

## Immunovant Development Update





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#### Agenda

- 1) Significant progress on IMVT-1402 development plan
- Graves' Disease, potential First-in-Class Opportunity, with impact on thyroidal and extrathyroidal disease
- 3 Difficult-to-Treat Rheumatoid Arthritis, potential Best-in-Class Opportunity
- 4 Conclusion

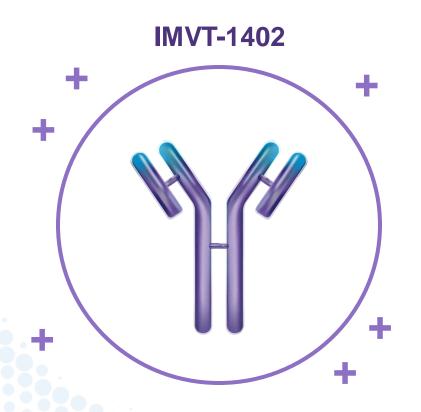
# IMVT-1402 Development Progress

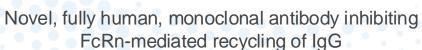




#### **Our lead asset:**

IMVT-1402 has a combination of potentially best-in-class attributes not seen with other anti-FcRns







**Deep IgG Lowering** Phase 1 data suggests deep dose-dependent IgG lowering



**Favorable Analyte Profile** Phase 1 data supports a favorable analyte profile with no or minimal effect on albumin and LDL



Convenient Administration Formulated for simple subcutaneous injection that may enable self-administration at home



Compelling Patent Protection Issued U.S. patent covers composition of matter, method of use and methods for manufacturing to 2043<sup>1</sup>



## Potential best-in-class product profile opens broad range of indication opportunities for IMVT-1402

#### First-in-Class

- Assuming differentiated benefit/risk profile and simple SC delivery, opportunity to leverage potency of IMVT-1402 to further expand applicable patient types for anti-FcRn development
- Example Graves' disease

High unmet need, biologic plausibility

#### **Best-in-Class**

- IgG autoantibodies part of disease pathophysiology
- Insights from later-stage anti-FcRn programs may be leveraged together with IMVT-1402 potency to optimize development approach for IMVT-1402
- Example Myasthenia Gravis

Classic autoAb, class data positive

**Best-in-Class** 

- Other underserved patient populations
- Potential to enhance PTS via focus on subset of patients with autoantibodies of interest and leverage IMVT-1402 potency
- Examples ACPA+ Difficult-to-Treat Rheumatoid Arthritis

Other autoimmune, class data suggestive



## Significant progress in advancing lead asset IMVT-1402 to potentially pivotal study initiations across broad development portfolio



Five INDs cleared across a range of therapeutic areas and FDA divisions, including GD (Endocrinology) and RA (Rheumatology)



On track to initiate an exciting portfolio of 10 indications by March 2026



Batoclimab experience informs ability to accelerate IMVT-1402 development



### Graves' Disease

First-in-class Potential







## Proof of concept achieved in Graves' Disease, positioning IMVT-1402 to potentially be best-in-class and first-in-class



>75% Response Rate in Patients Uncontrolled on Anti-Thyroid Drugs (ATDs): T3 and T4 rapidly normalized by Week 12 without an increase in ATDs in 76% of patients



>50% of Patients are ATD-Free Responders: 56% of patients not only achieved normal T3 and T4 levels but also ceased ATD therapy entirely by 12 weeks



Lower is Better: Deeper IgG reductions drove meaningfully higher response rates, positioning IMVT-1402 to potentially be best-in-class



**High Unmet Need Yields Attractive Commercial Opportunity**: 25-30% of Graves' Disease patients per year are uncontrolled on / intolerant to ATDs with no pharmacologic options



IMVT-1402 IND Cleared: Received FDA greenlight, enabling straight to pivotal transition

