UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): March 30, 2020

Immunovant, Inc.
(Exact name of Registrant as Specified in Its Charter)

Delaware	**001-38906**	**83-2771572**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**
320 West 37th Street, New York, NY		**10018**
(Address of Principal Executive Offices)		**(Zip Code)**

Registrant's Telephone Number, Including Area Code: (917) 580-3099

Not Applicable
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.0001 par value per share	**IMVT**	**The Nasdaq Stock Market LLC**
Warrants to receive one half of one share of Common Stock	**IMVTW**	**The Nasdaq Stock Market LLC**
Units, each consisting of one share of Common Stock and one Warrant to receive one half of one share of Common Stock	**IMVTU**	**The Nasdaq Stock Market LLC**

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☒

Item 7.01 Regulation FD Disclosure.

On March 30, 2020, Immunovant, Inc. ("Immunovant") issued a press release and held a conference call announcinginitial results from its ASCEND GO-1 trial. Immunovant also updated its corporate presentation, which has been posted on its website and will be used for presentations. A copy of the press release and presentation are attached hereto as Exhibits 99.1 and 99.2, respectively, and are incorporated herein by reference.

The information furnished under this Item 7.01, including Exhibits 99.1 and 99.2, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or subject to the liabilities of that section. The information shall not be deemed incorporated by reference into any other filing with the Securities and Exchange Commission made by Immunovant, regardless of any general incorporation language in such filing.

Item 8.01 Other Events.

On March 30, 2020, Immunovant issued a press release announcinginitial results from its ASCEND GO-1 trial.

The ASCEND GO-1 trial is an open label single-arm Phase 2a clinical trial of IMVT-1401 in Canada in patients with moderate-to-severe active thyroid eye disease ("TED", formerly referred to as Graves' ophthalmopathy). Seven patients were dosed weekly with subcutaneous injections for six weeks. Patients received a 680 mg dose for the first two administrations of study followed by a 340 mg dose for the final four administrations. All patients have completed the six-week treatment phase of the trial, and have entered the 12-week follow-up phase.

Mean reduction in total IgG levels from baseline to end of treatment was 65%. As evaluated at the end of treatment, 4/7 patients (57%) improved by ≥ 2 points on the Clinical Activity Score ("CAS"). Clinicians use CAS to measure disease activity in TED patients and is based on seven parameters, including spontaneous pain behind the eye, pain with eye movement, redness of the eyelids, redness of the conjunctiva, swelling of the eyelids, swelling of the caruncle and swelling of the conjunctiva. A score is calculated based on the number of parameters that are positive with scores of four or above considered to be cases of active disease. Of six patients with baseline diplopia, 4/6 patients (67%) demonstrated improvement in diplopia. 3/7 patients (43%) were proptosis responders, defined as the percentage of patients with a greater than or equal to 2 mm reduction in proptosis in study eye without deterioration in fellow eye. The safety and tolerability profile observed was consistent with the prior Phase 1 trial of IMVT-1401 in 99 healthy volunteers. All adverse events were mild or moderate and there were no headaches reported.

In addition, Immunovant has updated its anticipated clinical development timelines, in light of the significant uncertainty regarding the impact of the recent COVID-19 pandemic. Immunovant anticipates reporting top-line results from its ASCEND-MG trial, a Phase 2a clinical trial of IMVT-1401 in patients with myasthenia gravis, in the third quarter of calendar year 2020. Immunovant currently remains on track to report initial results from its Phase 2a trial of IMVT-1401 in patients with warm autoimmune hemolytic anemia by the end of calendar year 2020. Immunovant currently plans to report top-line results from its ASCEND GO-2 trial, a Phase 2b clinical trial of IMVT-1401 for TED in the United States, Canada and Europe, in the first half of calendar year 2021.

