistently associated with deeper clinical effect <sup>2</sup>
<b>Optimized Study Design</b>	Simple parallel continuous dose trial design with two dose options, designed to demonstrate a clear difference of effect between doses
<b>Potentially Registrational Trial Initiated</b>	Potentially registrational trial enrolling with self-administration via market-proven autoinjector

# MG patients and providers indicate a need for deeper and more durable disease control



# Phase 3 batoclimab MG data<sup>1</sup> positions IMVT-1402 as the potentially best-in-class anti-FcRn

01

**680 mg batoclimab outperformed other anti-FcRn, complement, and CD19 inhibitors, demonstrating highest MG-ADL reduction from baseline (-5.6 points) observed in any global Phase 3 MG trial to-date**

02

**Highest rate of patients with minimal symptom expression (42%) observed in MG patients across any FcRn in a Phase 3 trial**

03

**93% of patients achieve clinical response (MG-ADL reduction of 2 or more points), representing highest response rate achieved in a global Phase 3 trial**

04

**75% of patients who achieved Minimal Symptom Expression (MG-ADL = 0 or 1) on 680 mg dose by Week 6 maintained MSE status for  $\geq 6$  weeks**

Notes: Statements are based on cross-trial comparisons and not data from head-to-head studies. Caution should be exercised when evaluating data across trials due to differences in trial designs and participant characteristics.

MG data presented for acetylcholine receptor antibody-positive patients; MSE: Minimal Symptom Expression; MG-ADL: Myasthenia Gravis Activities of Daily Living scale

1. IMVT Investor Presentation March 19, 2025

# MG: IgG-mediated autoimmune disease with growing enthusiasm for the anti-FcRn class

## Market Opportunity

**59K – 116K**

Total MG patients in the US<sup>1,2</sup>



**85%**

anti-acetylcholine receptor (AChR) antibody positive<sup>3</sup>



**35%**

who are not well-controlled on standard of care<sup>4,5</sup>



**20K – 35K**

US addressable population

## Despite innovation, patients report residual and breakthrough symptoms on anti-FcRn therapy

**70%** of patients currently on an anti-FcRn report having very or extremely bothersome symptoms

- **97%** experiencing fatigue and muscle weakness
- **~3 in 4** report drooping eyelids, walking/coordination issues, blurred/double vision
- **~1 in 2** report difficulty chewing, speech difficulty, weakness of eye muscles

# Chronic Inflammatory Demyelinating Polyneuropathy

Best-in-Class Opportunity



# IMVT-1402 has the potential to deliver best-in-class efficacy in chronic inflammatory demyelinating polyneuropathy (CIDP)

## High Unmet Need

30-50% of CIDP patients are inadequately controlled with existing therapies<sup>1</sup>

## Lower is Better

First-gen anti-FcRn batoclimab demonstrated deeper IgG suppression delivered greatest in-class mean change from baseline in aINCAT score in CIDP patients<sup>2</sup>

## Optimized, Patient-Centric Study Design

Simplified study design leveraging prior batoclimab experience to eliminate need for patient worsening via washout prior to treatment

## Potentially Registrational Trial Initiated

Potentially registrational trial enrolling with self-administration via market-proven autoinjector

# Batoclimab CIDP Phase 2b proof-of-concept data<sup>1</sup> positions IMVT-1402 to potentially be best-in-class

**Best-in-class efficacy observed across multiple efficacy measures: aINCAT, I-RODS, MRC-SS, and grip strength<sup>2</sup>**



**Demonstrated that deeper IgG reductions translate to improved response with 84% aINCAT response rate in patients achieving  $\geq 70\%$  IgG reduction**



**Generated learnings to inform IMVT-1402 trial design optimization**



**Opportunity to accelerate registrational program for IMVT-1402 in CIDP**



CIDP patients and providers are seeking a new treatment option that reduces symptom and treatment burden<sup>1</sup>

**75% of HCPs prefer to treat CIDP patients as early and aggressively as possible**

### Sizable Market Opportunity

**58K**

Total CIDP Patients in the US<sup>2</sup>



**30%**

who are inadequately controlled on treatment<sup>4</sup>



**16K**

US addressable population

### Substantial Unmet Need

#### Lower Relapse Rates

30-50% of CIDP patients are inadequately controlled with existing therapies<sup>5</sup>

#### Improved Response and Durability

60% of physicians report a need for better response to treatment and more durable CIDP treatments

#### More Convenient Dosing Options

~90% of physicians noted a high need for treatments with improved ROA (e.g., at home administration)

#### Improved safety & tolerability

71% of US physicians report a need for treatment options with fewer side effects<sup>6</sup>

Note: All estimates are approximate.

1. Internal Market Research Market Dynamics 2024 2. Broers M, et al (2019) Incidence and prevalence of CIDP: a systematic review and meta-analysis. *Neuroepidemiology* 52(3-4):161-172; 3. Querol, L., et al. Systematic literature review of burden of illness in chronic inflammatory demyelinating polyneuropathy (CIDP). *J Neurol* 268, 3706-3716 (2021); 4. Kuitward K, Bos-Eyssen ME, Blomkrist-Markens PH et al (2009) Recurrences, vaccinations and long-term symptoms in GBS and CIDP. *J Peripher Nerv Syst* 14(4):310-315. <https://doi.org/10.1111/j.1529-8027.2009.00243/>; 5. Internal Market Research HCP Survey and KOL advising 2023 6. Internal Market Research CIDP Patient Journey 2022

# ACPA+ Difficult-to-Treat Rheumatoid Arthritis

First- and Best-in-Class Opportunity



# IMVT-1402 has the potential to achieve a first- and best-in-class profile for people with ACPA+ difficult-to-treat rheumatoid arthritis (D2T RA)

<b>High Unmet Need Subgroup</b>	5-20% of RA patients are difficult-to-treat (D2T), with inadequate or loss of response to multiple classes of advanced therapies <sup>1</sup>
<b>Autoantibody Pathology</b>	Autoantibodies such as ACPA play a key role in pathophysiology, and ACPA-positive RA is associated with severe disease and poor outcomes
<b>Lower is Better</b>	Phase 2 FcRn RA data demonstrated that greater IgG reduction led to greater autoantibody reductions, which correlated with greater clinical response <sup>2</sup>
<b>Potentially Registrational Trial Fully Enrolled</b>	Potentially registration trial fully enrolled with self-administration via market-proven autoinjector; topline results now expected in 2H 2026 (previously 2027)

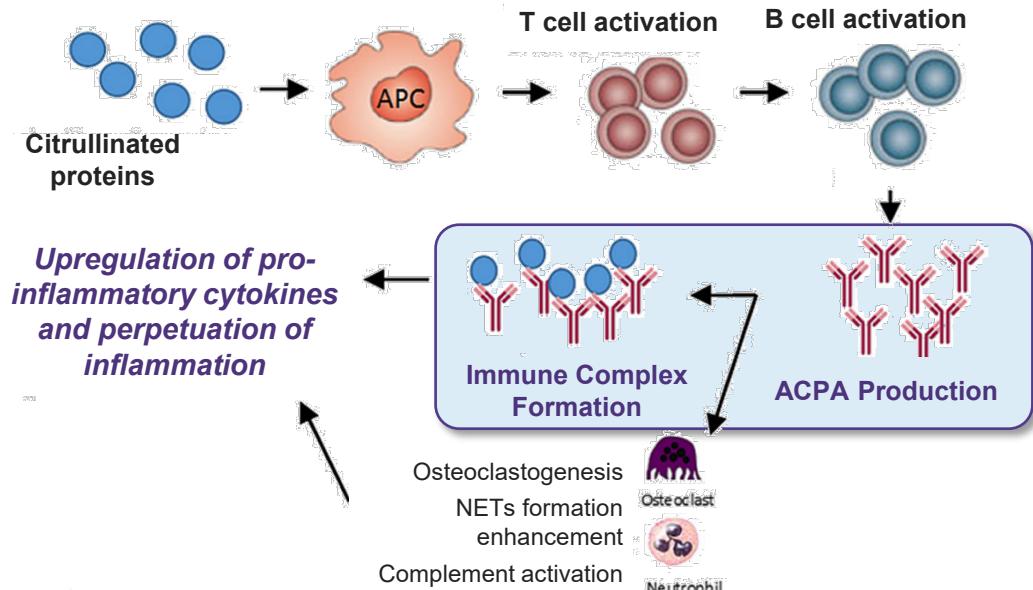
1. Takanashi S, et al. *Rheumatology*. 2021;60:5247-56 2. Taylor PC et al. "Efficacy and Safety of Nipocalimab in Patients with Moderate to Severe Active Rheumatoid Arthritis (RA): The Multicenter, Randomized, Double-blinded, Placebo-controlled Phase 2a IRIS-RA Study Presented at ACR, Nov 10-15, 2023. ACPA: anti-citrullinated protein antibody

In addition to cellular autoimmunity and cytokine dysregulation, autoantibodies like ACPA play a key role in the pathophysiology of RA

Autoantibodies such as Rheumatoid Factor (RF) and ACPA are present in ~75% of RA patients<sup>1</sup>

#### Role of ACPA in RA pathophysiology

- 1 Antigen presenting cells (APCs) process and present citrullinated peptides to T cells
- 2 T cells activate B cells to generate autoantibodies
- 3 Immune complex formation upregulates pro-inflammatory cytokines
- 4 ACPA may bind to osteoclasts and thereby promote bone erosion



Anti-FcRn has the potential to directly target underlying disease biology by lowering pathogenic autoantibodies (i.e., ACPA) and immune complexes

Difficult-to-treat RA is estimated to comprise 5-20% of RA patients whose disease cannot be managed by available therapies