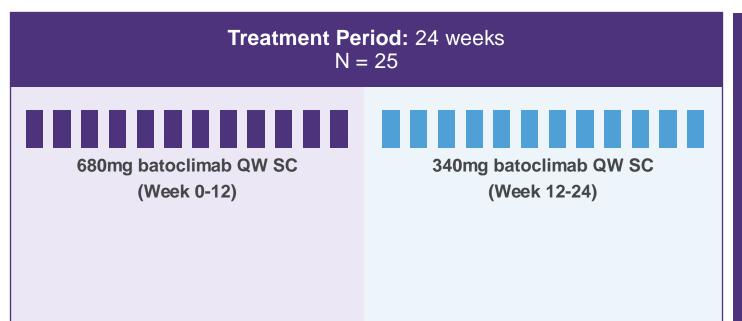


#### Graves' Disease Phase 2 study design tests two doses of batoclimab

#### 12 weeks of 680mg followed by 12 weeks of 340mg in Graves' Disease patients uncontrolled on ATDs

#### **Inclusion**<sup>a</sup>

- Subjects with active Graves' Disease as documented by presence of elevated stimulatory TSH-R-Ab
- Subjects hyperthyroid despite ATD



#### **Key Endpoint:**

Proportion of participants who:

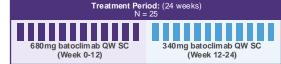
- Achieve normalization of T3 and T4 or have T3 / T4 below LLN, and
- Do not increase in ATD

**ATD Treatment:** 

Stable ATD dose at screening

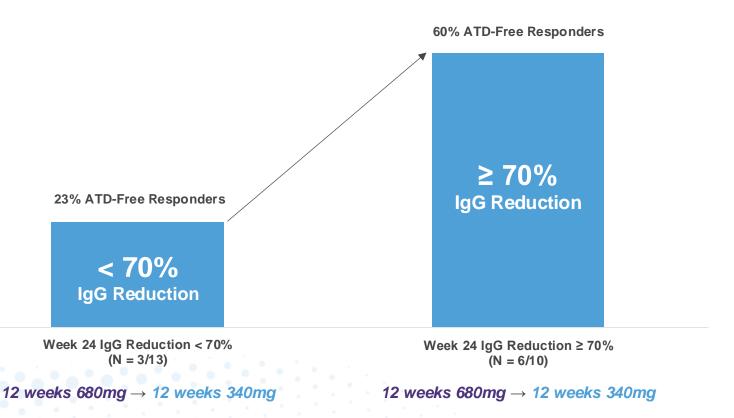
Goal to taper ATD during treatment period





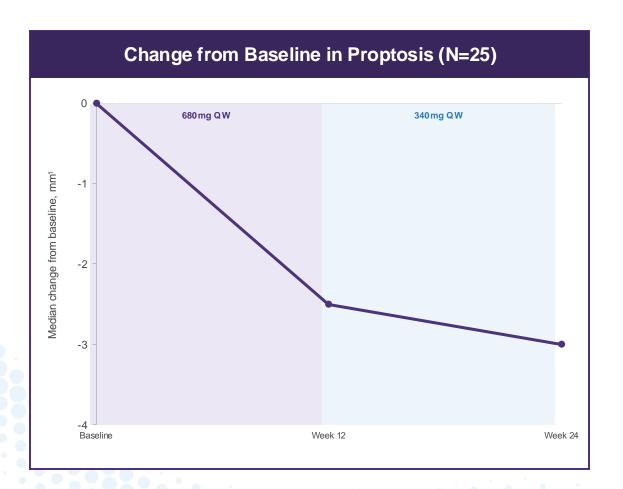
## Deeper IgG reduction at 24 weeks was associated with a meaningfully higher ATD-free responder rate

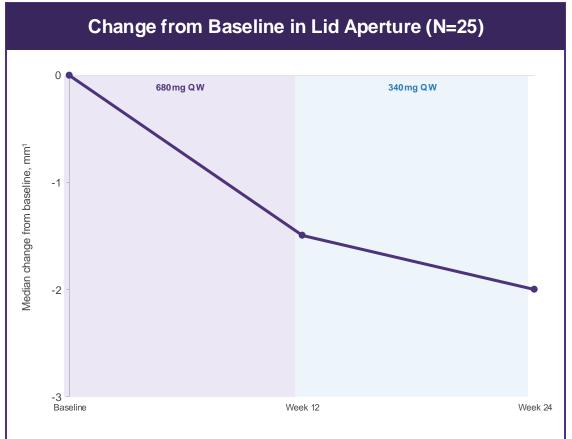
% of participants who achieve normal T3 and T4 or have T3 or T4 below LLN, and ceased all ATD medications