This Current Report on Form 8-K contains forward-looking statements for the purposes of the safe harbor provisions under The Private Securities Litigation Reform Act of 1995 and other federal securities laws. The use of words such as "may," "might," "will," "would," "should," "expect," "believe," "estimate," and other similar expressions are intended to identify forward-looking statements. For example, all statements Immunovant makes regarding the timing, progress and reporting of results of its clinical programs are forward-looking. All forward-looking statements are based on estimates and assumptions by Immunovant's management that, although Immunovant believes to be reasonable, are inherently uncertain. All forward-looking statements are subject to risks and uncertainties that may cause actual results to differ materially from those that Immunovant expected. Such risks and uncertainties include, among others, the availability of data from clinical trials; the continued development of Immunovant's product candidates; Immunovant's scientific approach and general development progress; and the potential impact of the recent COVID-19 pandemic on Immunovant's clinical development plans and timelines. These statements are also subject to a number of material risks and uncertainties that are described under the section titled "Risk Factors" in Immunovant's Form 10-Q filed with the Securities and Exchange Commission (SEC) on February 14, 2020, and Immunovant's subsequent filings with the SEC. Any forward-looking statement speaks only as of the date on which it was made. Immunovant undertakes no obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future events or otherwise.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	
99.1	Press release dated March 30, 2020.
99.2	Presentation dated March 30, 2020.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: March 30, 2020

IMMUNOVANT, INC.

By: /s/ Peter Salzmann, M.D.
Peter Salzmann, M.D.
Chief Executive Officer

EXHIBIT 99.1

Immunovant Announces Positive Clinical Results from Ongoing Phase 2a Proof-of-Concept Study of IMVT-1401, A Novel Investigational Anti-FcRn Antibody Delivered by Subcutaneous Injection, in Thyroid Eye Disease

Company to Host Conference Call on March 30, 2020 at 8:30am EDT

- 65% mean reduction in total IgG was observed from baseline to end of treatment, with a pharmacodynamic (PD) response nearly identical to modeled predictions for dosing regimen tested in trial
- IMVT-1401 was safe and generally well-tolerated with no serious adverse events (SAEs), no withdrawals due to adverse events (AEs), and no headaches
- 4/7 patients (57 %) improved by ≥ 2 points on the Clinical Activity Score (CAS) and 3/7 patients (43%) achieved a proptosis response
- Results establish first proof of concept for an anti-FcRn antibody in Thyroid Eye Disease

NEW YORK, March 30, 2020 /PRNewswire/Immunovant, Inc. (NASDAQ: IMVT), a clinical-stage biopharmaceutical company focused on enabling normal lives for patients with autoimmune disease, today announced initial results from the treatment phase of its ongoing Phase 2a study of IMVT-1401 (ASCEND GO-1) in patients with Thyroid Eye Disease (TED), also known as Graves' ophthalmopathy.

The multi-center, open-label, single-arm clinical trial evaluated two weekly 680mg subcutaneous doses of IMVT-1401 followed by four weekly 340mg subcutaneous doses of IMVT-1401 in seven adult patients with moderate-to-severe active TED. A planned eighth patient enrolled in ASCEND GO-2 instead of ASCEND GO-1. All patients in the trial have completed IMVT-1401 treatment and have entered the follow-up phase of the trial. Mean reduction in total IgG levels from baseline to end of treatment was 65%. As evaluated at the end of treatment, 4/7 patients (57%) improved by ≥ 2 points on the Clinical Activity Score (CAS). Of six patients with baseline diplopia, 4/6 patients (67%) demonstrated improvement in diplopia. 3/7 patients (43%) were proptosis responders. The safety and tolerability profile observed was consistent with the prior Phase 1 trial of IMVT-1401 in 99 healthy volunteers. All AEs were mild or moderate and there were no headaches reported.

"We are very excited by the initial results of this trial," said Pete Salzmann, M.D., Chief Executive Officer of Immunovant. "These results provide an early proof-of-concept of the potential for IMVT-1401 to ultimately become a safe and effective treatment for patients suffering from Thyroid Eye Disease. Importantly, IMVT-1401 was delivered by subcutaneous injection, opening the possibility of at-home treatment rather than infusion center-based treatment, for patients with Thyroid Eye Disease. We look forward to reporting the study's full results, including detailed lab observations and 12 weeks of follow up data, at an upcoming medical meeting."

"I am encouraged by IMVT-1401's early results showing promising efficacy and safety with a subcutaneous route of administration. If validated by additional data and approved by regulatory agencies, this drug could really benefit our patients suffering from active Thyroid Eye Disease," said Peter Dolman, M.D., Oculoplastics Division Head, Department of Ophthalmology and Visual Sciences at the University of British Columbia. Dr. Dolman serves as principal investigator for the ASCEND GO-1 trial. "Even in this small study population, the response across multiple measures is notable," he added.