### Need for More Options

- Estimated 5-20% of patients remain symptomatic despite multiple treatment rounds<sup>1</sup>
  - These patients need new therapies and approaches, according to a global survey of 410 rheumatologists
- Difficult-to-treat (D2T) RA defined by EULAR as<sup>2</sup>:
  - Multiple DMARD failures
  - Signs suggestive of active/progressive disease
  - Symptom management viewed as problematic to doctor and/or patient

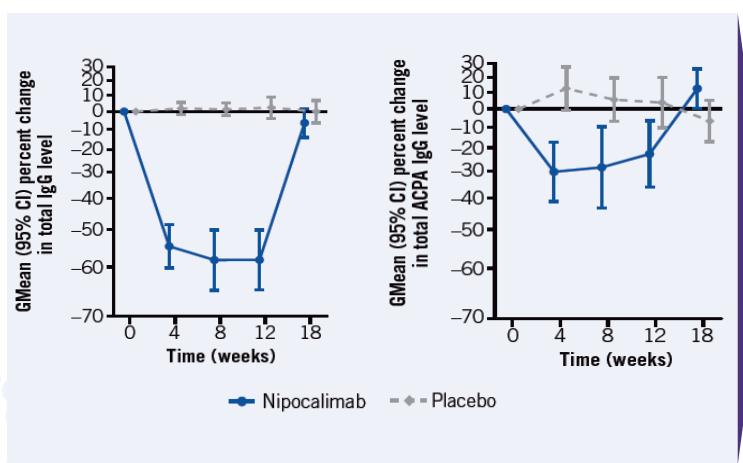
### D2T RA Criteria

- At least moderate disease activity as defined by composite endpoints which include tender and swollen joint counts
- Progressive joint damage on imaging
- Inability to decrease chronic glucocorticoid therapy below 7.5mg/day
- Ongoing RA symptoms and QoL impact despite therapy

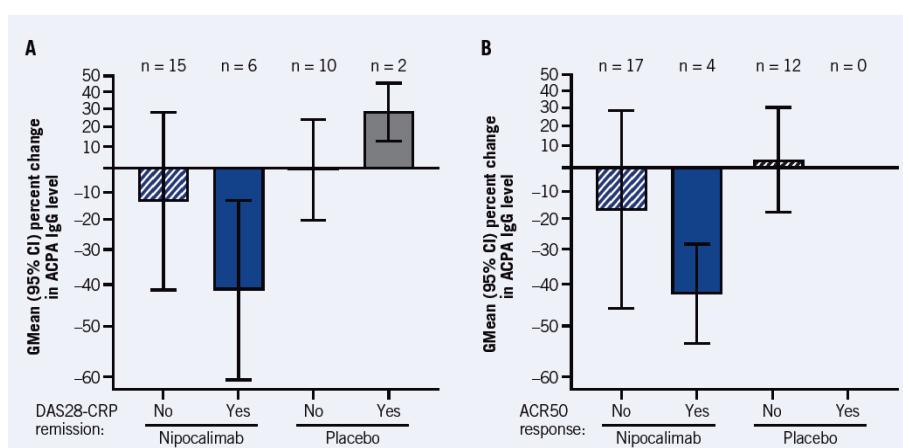
Publicly available nipocalimab data in RA showed that deeper autoantibody (ACPA) reduction correlated with clinical response<sup>1</sup>

## Select results from a study of FcRn blockage vs. placebo in biologic-experienced RA patients

~60% Total IgG And ~30% Pathogenic Auto-Ab (ACPA) Reductions In JNJ Phase 2 RA Study



Correlation Between Auto-Ab Reductions and Clinical Response using (A) DAS28-CRP Remission and (B) ACR50 Response at Week 12



Of the 1.5M US RA patients<sup>1</sup>, a subset progresses to D2T status in a relatively short period of time and requires new therapeutic options

## Market Opportunity

**490K**

US prevalence of severe RA<sup>2</sup>



**15%**

autoantibody positive with inadequate response to prior b/tsDMARD<sup>2,3</sup>



**70K**

US addressable population

## Patient Journey Learnings

**Fewer than 50% of RA patients remain on first therapy**

~50% of patients fail their first b/tsDMARD therapy within the first year of treatment<sup>4,5</sup>

**D2T emerges for some in ~4 years**

In a large US registry, the median time to meeting D2T criteria was 4 years in those who were D2T<sup>6</sup>

**5%-20% of RA patients are D2T**

5%-20% of all RA patients meet the criteria for D2T in the US<sup>6</sup>

# Sjögren's Disease

## Best-in-Class Opportunity



# Sjögren's disease (SjD) is a potentially best-in-class indication for IMVT-1402

## High Unmet Need Disease

No therapies are approved for the treatment of primary SjD

## Autoantibody Pathology

Autoantibodies detected in ~50-70% of patients with primary SjD; anti-FcRn proof of mechanism established

## Lower is Better

Nipocalimab data demonstrated that deeper IgG reduction leads to better clinical response across all primary and secondary endpoints

## Potentially Registrational Trial Initiated

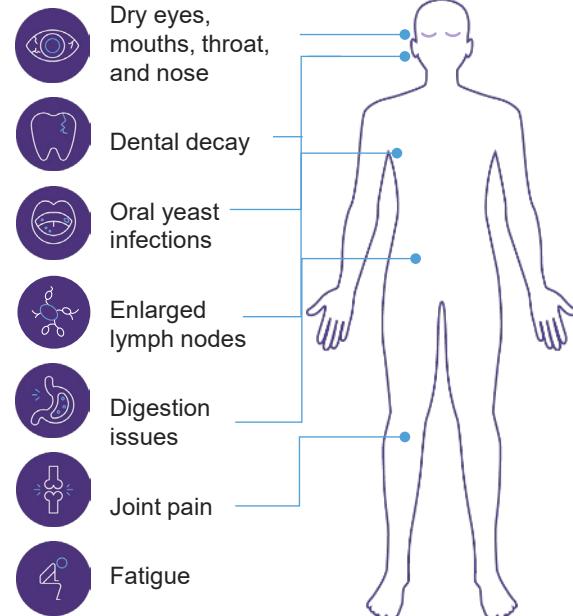
Potentially registrational trial enrolling with self-administration via market-proven autoinjector

# SjD is an autoimmune disease associated with a myriad of clinical manifestations

## Disease Overview

- SjD is a chronic autoimmune disease characterized by lymphocytic infiltration of the salivary and lacrimal glands
- Symptoms include severe dryness of the eyes and mouth; the latter frequently associated with difficulty swallowing or speaking, tooth decay, gum disease, and impaired QoL<sup>1,2</sup>
- May occur in isolation (primary SjD) or in association with another systemic autoimmune disease such as RA (secondary SjD)
- SjD can be challenging to diagnose due to the heterogeneity of presentation<sup>3</sup>
- ACR/EULAR classification criteria are now widely endorsed for diagnosing primary SjD

## Common symptoms

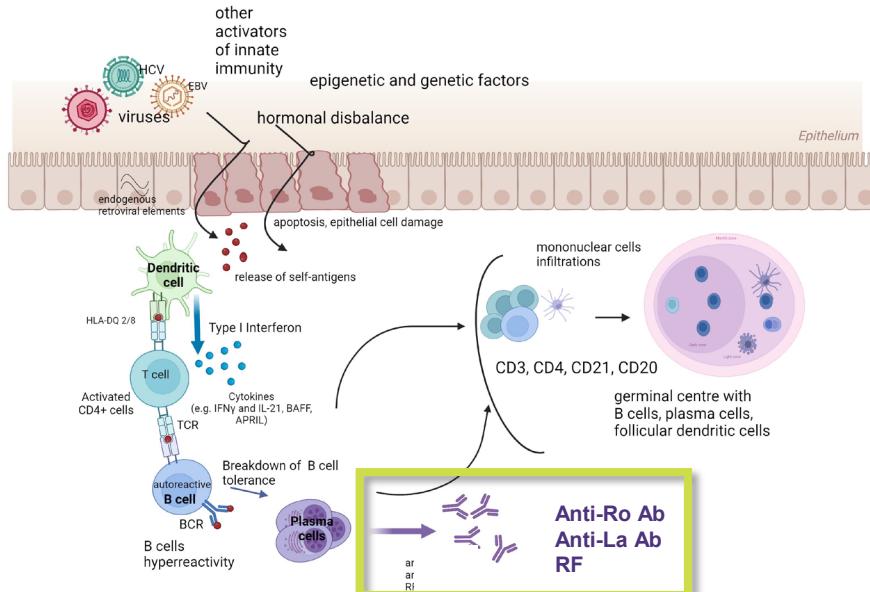


# Autoantibodies play crucial roles in both the diagnosis and prognosis of SjD

## Autoantibody Involvement

- Serological abnormalities are common in SjD and include autoantibodies, hypergammaglobulinemia, and hypocomplementemia<sup>1</sup>
- Identification of disease-precipitating antibodies were discovered back in 1975. Anti-Ro/SSA and anti-La/SSB antibodies were detected in patients with SjD in 1982<sup>2</sup>
- Present day, autoantibodies are detected in ~50-70% of patients with primary SjD