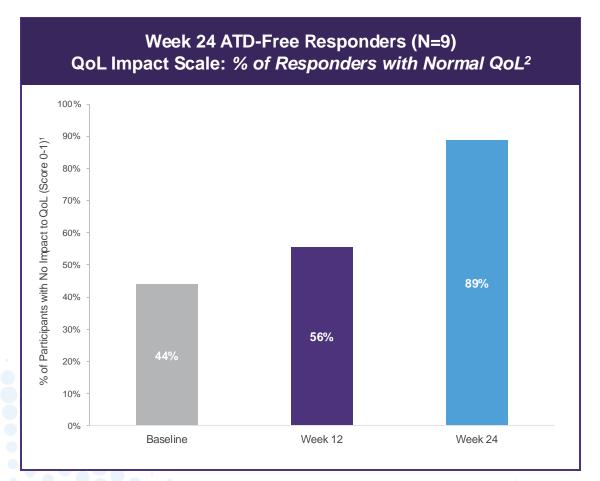
## We observed meaningful improvements in proptosis and lid aperture in Graves' Disease patients treated with batoclimab

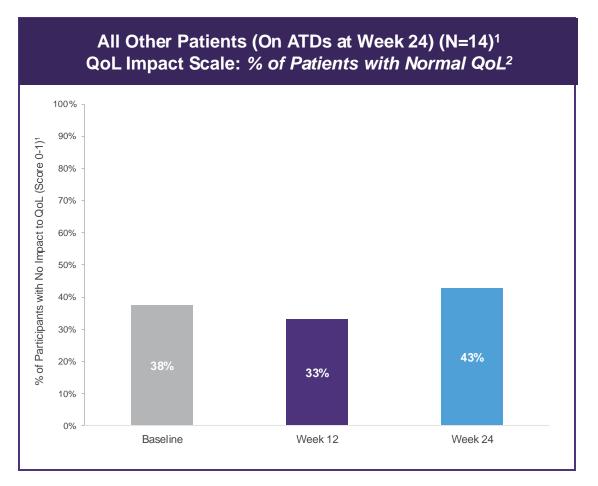






## ATD-free responders reported more pronounced improvements to quality of life, with ~90% experiencing normal quality of life by Week 24



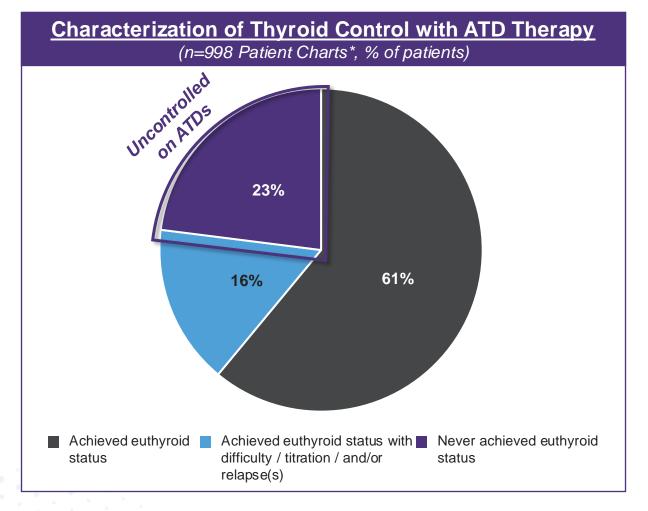




## Real-world in-depth chart review of 1,000+ patient records from 140 endocrinologists indicates ~25% have never achieved euthyroid status on ATDs

