



# Targeted science, Tailored solutions

*for people with autoimmune disease*



**Graves' Disease Program Update**  
**September 9, 2024**



# Forward-Looking Statements

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## 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

# Agenda

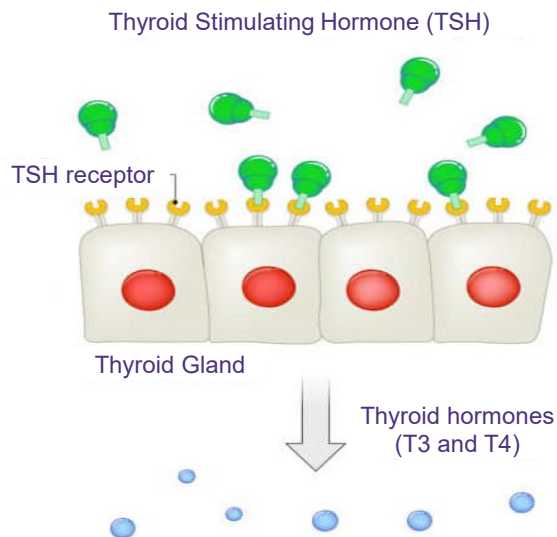
- 1 Graves' Disease Overview and Unmet Need
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- 4 Market Opportunity in Graves' Disease
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# Graves' Disease Overview and Unmet Need

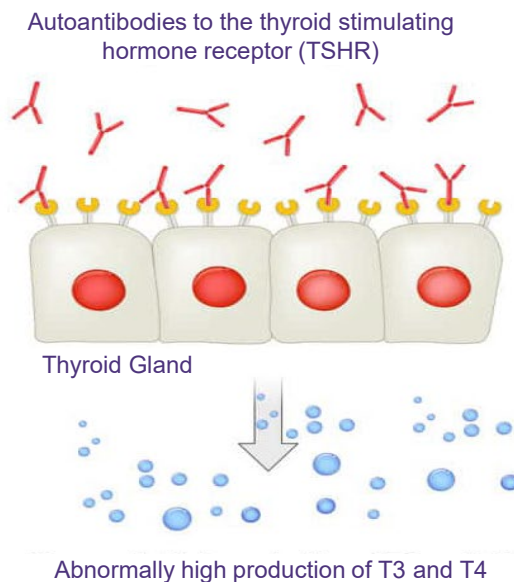
# Graves' Disease is a classic autoimmune condition driven by the presence of thyroid stimulating antibodies

## Pathogenesis of Graves' Disease

### Normal Function



### Graves' Disease



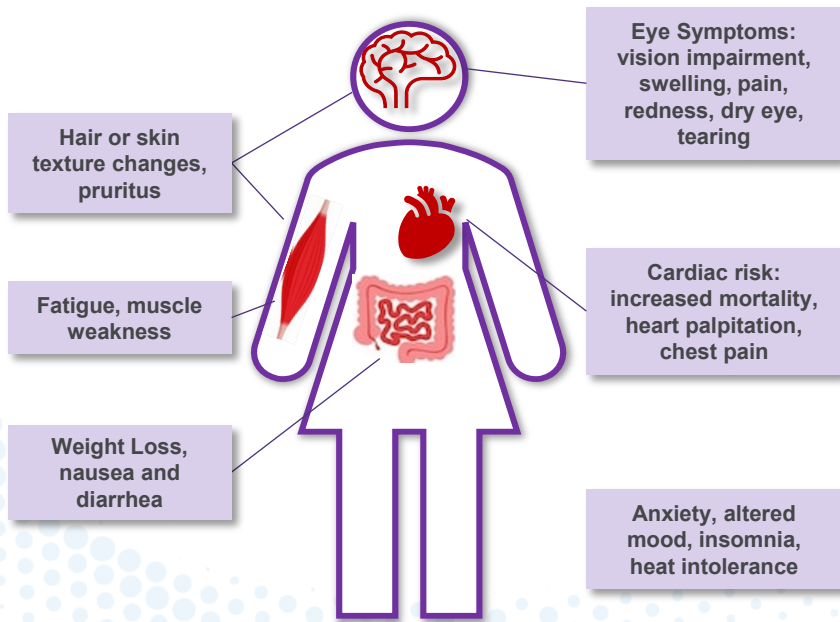
**1** Normally, TSH produced by the pituitary gland stimulates the thyroid gland to produce and release thyroid hormones (T3 and T4)

**2** Graves' Disease is caused by autoantibodies to the thyroid stimulating hormone receptor (TSHR), leading to excess thyroid hormone production



# Graves' Disease: high patient burden and significant morbidity

Symptoms impact many organ systems and leave many patients with substantial burden<sup>1,2</sup>



Substantial morbidity and loss of quality of life if untreated or insufficiently treated

## Cardiovascular Complications

- Graves' Disease patients have a 23% increase in all cause mortality and more than double the risk of a major CV event<sup>3</sup>

## Thyroid Eye Disease (TED)

- TED affects ~40% of patients diagnosed with Graves' Disease<sup>4</sup>
  - ~10% of TED patients on novel therapies experience hearing-related events including hearing loss<sup>5</sup>

## Pregnancy Complications<sup>6</sup>

- Miscarriage, stillbirth, neuro-intellectual impairment in offspring, fetal thyroid disease

## Other Significant Complications

- Thyroid storm (~20% mortality rate<sup>7</sup>), thyroid cancer, psychiatric issues