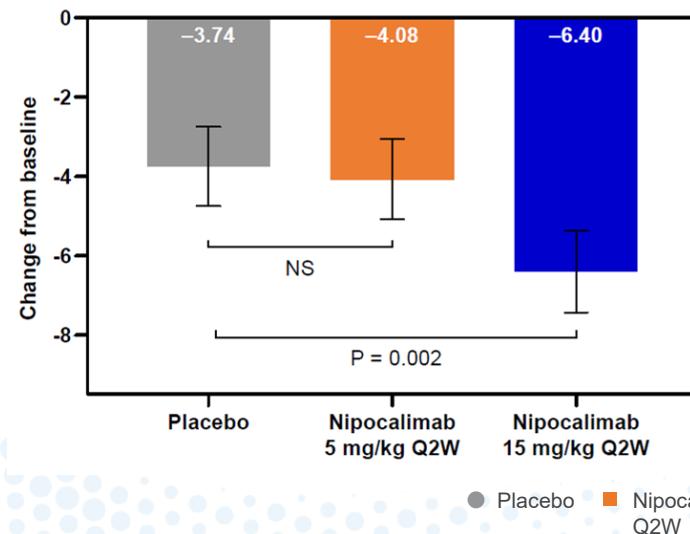
## Disease Pathogenesis<sup>3</sup>



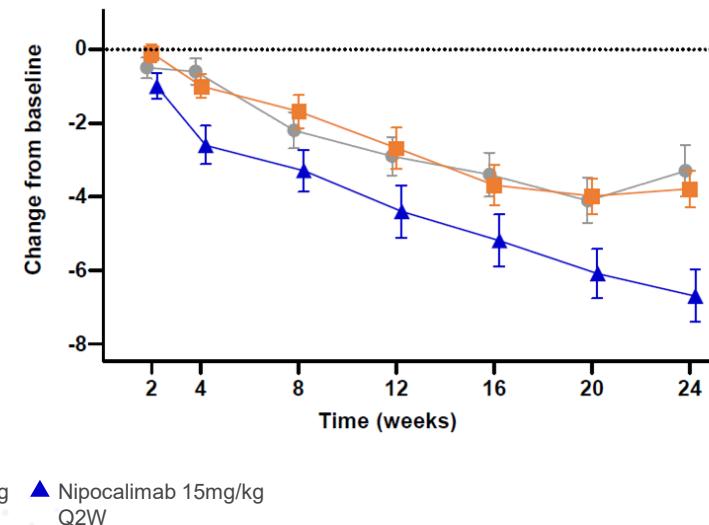
# Publicly available nipocalimab data support anti-FcRn proof of mechanism and dose response in SjD

## Select results from a study of FcRn blockage vs. placebo in primary SjD

LS mean (90%) change in ClinESSDAI score at Week 24



Mean (SE) change in ClinESSDAI score



CI: confidence interval; ClinESSDAI: clinical European League Against Rheumatism Sjögren's Syndrome Disease Activity Index; LS: least squares; NS: not significant; Q2W: every 2 weeks; SE: standard error. 1. Gottenberg JE et al. Efficacy and Safety of Nipocalimab, an Anti-FcRn Monoclonal Antibody, in Primary Sjögren's Disease: Results from a Phase 2, Multicenter, Randomized, Placebo-Controlled, Double-Blind Study (DAHLIAS). ACR Convergence 2024, November 16-19, 2024

# Sizable patient group with unmet need for an approved treatment option in SjD

## Market Opportunity

**290K**

US prevalence of primary Sjögren's disease<sup>1</sup>



**Up to 30%**

moderate-to-severe with anti-Ro/SSA antibodies<sup>2,3</sup>



**90K**

US addressable population

## Expansion Opportunities

**Secondary Sjögren's**

Potential to impact conditions with shared autoimmune pathology

**Glandular Disease**

Unmet need to improve glandular manifestations beyond symptom relief

**Less Severe Disease**

Disease impact on patient QoL varies widely; so-called "nuisance" symptoms can become debilitating if inadequately managed

# Cutaneous Lupus Erythematosus

First-in-Class Opportunity



# IMVT-1402 is potentially first-/best-in-class in Cutaneous Lupus Erythematosus (CLE)

## Untapped Market Opportunity

IMVT-1402 has potential to be the first novel targeted therapy for CLE in >50 years<sup>1</sup>

## IgG and Immune Complex Driven

Biologic, translational, and mechanistic evidence support the critical role of IgG autoantibodies and immune complexes in the pathogenesis of CLE

## Upstream Targeting

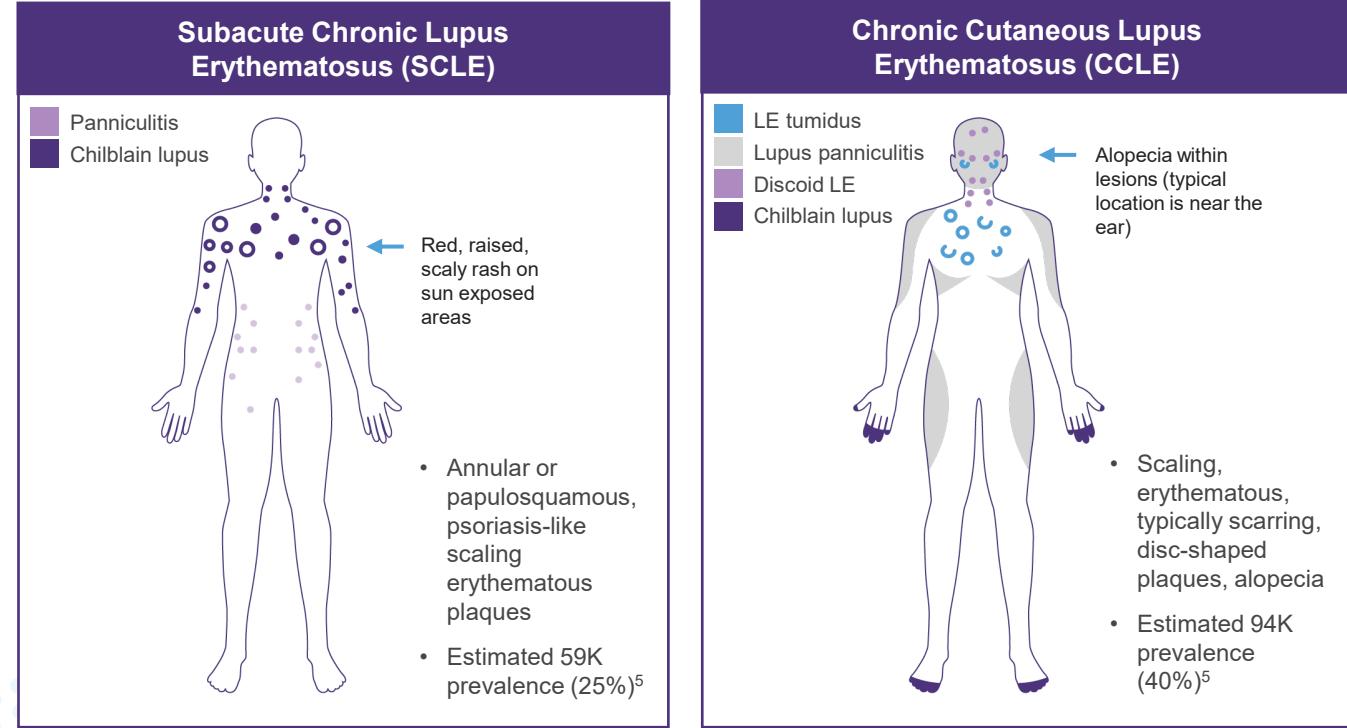
Disruption of CLE pathology by upstream targeted approach supported by IMVT-1402 patient case studies

## IMVT-1402 Trial Initiated

Proof-of-concept trial enrolling with self-administration via market-proven autoinjector

# CLE is a rare, chronic autoimmune disease affecting the skin, with limited available treatment options and high unmet need

- CLE is a rare, chronic skin disease characterized by skin-specific disease-activity, inflammation and eventually damage<sup>1,2</sup>
- Symptoms include painful skin lesions, itching, burning, and alopecia<sup>3</sup>
- Limited innovation and no novel therapies in >50 years<sup>4</sup>

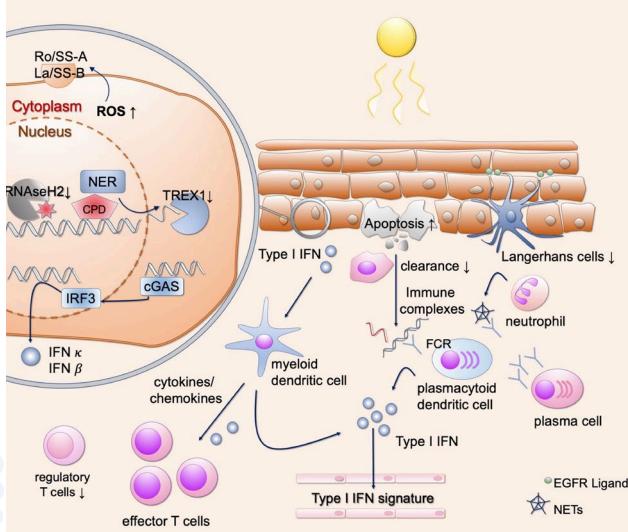


For the purposes of this presentation, reference to CLE is focused on SCLE and CCLE subtypes.