Immunovant will host a conference call on Monday, March 30 at 8:30am EDT. Following prepared remarks, the call will include a live question-and-answer session for the investment community. To access the webcast, please visit Immunovant's website at www.immunovant.com. Participants may also dial in using the numbers provided below:

Toll Free: 1-877-407-9039
Toll/International: 1-201-689-8470

An archived webcast recording will be available on the Immunovant's website for a limited time.

About Immunovant, Inc.
Immunovant, Inc is a clinical-stage biopharmaceutical company focused on enabling normal lives for patients with autoimmune diseases. Immunovant is developing IMVT-1401, a novel, fully human anti-FcRn monoclonal antibody, as a subcutaneous injection for the treatment of autoimmune diseases mediated by pathogenic IgG antibodies.

Forward-Looking Statements

This press release contains forward-looking statements for the purposes of the safe harbor provisions under The Private Securities Litigation Reform Act of 1995 and other federal securities laws. The use of words such as "may," "might," "will," "would," "should," "expect," "believe," "estimate," and other similar expressions are intended to identify forward-looking statements. For example, all statements Immunovant makes regarding Immunovant's progress towards its vision of enabling normal lives for patients with autoimmune diseases; the timing, progress and reporting of results of its clinical programs; and the potential of IMVT-1401 to become a treatment option for patients suffering from TED are forward-looking. All forward-looking statements are based on estimates and assumptions by Immunovant's management that, although Immunovant believes to be reasonable, are inherently uncertain. All forward-looking statements are subject to risks and uncertainties that may cause actual results to differ materially from those that Immunovant expected. Such risks and uncertainties include, among others, initial results or other preliminary analyses or results of early clinical trials may not be predictive final trial results or of the results of later clinical trials; the availability of data from clinical trials; the expectations for regulatory submissions and approvals; the continued development of Immunovant's product candidates; Immunovant's scientific approach and general development progress; the availability and commercial potential of Immunovant's product candidates including the size of potentially addressable markets and degree of market acceptance; and the potential impact of the recent COVID-19 pandemic on Immunovant's clinical development plans and timelines. These statements are also subject to a number of material risks and uncertainties that are described under the section titled "Risk Factors" in Immunovant's Form 10-Q filed with the Securities and Exchange Commission (SEC) on February 14, 2020, and Immunovant's subsequent filings with the SEC. Any forward-looking statement speaks only as of the date on which it was made. Immunovant undertakes no obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future events or otherwise.

Contact:
John Strumbos, PhD, MBA
Vice President, Finance
Immunovant, Inc.
info@immunovant.com

EXHIBIT 99.2

Corporate Overview

April 2020

This presentation contains forward-looking statements for the purposes of the safe harbor provisions under The Private Securities Litigation Reform Act of 1995 and other federal securities laws. The use of words such as "may," "might," "will," "expect," "plan," "anticipate," "believe," "estimate," "intend," "future," "potential," "continue" and other similar expressions (as well as other words or expressions referencing future events, conditions, or circumstances) are intended to identify forward-looking statements. For example, statements Immunovant makes regarding our business strategy, our plans to develop and commercialize our product candidates, the potential safety and efficacy of our product candidates, our expectations regarding timing, the design and results of clinical trials of our product candidates, our plans and expected timing with respect to regulatory filings and approvals, the size and growth potential of the markets for our product candidates, and our ability to serve those markets, and our plans and expected timing with respect to regulatory filings and approvals are forward-looking. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. The product candidates that Immunovant develops may not progress through clinical development or receive required regulatory approvals within expected timelines or at all. In addition, promising interim results or other preliminary analyses do not in any way ensure that later or final results in a clinical trial or in related or similar clinical trials will replicate those interim results. In addition, clinical trials may not confirm any safety, potency or other product characteristics described or assumed in this press release. In addition, such product candidates may not be beneficial to patients, or even if approved by regulatory authorities, successfully commercialized. The failure to meet expectations with respect to any of the foregoing matters may have a negative effect on Immunovant's stock price. All forward-looking statements are based on estimates and assumptions by Immunovant's management that, although Immunovant believes to be reasonable, are inherently uncertain. All forward-looking statements are subject to risks and uncertainties that may cause actual results to differ materially from those that Immunovant expected. Such risks and uncertainties include, among others, the initiation and conduct of preclinical studies and clinical trials; the availability of data from clinical trials; the expectations for regulatory submissions and approvals; the continued development of Immunovant's product candidates and platforms; Immunovant's scientific approach and general development progress; Immunovant's ability to maintain or scale up manufacturing processes and transition such processes; the availability and commercial potential of Immunovant's product candidates including the size of potentially addressable markets and degree of market acceptance; and the potential impact of the recent COVID-19 pandemic on Immunovant's clinical development plans and timelines. These statements are also subject to a number of material risks and uncertainties that are described in Immunovant's periodic and other reports filed with the Securities and Exchange Commission (SEC), including the risk factors detailed in Immunovant's most recent Quarterly Report on Form 10-Q filed with the SEC on February 14, 2020. Any forward-looking statement speaks only as of the date on which it was made. Immunovant undertakes no obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future events or otherwise.