# Minimal innovation in Graves' Disease treatment options over the past 70+ years

*No existing pharmacologic therapy addresses underlying disease pathology*

## Standard-of-Care Treatments

## Associated Challenges

### Anti-Thyroid Drugs (ATDs)

(e.g., Methimazole, Propylthiouracil)

- ~25-30% of patients are relapsed, uncontrolled or intolerant to ATDs<sup>1</sup>
- Potential for serious adverse events, including hepatotoxicity (liver injury ~3%) and agranulocytosis (loss of white blood cells ~0.3%)<sup>2,3</sup>

### Radioactive Iodine

- TED development and/or exacerbation in 15-33% of patients<sup>4</sup>
- Dose dependent, long-term increased risk of death (5-12% increased risk per 100-mGy dose) from solid cancers<sup>5</sup>
- Necessitates life-long thyroid replacement therapy

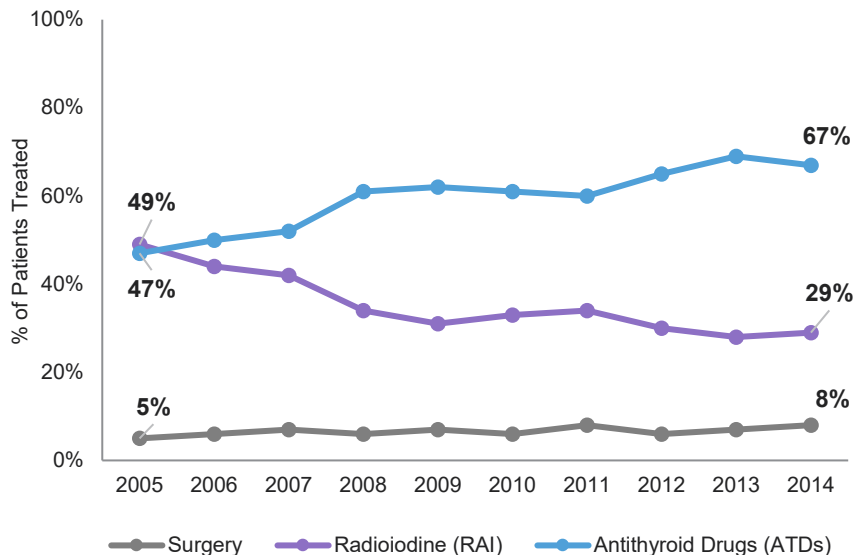
### Thyroidectomy

- Recurrent laryngeal nerve damage risk in 1-4% of patients leading to dysphonia<sup>3</sup>
- Permanent hypoparathyroidism observed in 2.6% of patients<sup>4</sup>
- Necessitates life-long thyroid replacement therapy

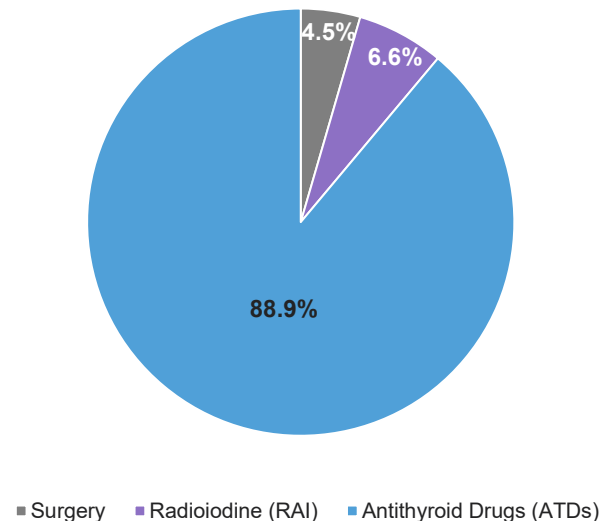


# In North America, the treatment paradigm for Graves' Disease continues to shift away from radioactive iodine and surgery