1. Vale ECSD and Garcia LC. An Bras Dermatol. 2023;98(3):355-372. 2. Presto JK, Werth VP. Cutaneous Lupus Erythematosus: Current Treatment Options. Curr Treat Option Rheumatol. 2016; 2(1): 36-48 Stull, et al. The Journal of Rheumatology 2023;50:27-35; doi:10.3899/jrheum.220089 3. Klein R, et al. J Am Acad Dermatol. 2011;64(5):849-858. 4. Wahie S, Meggitt SJ. Long-term response to hydroxychloroquine in patients with discoid lupus erythematosus. Br J Dermatol. 2013 Sep;169(3):653-9. doi: 10.1111/bjd.12378. PMID: 23581274 5. Internal market research Spherix 2024

# CLE: IgG autoantibodies and immune complexes mediate a cycle of self-amplifying skin inflammation and tissue damage in the skin

## Pathogenesis of CLE Disease



UV light triggers enhanced cell death, IgG autoantibody immune response, and produces immune complex formation, leading to skin tissue damage and increased inflammation<sup>1</sup>

### Autoantibody Involvement<sup>2</sup>

CLE specific IgG autoantibodies produced (i.e., Ro/SSA, La/SSB)

#### IgG Autoantibodies:

- Induce skin cell death
- Trigger recruitment of inflammatory cells that form immune complexes

### Immune Complex Involvement<sup>2</sup>

Immune complexes can activate receptors of the innate immune system that drive:

- Inflammation
- Tissue damage
- Skin cell death
- Recruit other immune cells

FcRn blockage has the potential to disrupt CLE pathology

IMVT-1402's deep suppression of IgG autoantibodies and immune complexes has the potential to dampen multiple downstream inflammatory cascades by providing upstream inhibition of inflammatory cascade

1. Klein Benjamin, Kunz Manfred. Current concepts of photosensitivity in cutaneous lupus erythematosus. *Frontiers in Medicine*, 2022. 10.3389/fmed.2022.939594.  
2. Achtman, J.C., Werth, V.P. Pathophysiology of cutaneous lupus erythematosus. *Arthritis Res Ther* 17, 182 (2015). <https://doi.org/10.1186/s13075-015-0706-2>

# Case Study: 12-Week Treatment with IMVT-1402 in CLE

## Baseline Demographics

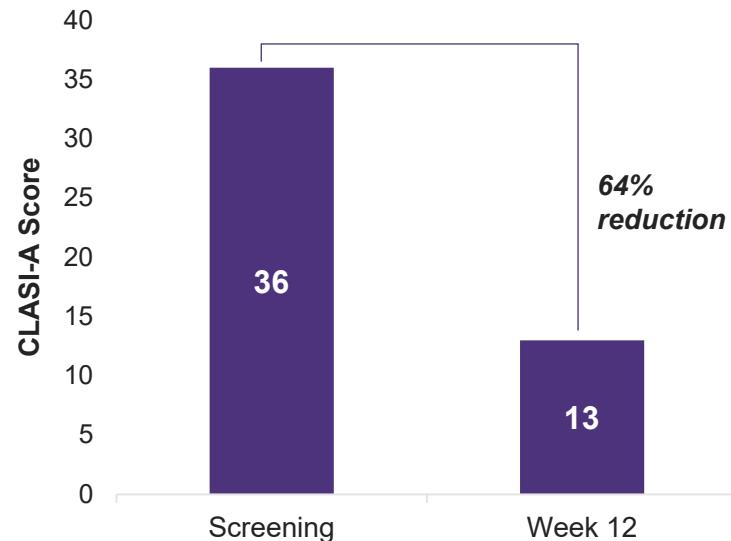
- Female, 57
- Subacute CLE and alopecia
- Multiple skin locations affected
- CLASI-A score at screening = 36
- Background medications: hydroxy-chloroquine, methotrexate, leflunomide

## Treatment Outcomes

- **>60% reduction in CLASI-A score to 13 by week 12**
- Significant clinical **improvement in both skin lesions and alopecia**
- **78% total IgG reduction** from baseline achieved by week 12

## IMVT-1402 Case Study: Patient 1

Patient treated with 600 mg QW SC open-label for 12 weeks



**Second patient dosed also showed >50% improvement in CLASI-A score by week 12  
(CLASI-A at screening of 18 reduced to 8 by week 12)**

Dermatologists desire a skin-focused, targeted biologic that addresses CLE unmet needs<sup>1</sup>

**IMVT-1402 has potential to be the first novel dermatology therapy for CLE in >50 years<sup>2</sup>**

### Considerable Market Opportunity

**153K**

US prevalence of SCLE and CCLE<sup>3</sup>



**Up to 50%**

Non-responders to antimalarials or topicals<sup>4</sup>



**75K**

Target addressable US population

### Potential Differentiated Profile

**Targeted Biologic**

Dermatologists are frustrated by the skin-specific therapies currently available

**Quick control**

Speed of action is critical to disease control and QoL- prevention of scarring and potential disfigurement<sup>1</sup>

**Sustained remission**

90% of dermatologists cite sustained remission and reduced severity of flares as top unmet needs<sup>1</sup>

**Improved safety & tolerability**

80% of HCPs report lack of long-term efficacy, tolerability and toxicity risks with current CLE treatments<sup>2</sup>

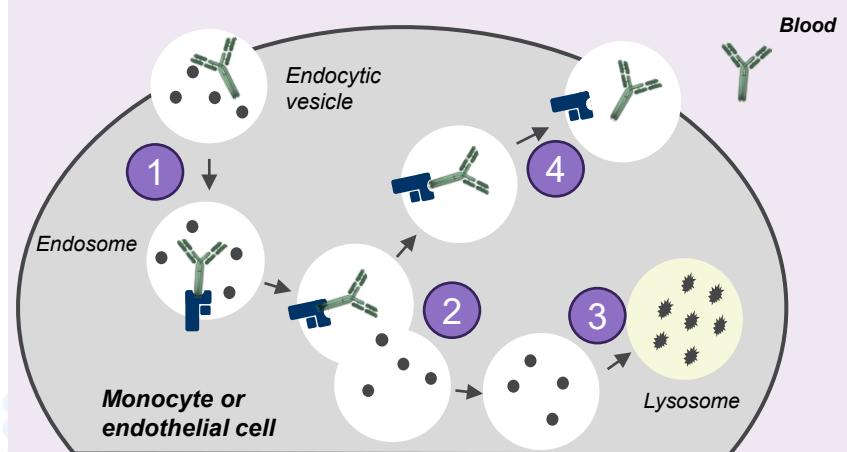
Note: All estimates are approximate

1. Internal Market Research CLE Dermatologist Unmet Need 2023, Internal Market Research CLE Patient Journey 2024 2. Presto JK, Werth VP: Cutaneous Lupus Erythematosus: Current Treatment Options. Curr Treat Option Rheumatol. 2016; 2(1): 36–48 3. Jarukitsopa et al 2015; IMVT Spherix Internal Market Research 4. Wahie S, Meggitt SJ. Long-term response to hydroxychloroquine in patients with discoid lupus erythematosus. Br J Dermatol. 2013 Sep;169(3):653-9. doi: 10.1111/bjd.12378. PMID: 23581274

# Appendix

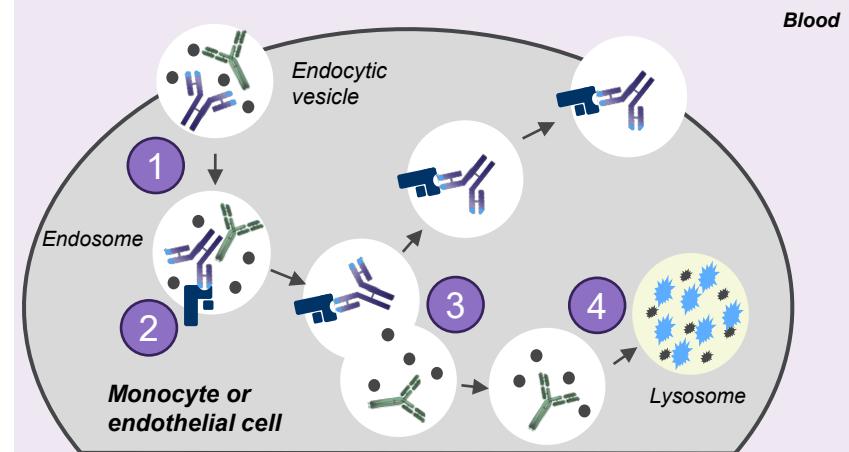
# Our target: Neonatal Fc receptor (FcRn)

FcRn maintains levels of antibodies (IgG) in circulation by preventing their degradation



1. IgG is taken up into cells in endocytic vesicle
2. FcRn-IgG complexes are sorted from unbound proteins
3. Unbound proteins are trafficked to lysosome for degradation
4. IgG is recycled back into circulation

Anti-FcRn blocks binding of IgG to FcRn and promotes their removal and degradation



1. IgG and FcRn blocker are taken up into cells in endocytic vesicles
2. FcRn blocker binds to FcRn in endosomes
3. IgGs are blocked from forming complexes with FcRn
4. Non-receptor bound IgGs are degraded in lysosomes

# Totality of FcRn clinical evidence demonstrates that deeper IgG reductions result in better clinical outcomes across multiple indications