Immunovant

Our vision: Normal lives for patients with autoimmune diseases

Our asset: IMVT-1401, a novel, fully human monoclonal antibody inhibiting FcRn-mediated recycling of IgG

Our strategy for IMVT-1401:

- **Be best-in-class** in target indications where anti-FcRn mechanism has already established clinical proof-of-concept
- **Be first** to study FcRn inhibition in target indications with clear biologic rationale and no known in-class competition

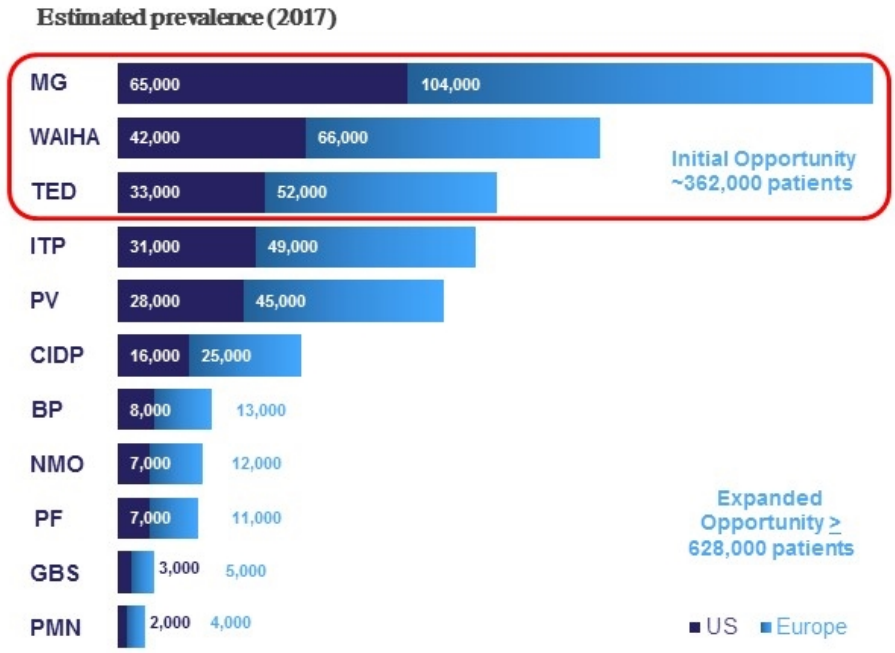
Our near-term value drivers: Four anticipated data readouts over the next 20 months