US Claims Data (2005-2014)<sup>1</sup>

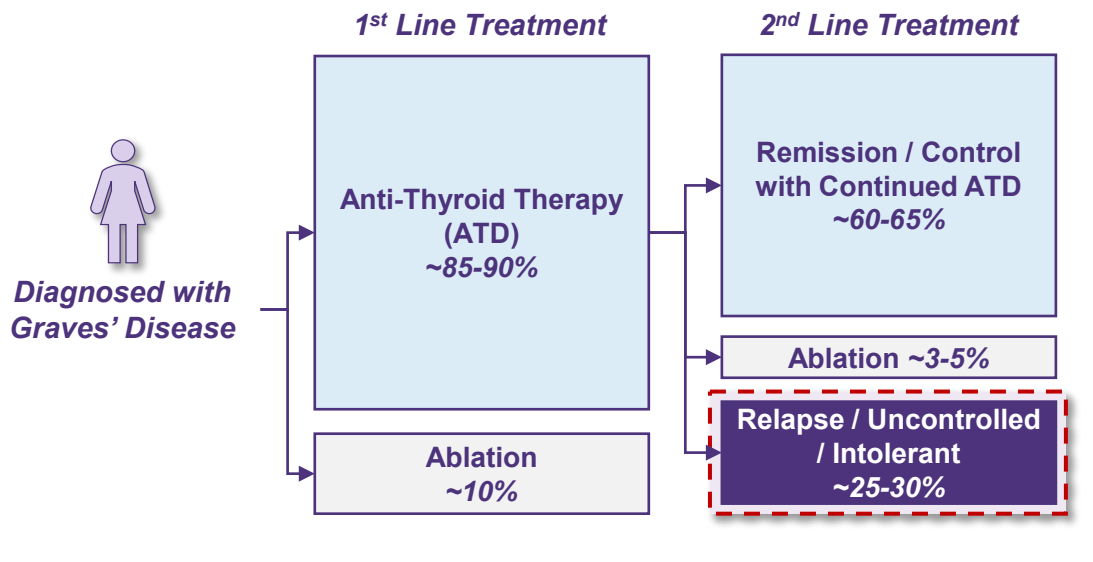


Real-World US Claims Analysis (2021-2022)<sup>2</sup>



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

### Graves' Disease Patient Journey:



### Unmet Need

- 25-30% of patients are relapsed, uncontrolled on or intolerant to ATDs
- Ablation rates in the US indicate that despite lack of disease control on ATDs, patients are choosing not to pursue ablation
- Patients and healthcare providers seek therapeutic options that address underlying disease pathology

# Batoclimab Graves' Disease Phase 2 Data

## Goals for the Graves' Disease Phase 2 Program

**Generate proof of concept efficacy data for first disease-modifying therapy in Graves' Disease**



**Lower is better: establish need for deeper IgG reductions to drive higher response rates**



**Generate ATD tapering data to inform pivotal trial design**



**Enable IND clearance and transition straight to pivotal program for IMVT-1402**



# 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

## Treatment Period: 24 weeks N = 25



680mg batoclimab QW SC  
(Week 0-12)



340mg batoclimab QW SC  
(Week 12-24)

## 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:

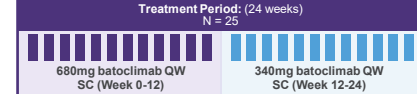
Stable ATD dose  
at screening

Goal to taper ATD during treatment period

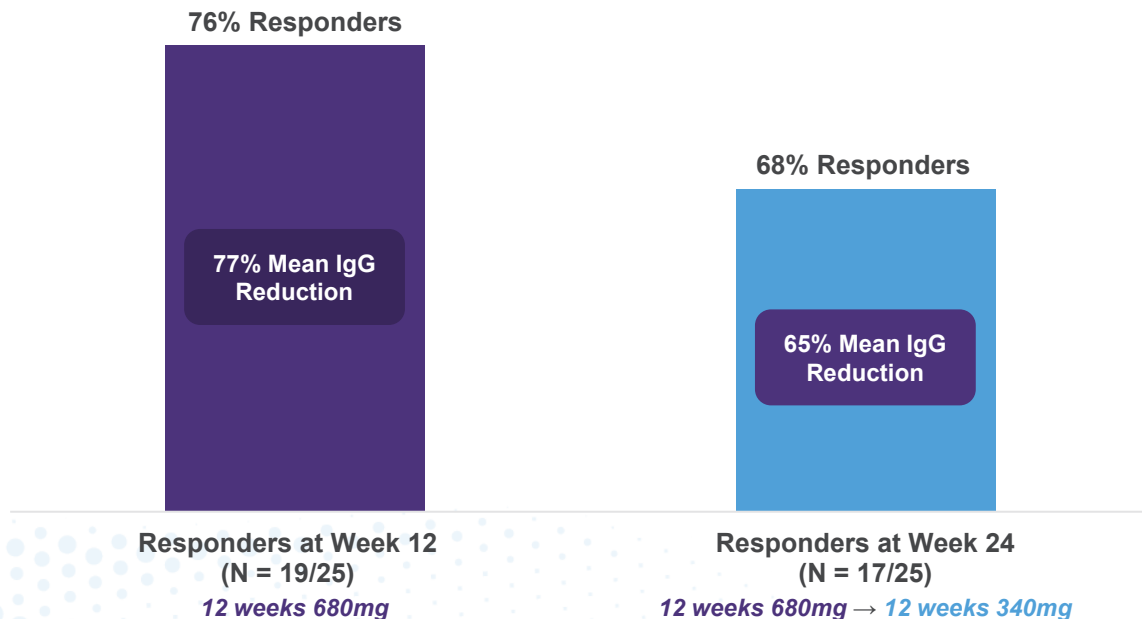
The trial population was representative of an uncontrolled population, despite ATD use

	Batoclimab SC QW
	N = 25
	Mean unless otherwise noted
Age, years	47.4
Sex, % female	80%
Race, % white	92%
BMI, kg/m <sup>2</sup>	25.4
Median time since diagnosis, months	15.7
Baseline FT3, pmol/L (ULN=6.8 pmol/L)	15.4
Baseline FT4, pmol/L (ULN=22 pmol/L)	33.9
Baseline TRAb, IU/L (ULN=1.75 IU/L)	18.0

# Batoclimab demonstrated potentially transformational results in ATD uncontrolled patients with greater response driven by higher IgG lowering