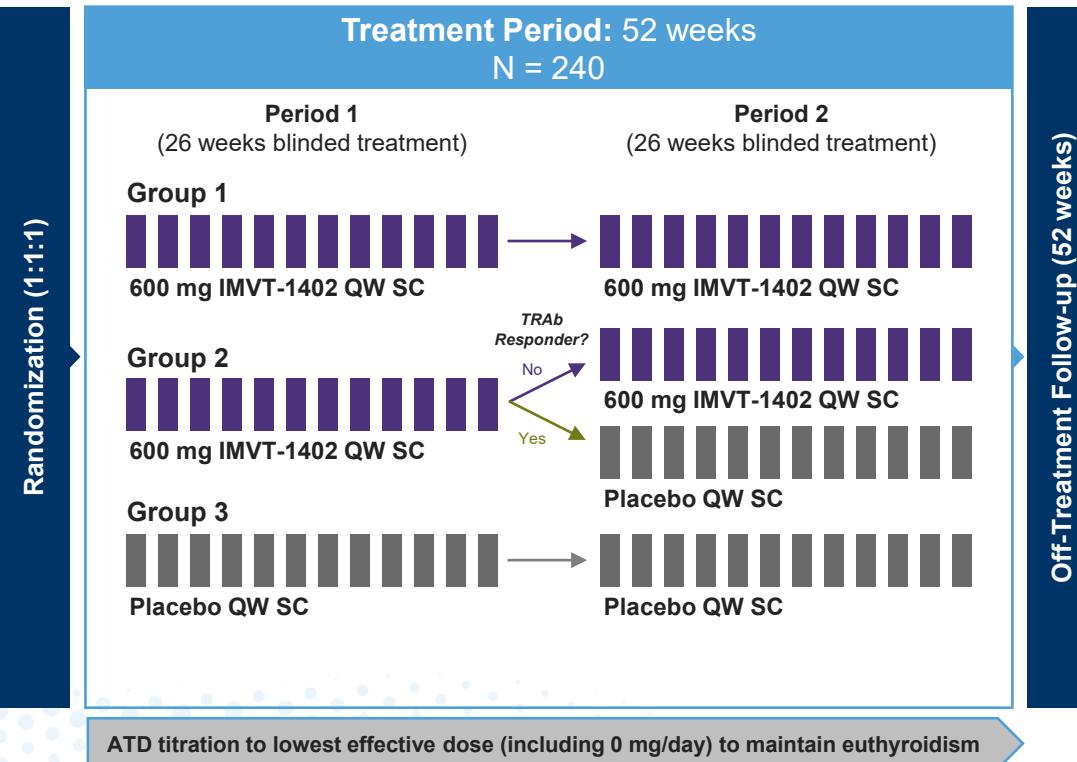
Company		Evidence of Greater IgG Reductions Translating to Clinical Benefit
GD		<u>Phase 2:</u> Greater IgG reduction across treatment cohorts → higher rates of anti-TSHR antibody reduction and numerically higher responses for ATD dose tapering and ATD discontinuation
CIDP		<u>Phase 2b:</u> Greater IgG reduction across treatment cohorts → higher aINCAT response rates
MG		<u>Phase 2:</u> Deeper IgG across treatment arms → AChR autoantibody reductions and enhanced clinical activity
		<u>Phase 3:</u> 680 mg dose with greater IgG reduction out-performs 340 mg dose across endpoints
		<u>Phase 2:</u> Patient-level scatter plot demonstrating greater IgG declines → greater MG-ADL improvements <sup>2</sup>
TED		<u>Phase 2s:</u> Greater IgG reduction across arms → higher rates of anti-TSHR antibody reduction and greater clinical response rates
		<u>Phase 2:</u> Dose-dependent efficacy → deeper IgG reduction (same dose regimen used in RA trial) led to better clinical response <sup>4</sup>
		<u>Phase 2:</u> In those patients with greater IgG reduction → correlation with greater autoAb reduction → correlation with greater clinical response <sup>5</sup>
ITP		<u>Phase 2:</u> Greater IgG reduction across arms → greater platelet responses <sup>6</sup>
PV/PF		<u>Phase 2:</u> More intensive dosing regimens across arms led to deeper IgG lowering → deeper skin responses and lower rates of relapse <sup>7</sup>

1. Many of the analyses above were post-hoc and not all were statistically significant. Cross trial and post-hoc analyses are inherently limited and are presented for hypothesis generating purposes only, nevertheless consistent and numerically positive increases in efficacy were observed as noted above; 2. Momenta Vivacity-MG Interim Phase 2 Investor Presentation, 2020; 3. argenx JP Morgan Healthcare Conference Presentation January 2021; 4. EULAR 2024 Abstract. 5. Janssen Research & Development, ACR poster, November 2023. 6. IgG reduction at day 8 estimated by WebPlotDigitizer for 4mg/kg, 7mg/kg and 10mg/kg doses. 7. Argenx phase 2 PV/PF publication, Br J Dermatol. 2022 Mar;186(3):429-439; MG: Myasthenia gravis; TED: Thyroid eye disease; GD: Graves' disease; ITP: Immune thrombocytopenic purpura; RA: Rheumatoid arthritis;

# IMVT-1402 potentially registrational trial in Graves' disease

## Inclusion<sup>a</sup>

- Adults with active Graves' disease as documented by presence of TSH-R binding autoantibodies (TRAb)
- Subjects on an ATD for  $\geq 12$  weeks before the Screening Visit
- Subjects who are hyperthyroid based on suppressed TSH despite ATD treatment



**Primary Endpoint at Week 26:** Proportion of participants who become euthyroid<sup>b</sup> and stop ATD

**Key Secondary Endpoint at Week 52:** Proportion of participants who become euthyroid<sup>b</sup> and stop ATD

**Design enables study of remission as upside**

# IMVT-1402 second potentially registrational trial in Graves' disease

## Inclusion<sup>a</sup>

- Adults with active Graves' disease who are hyperthyroid based on suppressed TSH despite ATD treatment

Randomization (1:1:1)

## Blinded Treatment Period: 26 weeks

N = 210



ATD titration to lowest effective dose (including 0 mg/day) to maintain euthyroidism

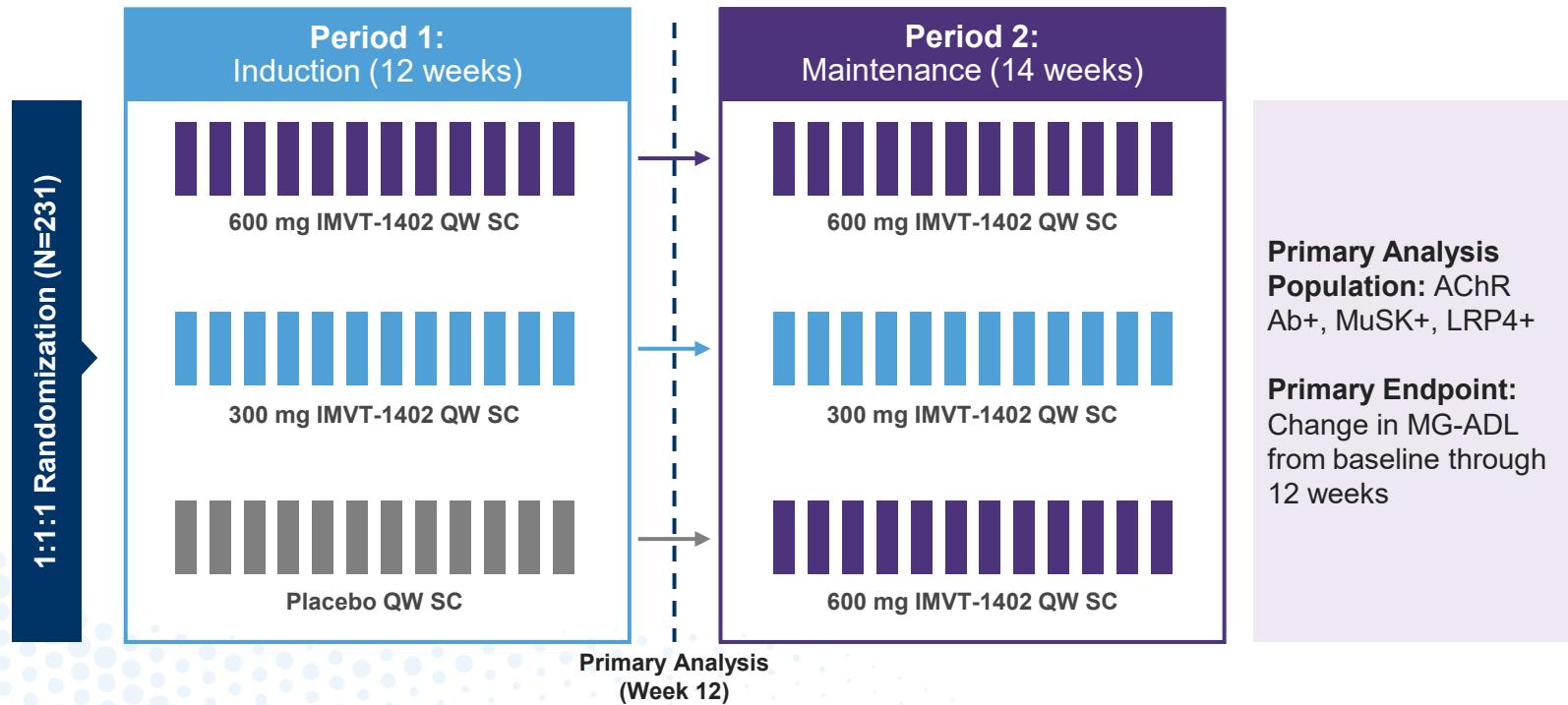
**Primary Endpoint at Week 26:** Proportion of participants on 600 mg who become euthyroid<sup>b</sup> and off ATD versus placebo

Off-Treatment Follow-up

**Secondary Endpoint at Week 26:** Proportion of participants on 600 mg who have T3 (Total T3 or FT3) and FT4  $\leq$  ULN and off ATD