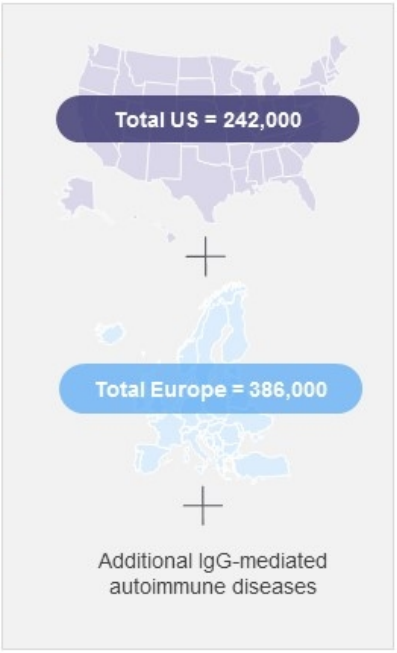
IMVT-1401: A pipeline in a product

Target Indication	H1:20	H2:20	H1:21	Anticipated Milestones
Myasthenia Gravis (MG)	ASCEND MG			Phase 2a topline results expected in Q3 2020
Thyroid Eye Disease (TED)	ASCEND GO-2			Phase 2b topline results expected in H1 2021
Warm Autoimmune Hemolytic Anemia (WAIHA)	ASCEND WAIHA			Phase 2a initial results expected by YE 2020

Attractive market in autoimmune diseases mediated by excess IgG

Inhibiting FcRn lowers IgG levels, suggestive of utility in these autoimmune disorders





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Note: List of diseases is illustrative only and does not represent our targeted indications (for more information, see Immunovant's most recent Quarterly Report on Form 10-Q filed with the SEC on February 14, 2020). MG: Myasthenia Gravis; WAIHA: Warm Autoimmune Hemolytic Anemia; TED: Thyroid Eye Disease; ITP: Idiopathic Thrombocytopenic Purpura; PV: Pemphigus Vulgaris; CIDP: Chronic Inflammatory Demyelinating Polyneuropathy; BP: Bullous Pemphigoid; NMO: Neuromyelitis Optica; PF: Pemphigus Foliaceus; GBS: Guillain-Barré Syndrome; PMN: PLA2R+ Membranous Nephropathy

IMVT-1401

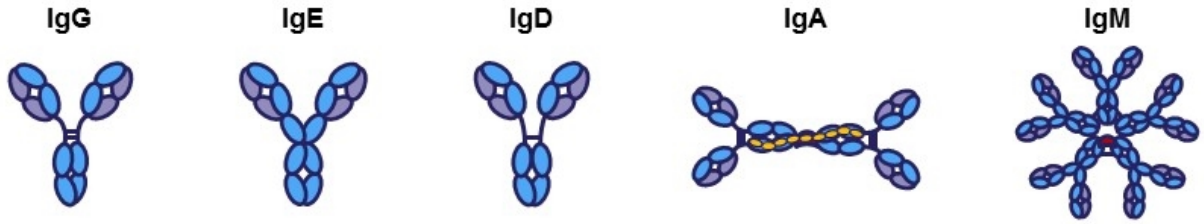
IgG antibodies implicated in certain autoimmune diseases

Antibodies in healthy individuals

- Antibodies play an important role in immune defense against pathogens[1]
  - Clearing bacteria, viruses, and other harmful organisms and substances
  - Eliciting an immune response that leads to inflammation
- IgG antibody subclass accounts for ~75% of antibodies in the plasma of healthy people[1]

Antibodies in autoimmune disease

- In many autoimmune diseases, IgG antibodies develop that can recognize and bind to normal tissues[2]
  - Targets may include cell-surface receptors or circulating proteins
  - Result is a harmful immune response that damages critical tissues and organs
- Predisposing factors may include genetic susceptibility, environmental triggers, and factors not yet known[3]



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1. Leusen J.H.W. The Role of IgG in Immune Responses. Molecular and Cellular Mechanisms of Antibody Activity, 2013
2. Isabela S., et al. The role of autoantibodies in health and disease. Romanian Journal of Morphology and Embryology, 2016
3. Mariani S.M. Genes and autoimmune diseases - a complex inheritance. MedGenMed, 2004