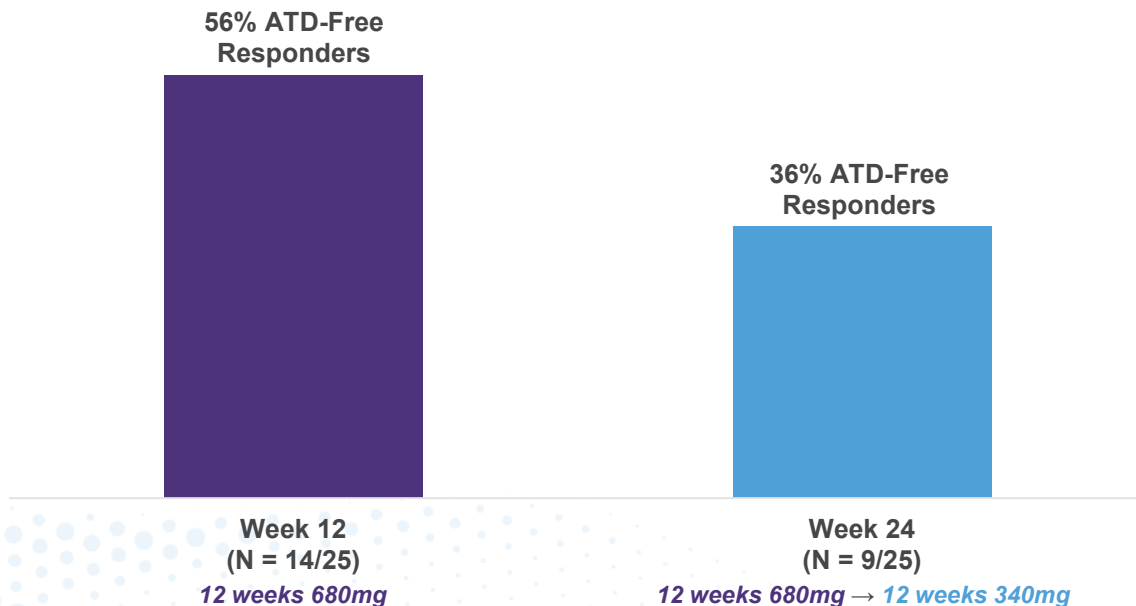
% of participants who achieve normal T3 and T4 or have T3 or T4 below LLN, without increase in ATD





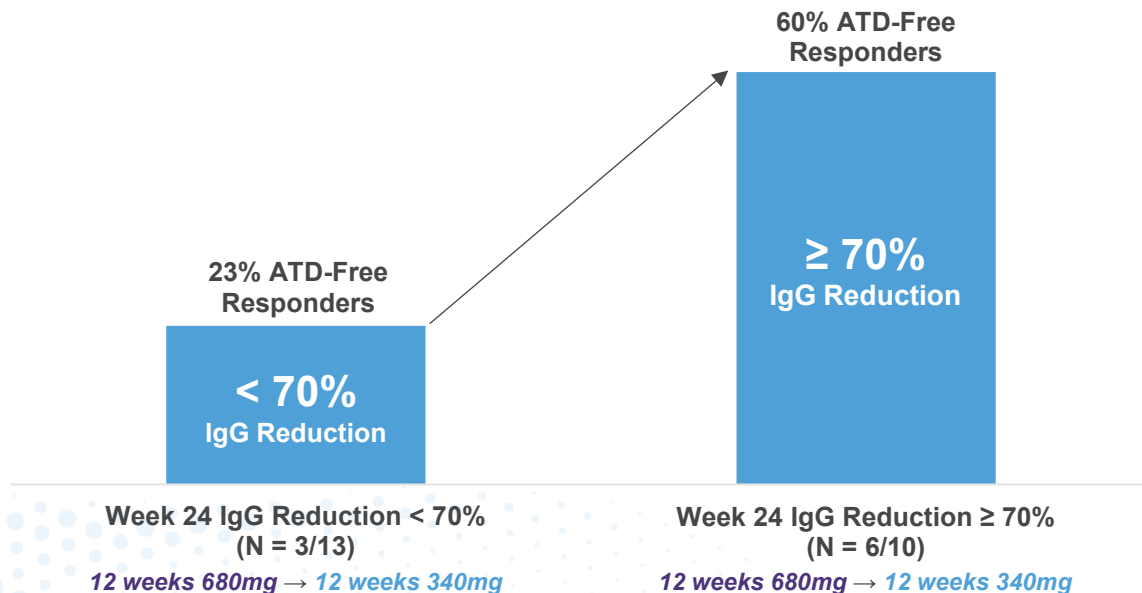
>50% of patients receiving high-dose batoclimab not only achieved normal T3 and T4 levels but also ceased ATD entirely by 12 weeks