#### **Real World Chart Audit Methodology**

- 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

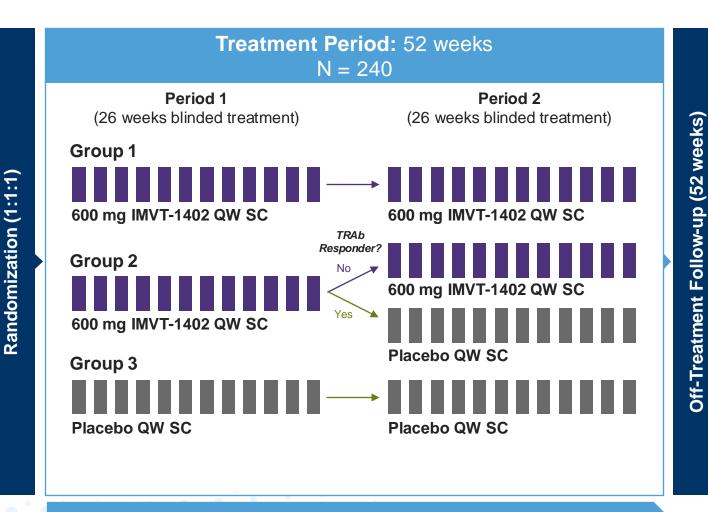




#### First pivotal trial for IMVT-1402 in Graves' Disease

#### **Inclusion**<sup>a</sup>

- Adults with active Graves' Disease as documented by presence of TSH-R binding autoantibodies
- Subjects on an ATD for ≥12 weeks before the Screening Visit
- Subjects who are hyperthyroid based on suppressed TSH despite ATD



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

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



#### IMVT-1402 is potentially best and first-in-class in Graves' Disease

- High dose batoclimab rapidly achieved a 76% response rate in patients uncontrolled on ATDs, meaningfully exceeding 50% response rate bar
- High dose batoclimab rapidly achieved a 56% ATD-free response rate in patients uncontrolled on ATDs, meaningfully exceeding 30% ATD-free response rate bar
- Strong correlation observed between degree of IgG lowering and clinical outcomes yields potential best-in-class and first-in-class opportunity for IMVT-1402
- 1MVT-1402 Graves' Disease IND cleared, enabling straight to pivotal transition
- Real world claims data indicates 25-30% of Graves' Disease patients per year are relapsed, uncontrolled on or intolerant to ATDs with no existing pharmacologic options representing an attractive commercial opportunity with limited competition



## Difficult-to-Treat Rheumatoid Arthritis

Best-in-Class Potential





### KOL Discussion



**Pete Salzmann, MD**Chief Executive Officer,
Immunovant



**Peter Taylor, MA, PhD, FRCP, FRCPE** University of Oxford

## Despite tremendous progress in the treatment of rheumatoid arthritis (RA), a subset of patients do not respond well to available therapies

#### Key Takeaways<sup>1</sup>

- RA is a chronic, progressive disease that causes joint inflammation and pain
- Most common systemic autoimmune disease, affecting 18M globally and 1.5M in the US
- Medical therapy is used to help control joint inflammation; treatment options include a variety of conventional oral, targeted synthetic and biologic DMARDs
- Inadequate disease control can result in irreversible joint erosions

#### **Significant Impact**





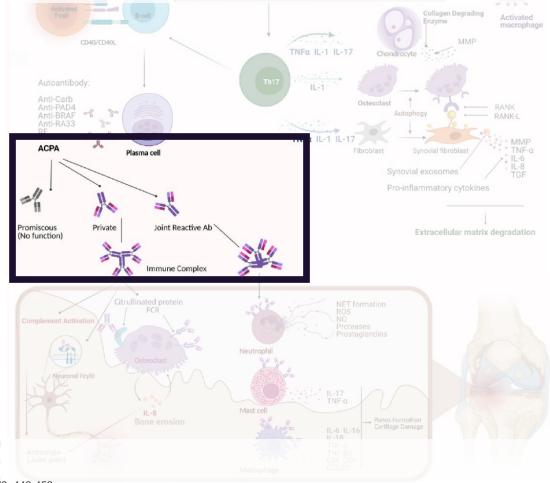
PA view of the hands shows joint space narrowing, erosions, and diffused osteoporosis Source: Nakshabandi N al. et al. Radiology in Rheumatology, 2021.



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

Rheumatoid factor (RF) and ACPA autoantibodies are present in ~75% of RA patients<sup>1</sup>