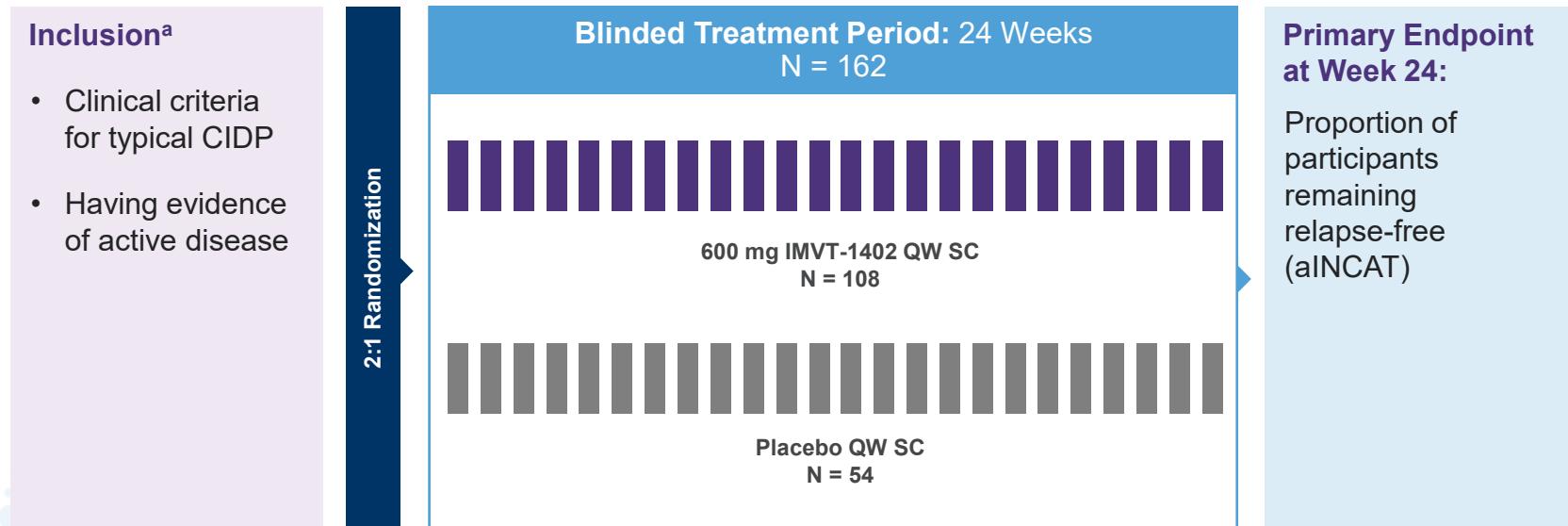
# IMVT-1402 potentially registrational trial in MG

Trial designed to enable demonstration of deep, durable responses



# IMVT-1402 potentially registrational trial in CIDP

Trial designed to maximize dose response with IMVT-1402 600 mg



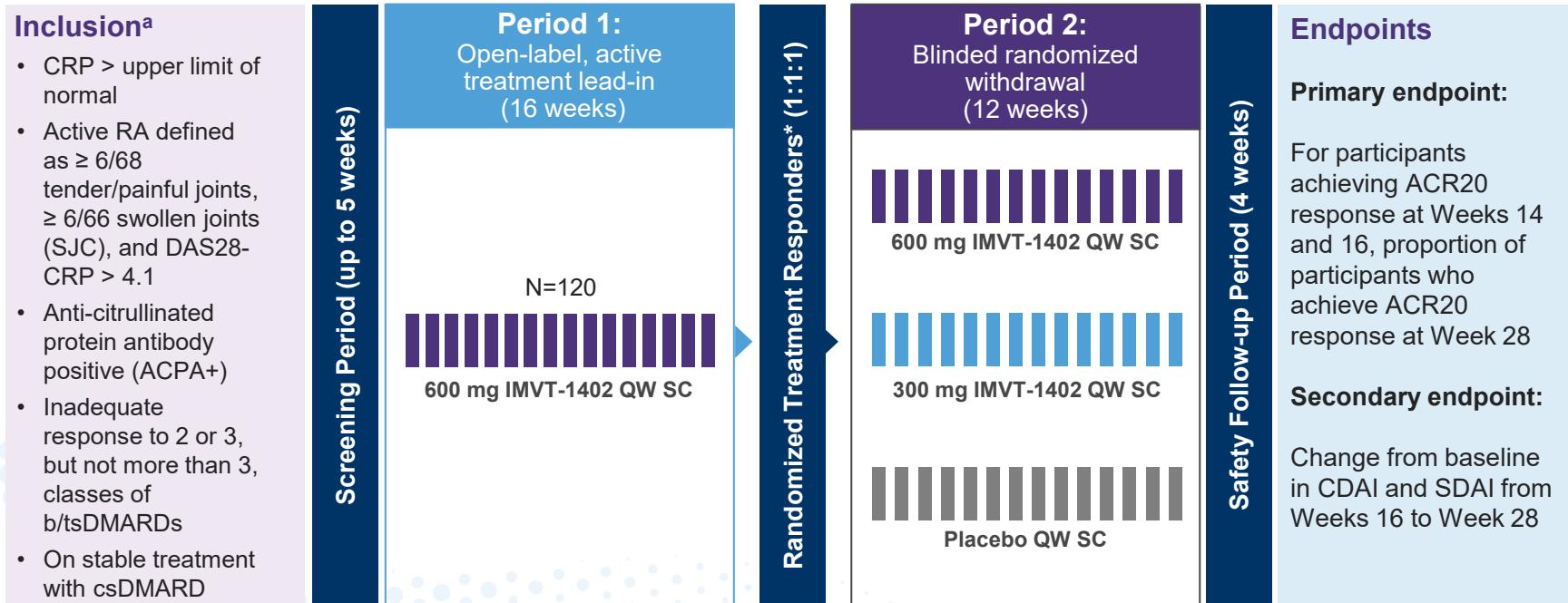
Simplified study design without washout period and flare requirement prior to randomization based on experience in the batoclimab CIDP study in identifying patients with active disease

# IMVT-1402 potentially registrational trial in ACPA+ D2T RA

**Trial designed as open label lead-in with randomized withdrawal D2T population enriched for higher baseline ACPA levels**

## Inclusion<sup>a</sup>

- CRP > upper limit of normal
- Active RA defined as  $\geq 6/68$  tender/painful joints,  $\geq 6/66$  swollen joints (SJC), and DAS28-CRP  $> 4.1$
- Anti-citrullinated protein antibody positive (ACPA+)
- Inadequate response to 2 or 3, but not more than 3, classes of b/tsDMARDs
- On stable treatment with csDMARD

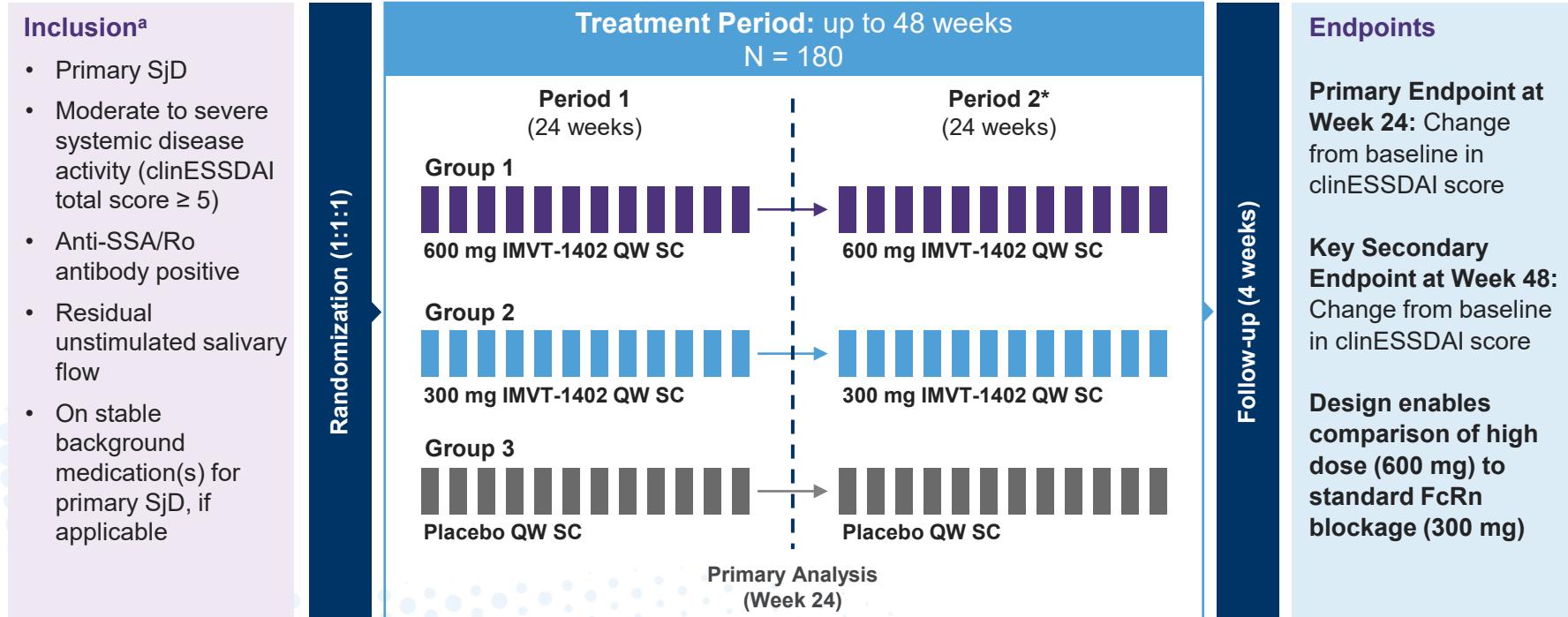


\*Meets ACR20 criteria at Week 14 & Week 16

a. Additional inclusion and exclusion criteria not listed on slide. C-reactive protein (CRP); Disease Activity Score-28 (DAS28); Clinical Disease Activity Index (CDAI); Simplified Disease Activity Index (SDAI); Disease-modifying antirheumatic drugs (DMARDs); American College of Rheumatology (ACR)