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

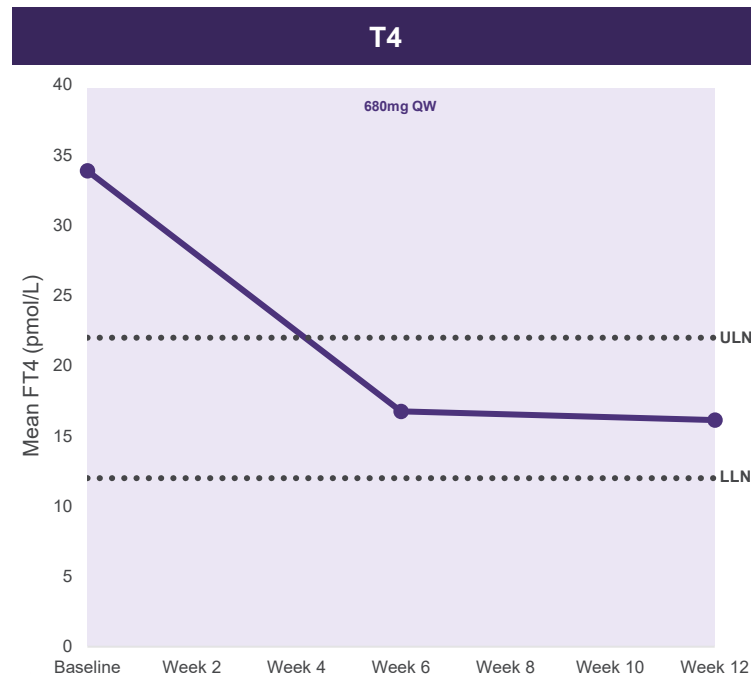
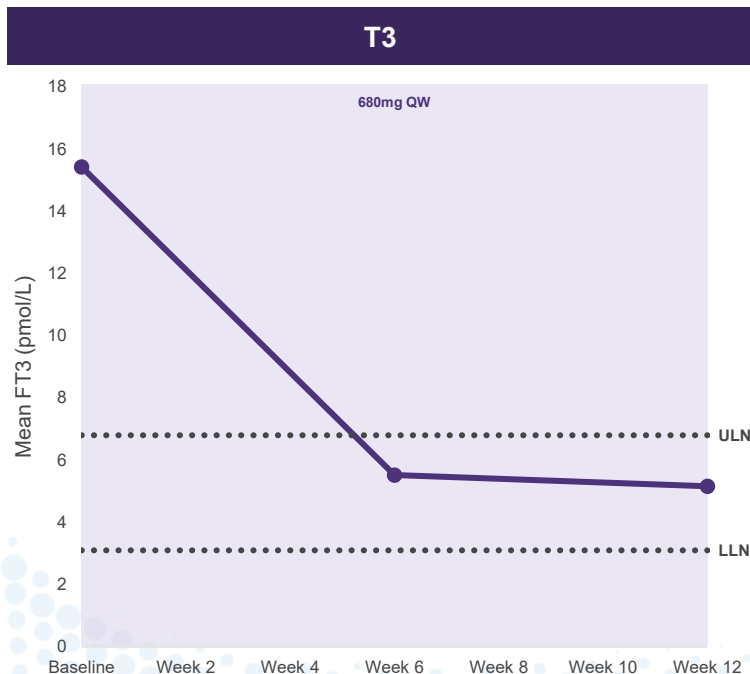
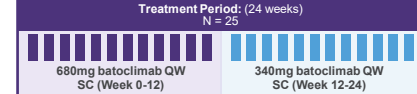


Deeper IgG reduction at 24 weeks was associated with a meaningfully higher ATD-free responder rate

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



# High-dose batoclimab drives rapid normalization of T3 and T4 and ATD tapering



## Batoclimab was well-tolerated with no new safety signals identified

	Batoclimab SC QW
	N = 25 n (%)
Patients with any TEAE	25 (100)
Patients with any Serious TEAE	1 (4)
Patients with any Treatment-related Serious TEAE	0
Patients with any Treatment-related TEAE Leading to Study Drug Withdrawal	0
Patients with any TEAE Leading to Study Drug Dose Reduction or Interruption <sup>1</sup>	1 (4)
Patients with any TEAE Leading to Study Discontinuation <sup>2</sup>	1 (4)
Deaths	0

**All treatment-related TEAEs were mild or moderate with no serious treatment-related TEAEs reported**

# IMVT-1402 Path Forward in Graves' Disease

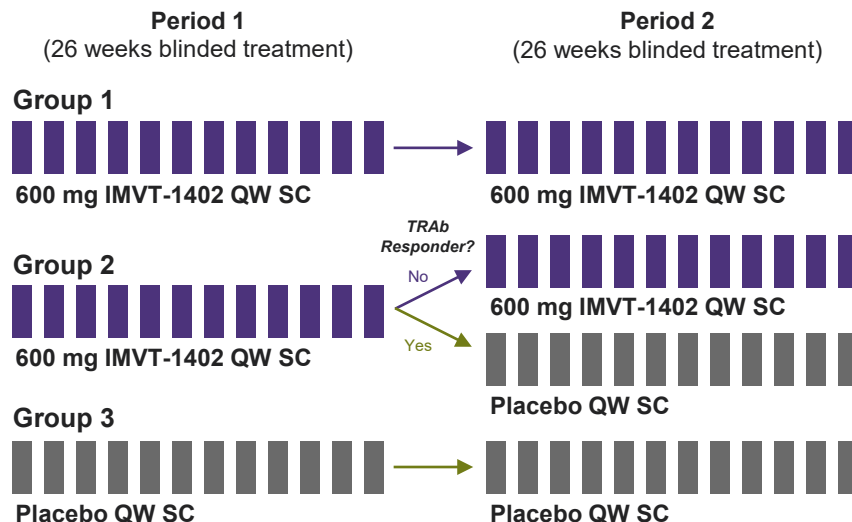
# First pivotal trial for IMVT-1402 in Graves' Disease

## Inclusion<sup>a</sup>

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

Randomization (1:1:1)

## Treatment Period: 52 weeks N = 240



Off-Treatment Follow-up (52 weeks)

## 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

# Market Opportunity in Graves' Disease



## Multiple market-sizing analyses confirm high unmet need in Graves' Disease with at least 25-30% of patients relapsed, uncontrolled, or intolerant to ATDs