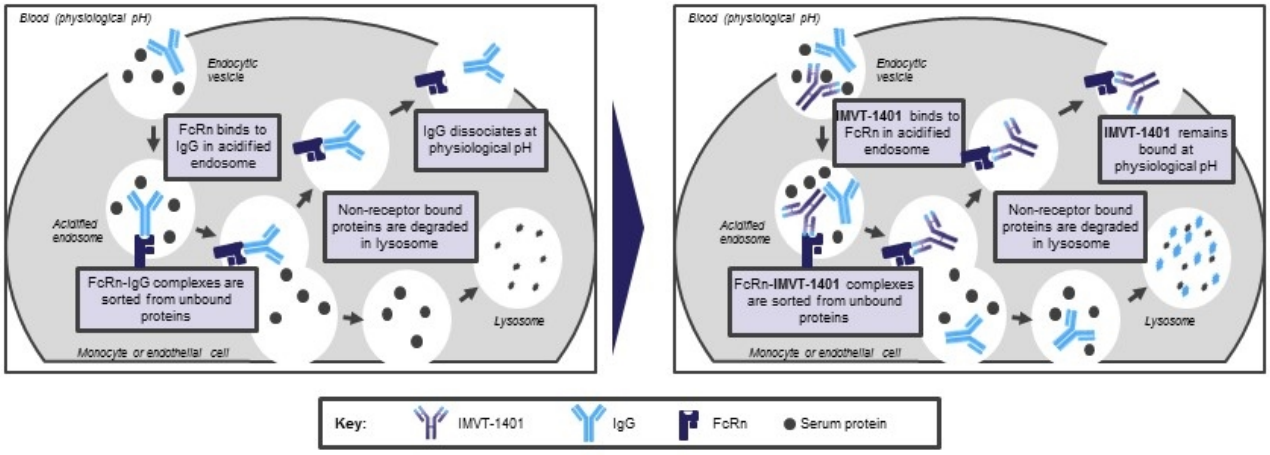
IMVT-1401 promotes IgG degradation[1]

FcRn prolongs the half-life of IgG[2]

- **FcRn intercepts IgG**, which would otherwise be degraded in lysosomes
- The FcRn–IgG complex is then recycled to the cell surface and free IgG is **released back into circulation**

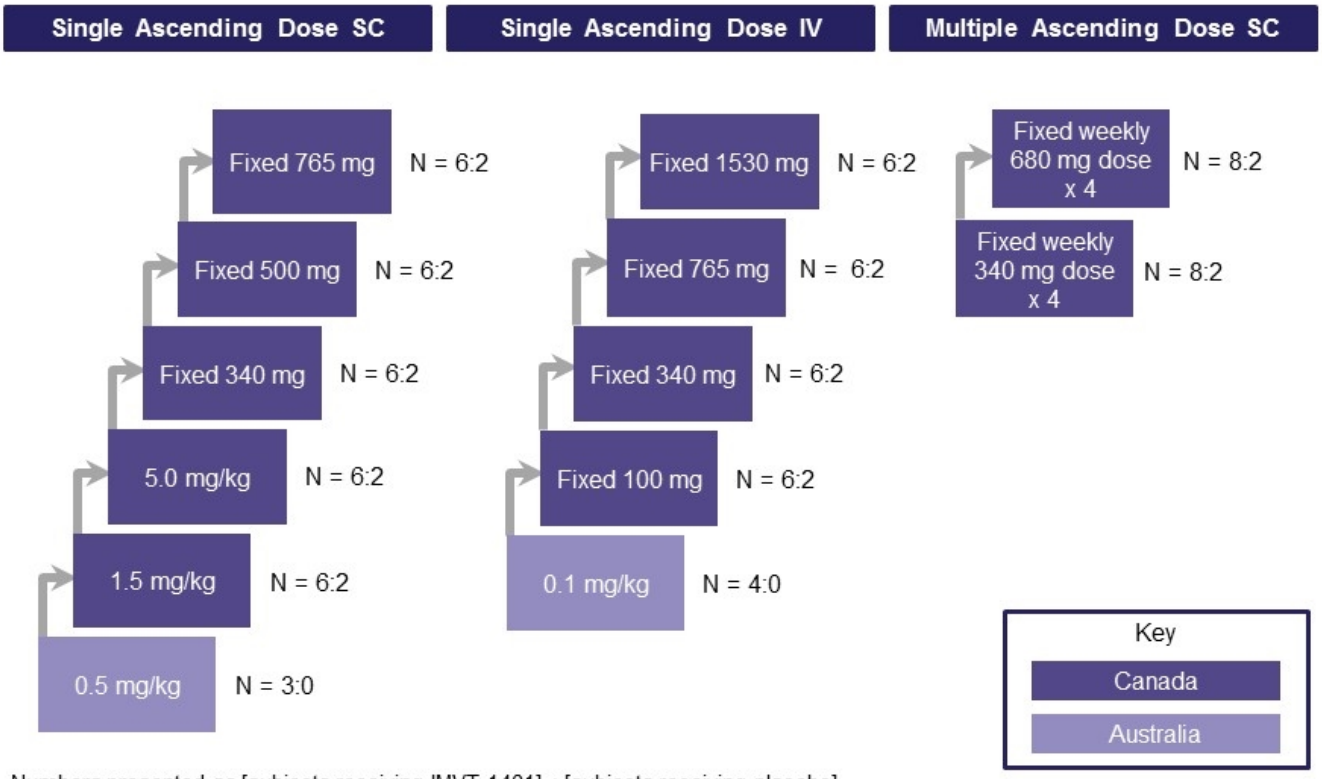
Inhibiting FcRn promotes IgG degradation[2]