# IMVT-1402 potentially registrational trial in SjD

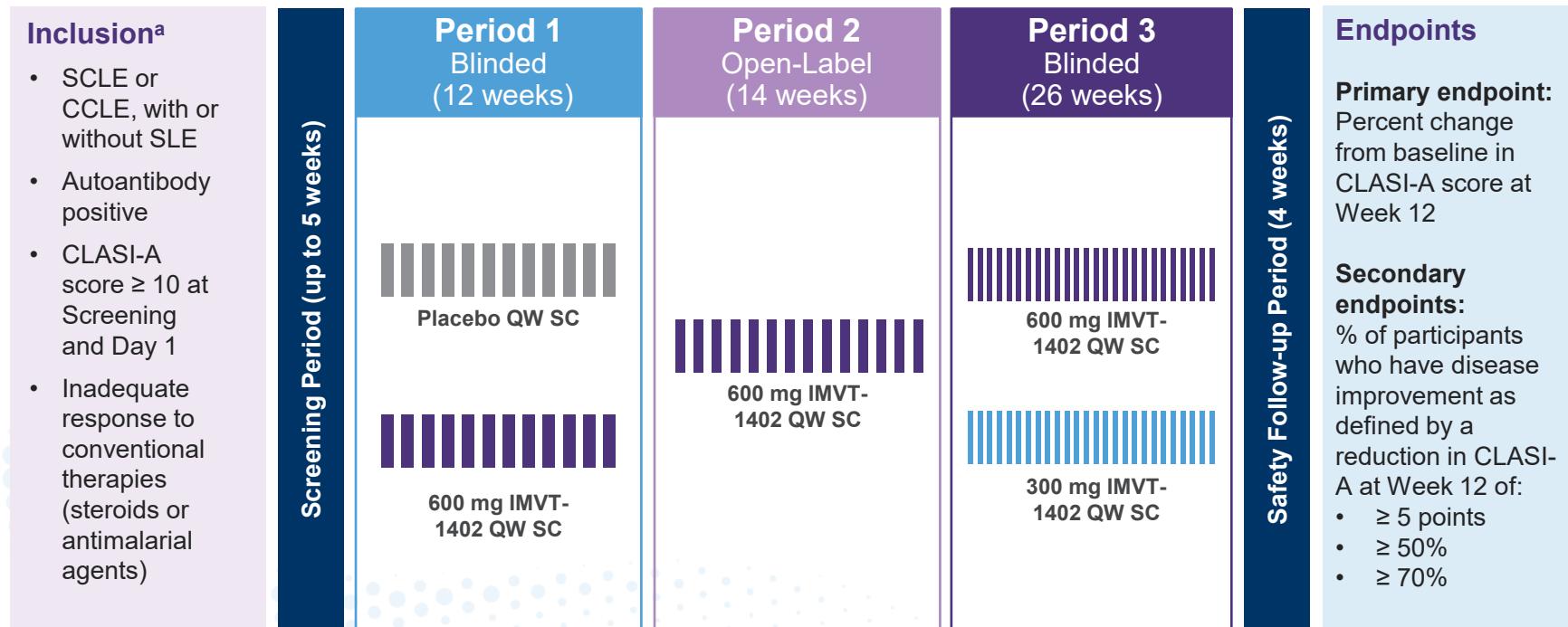
Trial enables comparison of high dose to low dose FcRn blockage



a. Additional inclusion and exclusion criteria not listed on slide  
QW: Weekly; SC: Subcutaneous; ClinESSDAI: clinical European League Against Rheumatism Sjögren's Syndrome Disease Activity Index

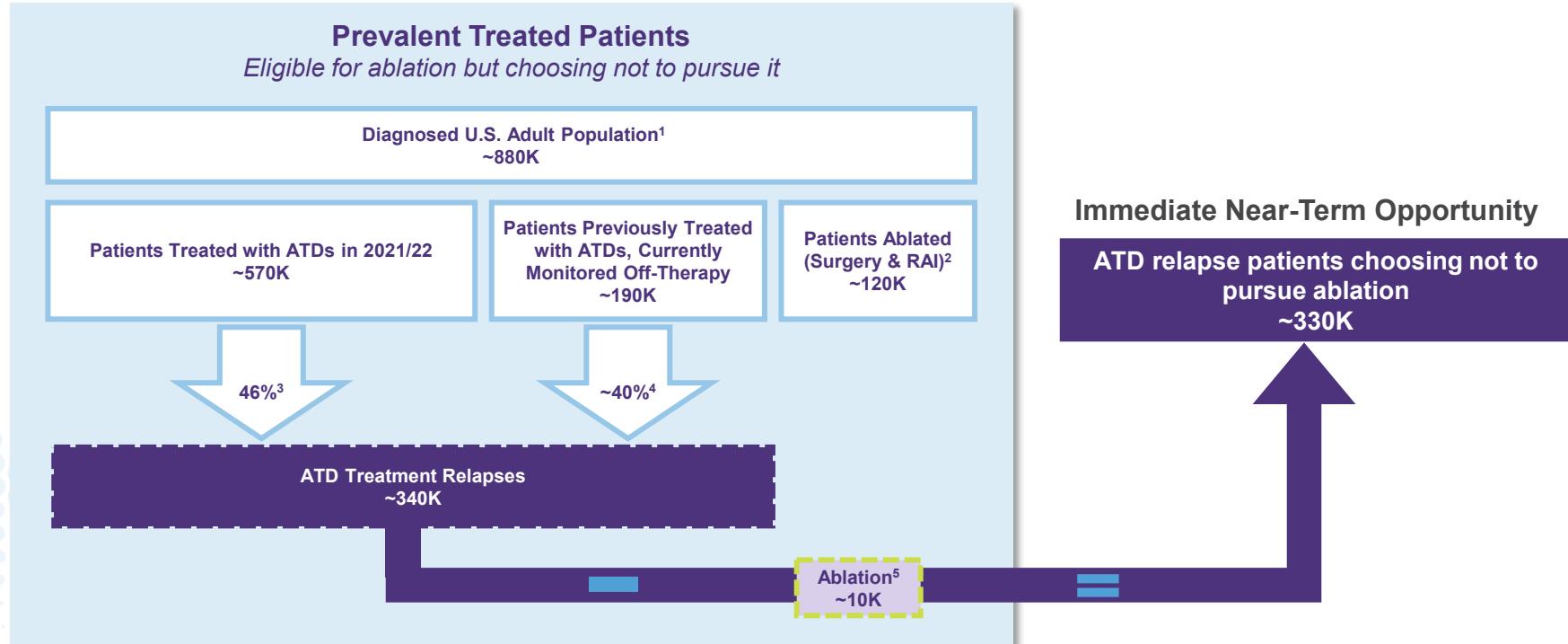
# IMVT-1402 proof-of-concept study in CLE

Global trial with N=56 participants; designed to demonstrate short-term and long-term efficacy



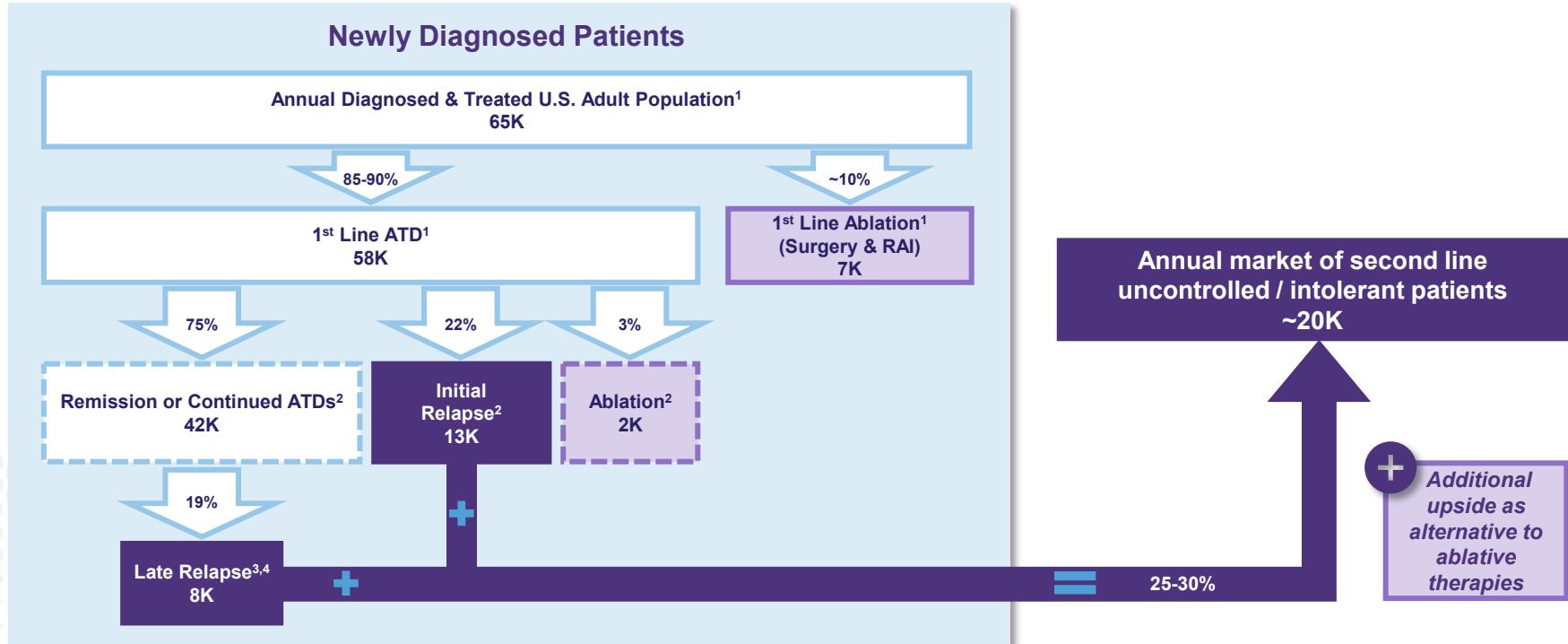
# Market Opportunity in Graves' Disease

# Analysis #1: Real world claims analysis indicates a substantial untapped opportunity in the prevalent treated Graves' Disease market



Sources: 1. Roivant Claims Analysis – 2022 prevalent patient population based on a two-year lookback for diagnosis, 2. Of the 120K patients ablated, ~80K were ablated prior to 2021 and ~40K were ablated in 2021/2022. 3. Azizi et al. (2019): Note, the relapse rate was calculated as a weighted average considering relapse rate in patients on ATDs <18months is 53% compared to patients on ATDs >18months is 15%. Of the 570K patients treated with ATDs, ~470K are on ATDs <18months and ~100K are on ATDs for >18months. Rates have been applied proportionally. 4. Bandai et al. (2019): Of the ~190K patients previously treated with ATDs and currently monitored off-therapy, ~40% experience relapse, which is 75K. 5. Grove-Laugesen et al. (2023): 3.4% of ATD relapse patients will pursue ablation. 3.4% applied to the ~340K ATD treatment relapse patients is ~10K.