1

Conservative Inovalon claims analysis yields ~880K prevalent Graves' Disease patients

2

Conservative Inovalon claims analysis yields ~65K incident Graves' Disease 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

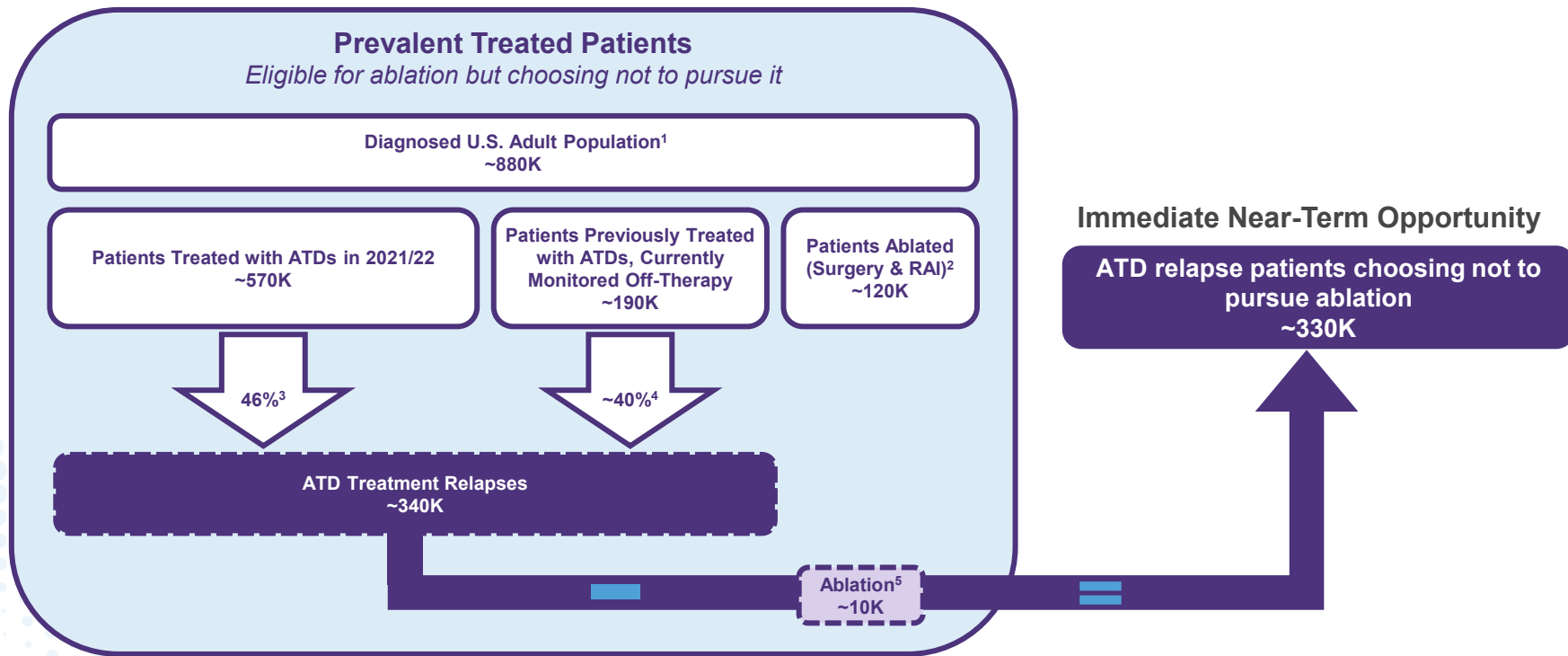
4

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

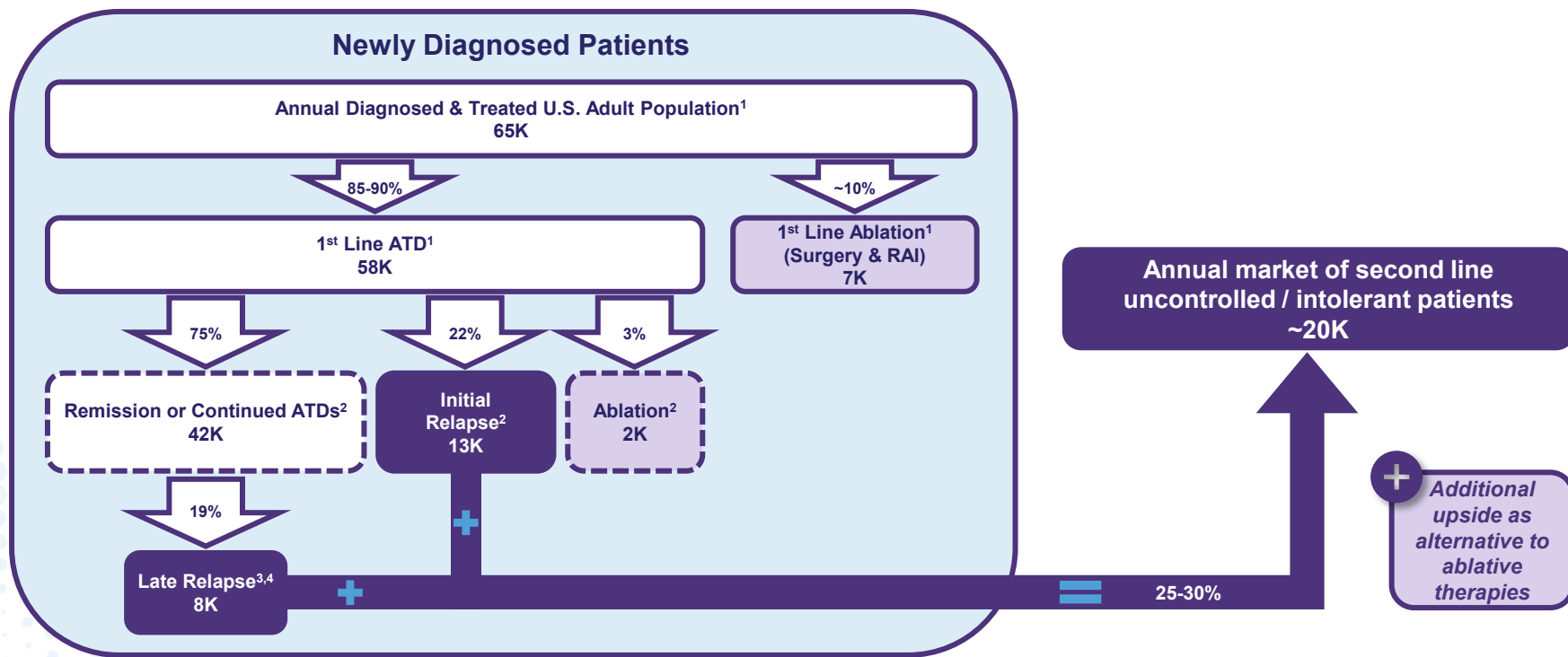
5

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

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