- **IMVT-1401 binds to FcRn**, thereby preventing it from recycling IgG antibodies back to circulation
- As a result, IgG is **increasingly delivered to lysosomes** for degradation



1. Collins J. and Jones L., et al. IMVT-1401 (RVT-1401), A Novel Anti-FcRn Monoclonal Antibody, Was Well Tolerated in Healthy Subjects and Reduced Serum IgG Following Subcutaneous or Intravenous Administration. Presented at American Academy of Neurology Annual Conference, 2019. Program # P5.2-079
2. Derry C., et al. FcRn: the neonatal Fc receptor comes of age. Nature Reviews Immunology, 2007

Phase 1 SAD/MAD study design



Numbers presented as [subjects receiving IMVT-1401] : [subjects receiving placebo]

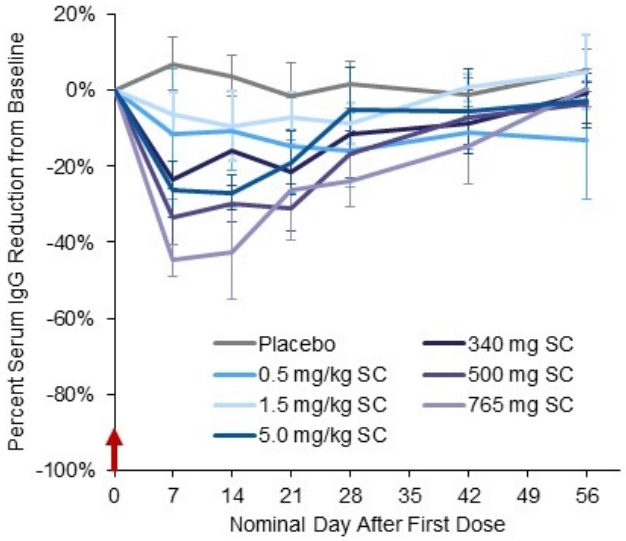
IMVT-1401 produced clinically meaningful IgG reductions in Phase 1 study

Preliminary results from Phase 1 SAD/MAD cohorts

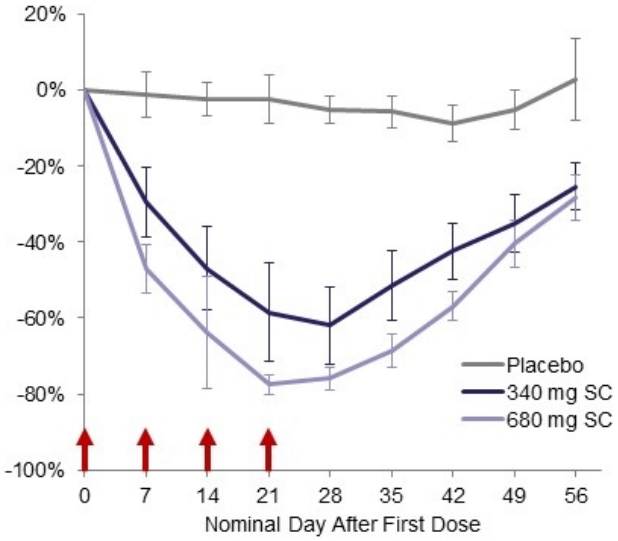
Single-dose administration produced dose-dependent IgG reductions