Anti-FcRn mechanism may lower pathogenic IgG autoantibodies and immune complexes



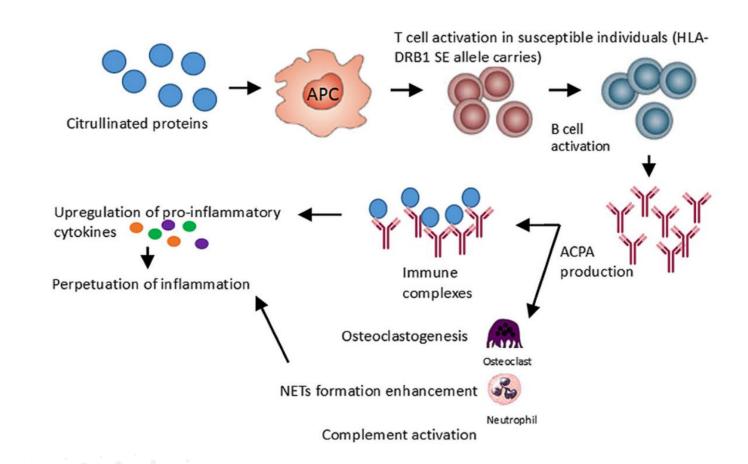


<sup>1.</sup> Okada et al. Ann Rheum Dis 2019;78; 446-453

<sup>2.</sup> Image: Mueller A-L et al. Cells, 2021; 10(11), 3017

## Understanding the pathophysiologic relevance of ACPA autoantibodies in rheumatoid arthritis

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





#### What is difficult-to-treat RA and why is innovation needed?

#### **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**

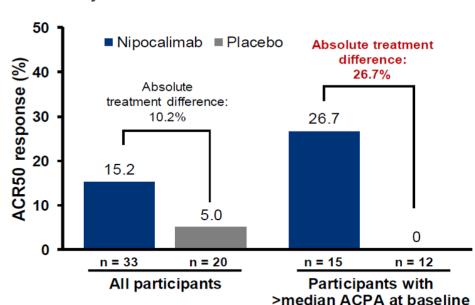
- At least moderate disease activity as defined by composite endpoints which include tender and swollen joint counts
- Progressive joint damage on imaging
- Inability to decrease chronic glucocorticoid therapy below 7.5mg/day
- Ongoing RA symptoms and QoL impact despite therapy



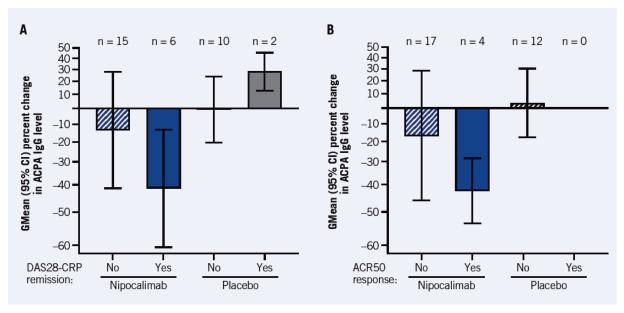
## Publicly available nipocalimab data in RA demonstrated proof of mechanism and showed that deeper ACPA IgG reduction correlated with clinical response<sup>1</sup>

#### Select results from a study of FcRn inhibition vs placebo in biologic experienced RA patients

Proportions of Participants Who Achieved ACR50 Response at Week 12 by ACPA



Percent Changes from Baseline at Trough in ACPA IgG Levels versus (A) DAS-28 CRP Remission and (B) ACR50 Response at Week 12



ACPA, anti-citrullinated protein autoantibody; ACR50, ≥50% response in American College of Rheumatology response criteria; anti-CCP2, anti-cyclic citrullinated peptide 2 antibody; CI, confidence interval; DAS28-CRP, Disease Activity Score 28 using C-reactive protein; GMean, geometric mean; IgG, immunoglobulin G.



## 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

#### **Epidemiology** Severe Disease: 490K<sup>2</sup> **Autoantibody Positive:** 75%<sup>3</sup> Inadequate Response to Prior b/tsDMARDs: 20%2 ~70K Target **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>



# IMVT-1402 Path Forward in Difficult-to-Treat Rheumatoid Arthritis



#### Pivotal study design in rheumatoid arthritis

#### **Global Trial with N=120 Participants**

Screening Period (up to 5 wks)

#### Inclusion



- CRP > upper limit of normal (ULN)
- Active RA defined as ≥ 6/68 tender/painful joints (TJC), ≥ 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

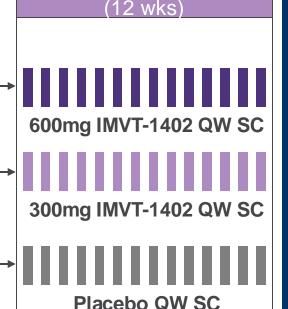
## Period 1: Open-label, active treatment lead-in (16 wks) 600mg IMVT-1402 QW SC

#### d 1: Period 2:

Responders\* (1:1:1)

Randomized Treatment

Blinded randomized withdrawal (12 wks)



#### **Endpoints**



#### **Primary endpoint:**

(4 wks)