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



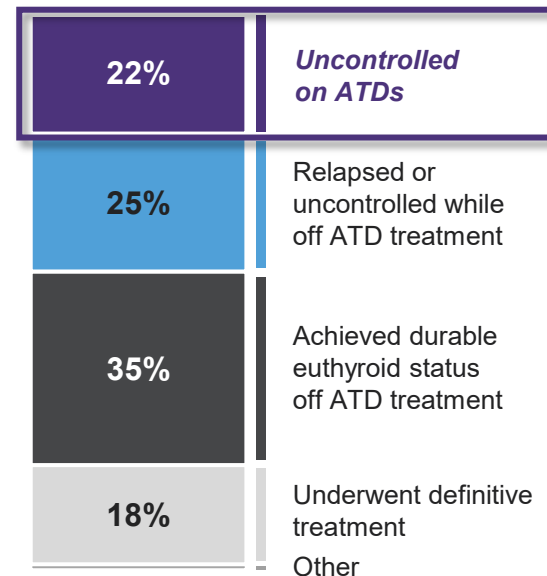
## Analysis #3: Surveyed endocrinologists indicate that ~25% of their patients remain uncontrolled on ATDs

### 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 ≥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)



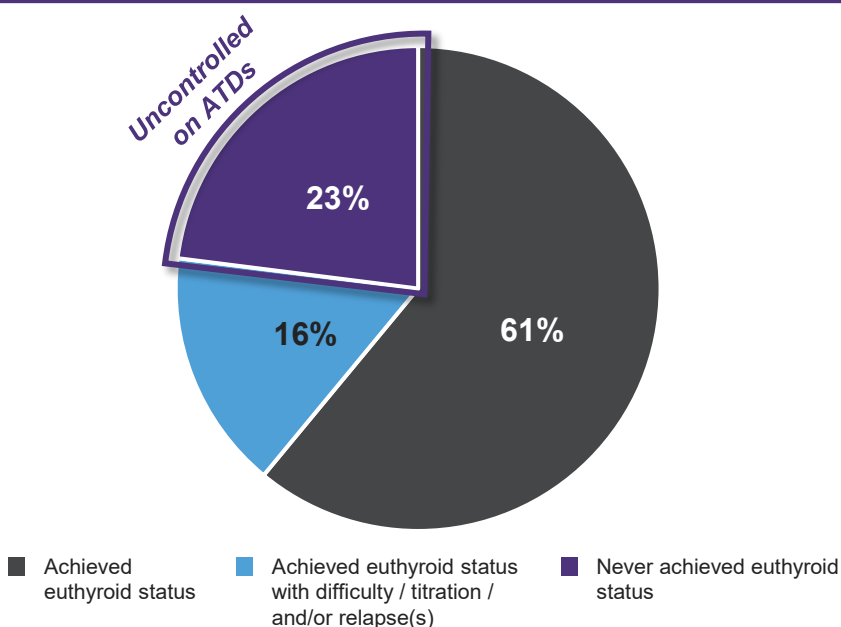
## Analysis #4: Real-world in-depth chart review of 1,000+ patient records from 140 endocrinologists indicates ~25% have never achieved euthyroid status on ATDs