## Analysis #2: Real world claims analysis conservatively estimates an incident US population of ~65K leading to an annual second line market of ~20K patients

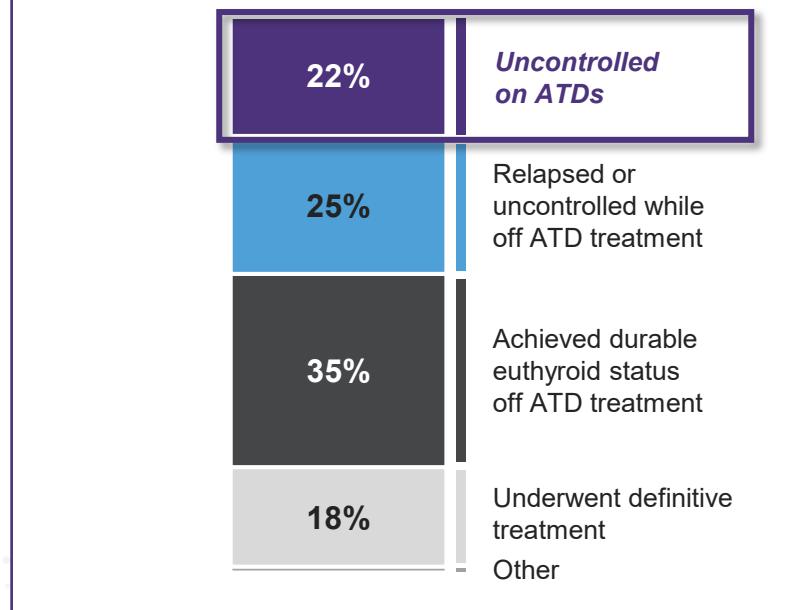


## Analysis #3: Surveyed endocrinologists indicate that ~25% of their patients remain uncontrolled on ATDs

### Endocrinologist Survey Methodology

1. Board-certified endocrinologists (N=140) were screened based on Graves' disease patient volume (10+ patients in the past 3 months) and time in practice (2-40 years in practice with  $\geq 50\%$  of time spent in direct patient care)
2. The N=140 endocrinologists completed a double-blinded online quantitative survey regarding their treatment experience

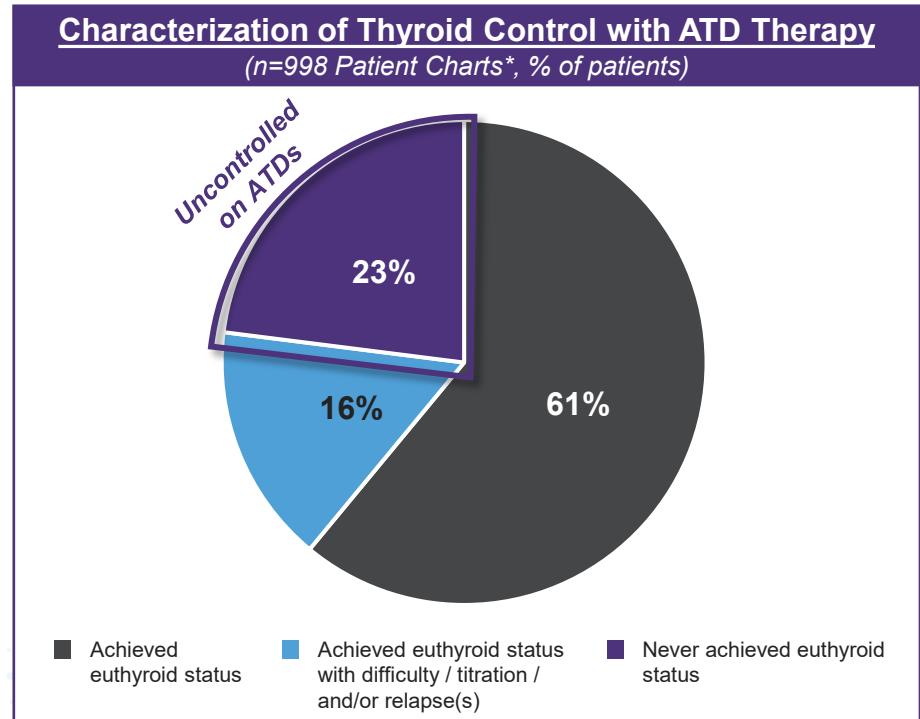
### Graves' Disease Patient Types: HCP Survey (n=140 HCPs, % of patients)



## Analysis #4: Real-world in-depth chart review of 1,000+ patient records from 140 endocrinologists indicates ~25% have never achieved euthyroid status on ATDs

### Real World Chart Audit Methodology

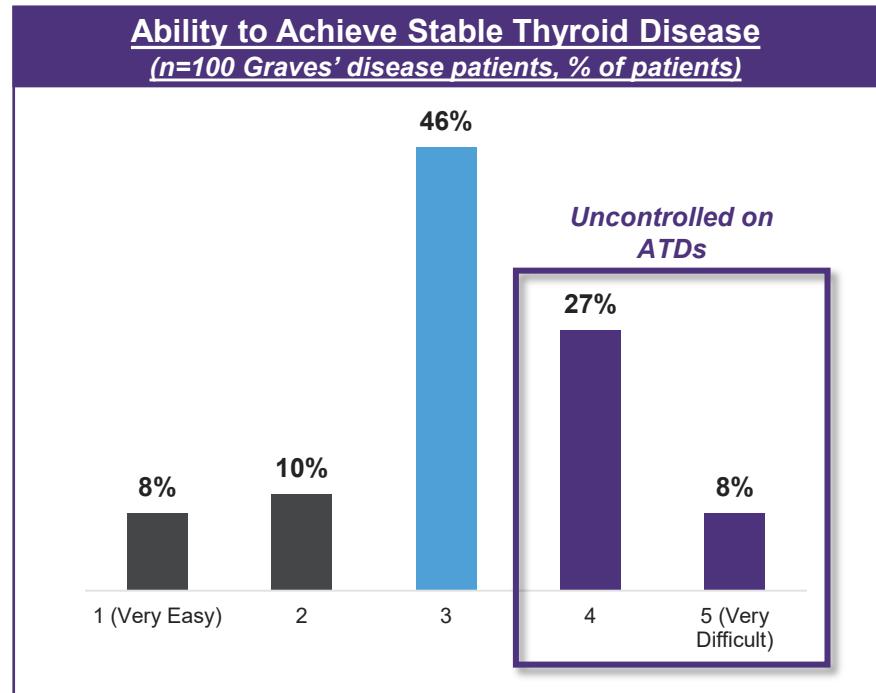
1. As part of the endocrinologist survey, each healthcare provider was asked to complete N=8 Graves' disease patient charts for a total of 1,120 charts collected via randomized selection to minimize bias
2. Chart selection followed various qualifications:
  1. Diagnosed with Graves' disease
  2. Seen by the healthcare provider in the past 3 months
  3. Under the healthcare provider's care for at least 6 months
  4. First visit in the past 3 years
  5. Either on ATD therapy currently or previously



## Analysis #5: ~35% of Graves' disease patients report that they have found it difficult or very difficult to achieve stable thyroid disease while on ATDs

### Patient Survey Methodology

1. A double-blinded online survey was conducted with N=100 patients who reported being diagnosed by a healthcare provider with Graves' disease
2. Screening criteria included patients who were diagnosed in the past 3 years OR diagnosed in the past 5 years with a recurrence in the past year
3. Excluded patients who had received radioactive iodine or thyroidectomy



# Graves' US market-sizing analyses confirm high unmet need with ~330K prevalent patients relapsed, uncontrolled, or intolerant to ATDs

1

Conservative Inovalon claims analysis<sup>1</sup> yields ~880K prevalent Graves' disease patients, including ~330K prevalent ATD relapsed patients choosing not to pursue ablation

2

Conservative Inovalon claims analysis<sup>2</sup> yields ~65K annual incident Graves' disease patients, including ~20K annual incident second line uncontrolled / intolerant patients

3

Deep dive endocrinologist survey of 140 healthcare providers treating Graves' disease patients indicates ~25-30% of patients are relapsed, uncontrolled, or intolerant to ATDs

4

Real-world chart audit of 1,120 Graves' disease patients treated by surveyed endocrinologists indicates ~25-30% of patients are relapsed, uncontrolled, or intolerant to ATDs

5

Patient survey of 100 diagnosed Graves' disease patients indicates ~25-30% of patients are relapsed, uncontrolled, or intolerant to ATDs