Period

Safety Follow-up

For participants achieving ACR20 response at Weeks 14 and 16, proportion of participants who achieve ACR20 response at Week 28

#### **Secondary endpoint:**

Change from baseline in CDAI and SDAI at Weeks 16 to Week 28



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## With pivotal program in RA, IMVT-1402 has the potential to achieve a best-in-class profile for people with difficult-to-treat RA

#### High Unmet Need Subgroup

5-20% of RA patients are difficult-to-treat (D2T) (failed at least 3 therapies)<sup>1</sup>

#### Autoantibody Pathology

ACPA positive RA is associated with severe disease and poor outcomes; publicly disclosed, in-class data from another FcRn inhibitor encouraging<sup>2</sup>

### **Enhanced Study Design**

Open label lead-in with randomized withdrawal attractive for D2T population that is enriched for higher baseline ACPA levels

#### Lower is Better

We believe deeper ACPA antibody reduction expected to correlate with improved clinical efficacy within the anti-FcRn class

#### IMVT-1402 IND Active

Received FDA IND clearance, enabling planned study initiation in early calendar year 2025



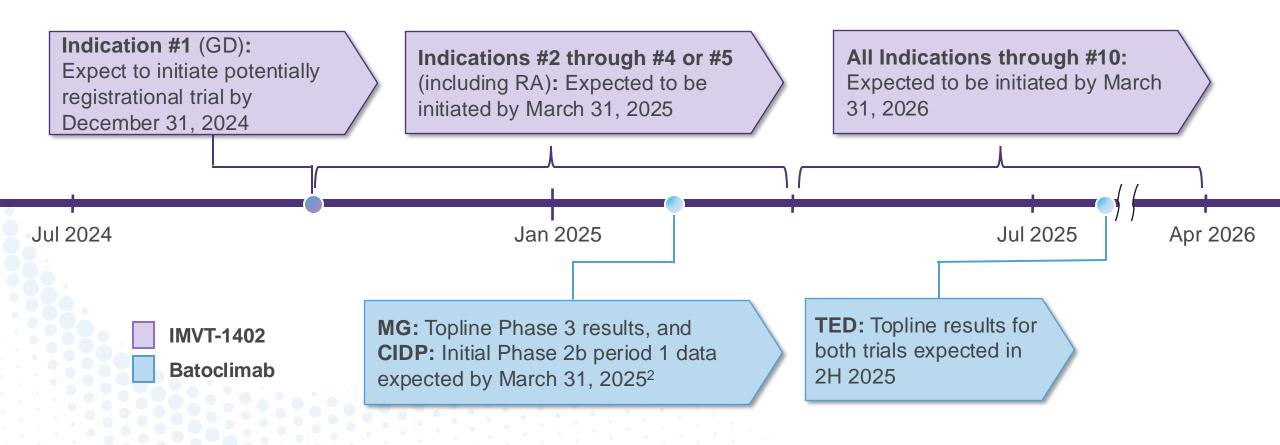
#### Two opportunities for lead asset IMVT-1402 to potentially transform the treatment paradigm for patients struggling to achieve success with existing therapies

		Graves' Disease First-in-Class Potential	Rheumatoid Arthritis  Best-in-Class Potential
01	Meaningful unmet need for subset of patients	Patients not well controlled on ATDs	Patients with D2T RA, multiple therapies failed
02	Underlying pathology driven by IgG Ab	FcRn inhibition observed to lower TRAb	FcRn inhibition observed to lower ACPA
03	In-class proof-of-concept data	Higher response rate across multiple measures with ≥70% IgG reduction¹	Response rate higher for patients with high baseline ACPA & deep IgG reduction <sup>2</sup>
04	IMVT-1402 trial design	600mg dose for deep IgG reduction; Primary endpoint includes off-ATD	600mg dose for deep IgG reduction; Open-label lead-in



#### Multiple near-term milestones for enhanced value creation

On track to initiate 4-5 potentially registrational programs for IMVT-1402 by March 31, 2025 and trials in a total of 10 indications by March 31, 2026<sup>1</sup>





<sup>1.</sup> Indications #1 through #5 will be potentially registrational programs, Indications #6 through #10 may be proof-of-concept or potentially registrational programs 2. Enrollment completed for MG. For CIDP, enrollment completed for patients included in the period 1 data expected by March 31, 2025. No further patients will be enrolled until after such period 1 data is disclosed.