### 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

### Characterization of Thyroid Control with ATD Therapy

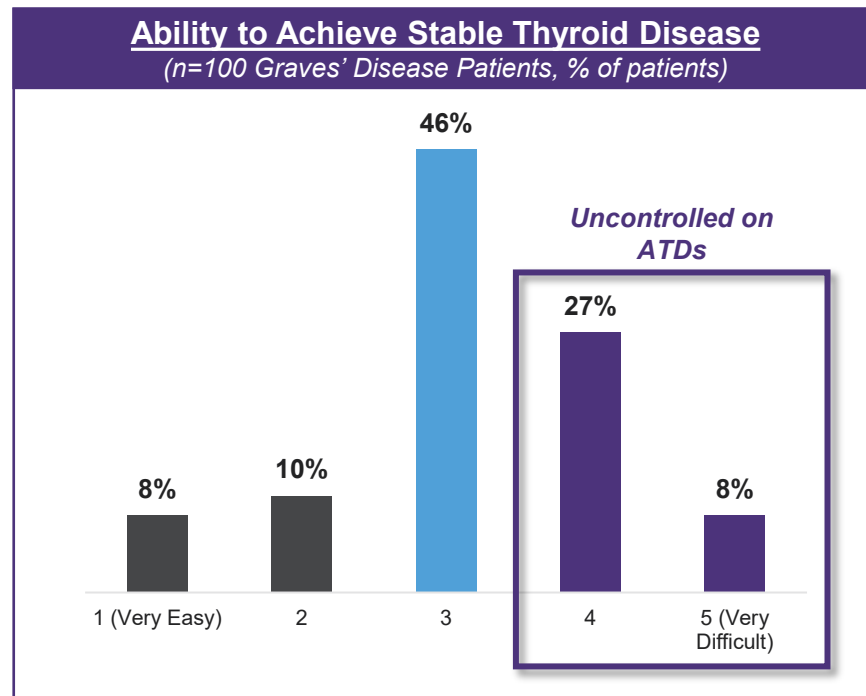
(n=998 Patient Charts\*, % of patients)



## 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

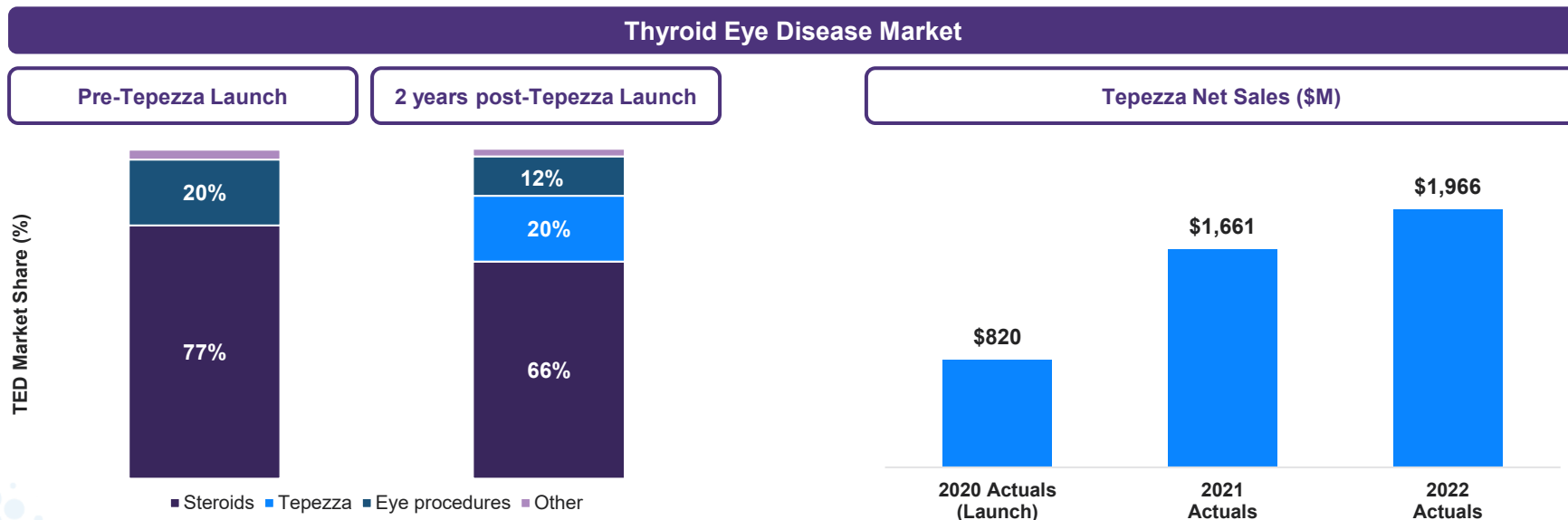
1. A double-blinded online survey was conducted with N=100 patients who reported being diagnosed by a healthcare provider with Graves' Disease
2. Screening criteria included patients who were diagnosed in the past 3 years OR diagnosed in the past 5 years with a recurrence in the past year
3. Excluded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



# Commercial Considerations



# Tepezza®'s fast ramp in a TED market dominated by generics and procedures illustrates the potential of IMVT-1402 in Graves' Disease



- In January 2020, Tepezza became the first approved targeted therapy labeled for treatment of TED
- Within two years post-launch, Tepezza saw rapid adoption, taking a 20% market share and generating ~\$2B net sales in a market dominated by generic steroids and procedures, despite risk of hearing loss

# Conclusion

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

**01**

High dose batoclimab rapidly achieved a 76% response rate in patients uncontrolled on ATDs, meaningfully exceeding 50% response rate bar

**02**

High dose batoclimab rapidly achieved a 56% ATD-free response rate in patients uncontrolled on ATDs, meaningfully exceeding 30% ATD-free response rate bar

**03**

Strong correlation observed between degree of IgG lowering and clinical outcomes yields potential best-in-class and first-in-class opportunity for IMVT-1402

**04**

IMVT-1402 Graves' Disease IND cleared, enabling straight to pivotal transition

**05**

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