Repeat dosing at 680 mg SC resulted in a 78% IgG reduction without the need for IV induction

Mean total IgG reduction after single dose in healthy volunteers

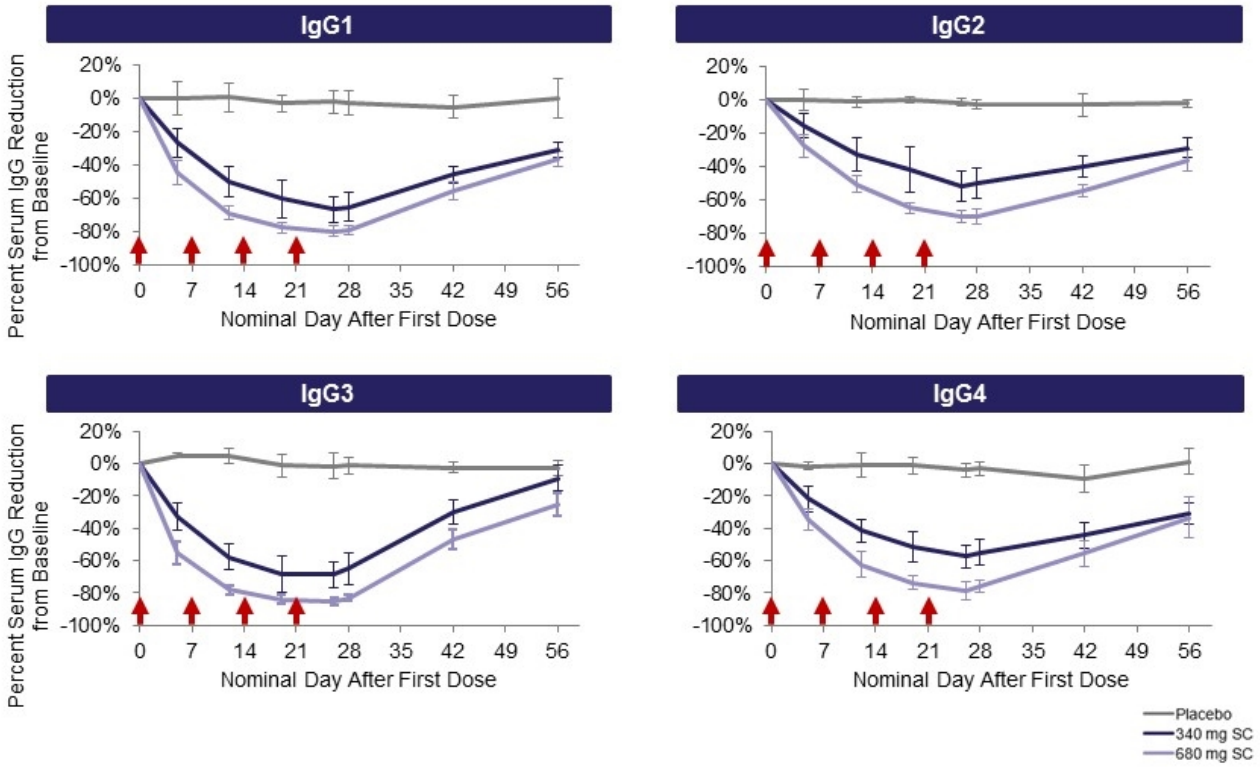


Mean total IgG reduction after 4 weekly doses in healthy volunteers



IMVT-1401 reduced levels of all four IgG subtypes

Preliminary results from Phase 1 MAD cohorts



Generally well-tolerated in Phase 1 study

Preliminary results from Phase 1 SAD/MAD cohorts

- 99 subjects dosed to date through SAD and MAD portions of Phase 1
  - IMVT-1401: 77 subjects
  - Placebo: 22 subjects
- Most common AEs were mild erythema and swelling at injection site
  - Injection site reactions were not dose or frequency related
  - Occurred at similar incidence for drug and placebo treated subjects
- No headaches observed in 680 mg SC MAD cohort
- Albumin changes:
  - Dose-dependent, reversible, and asymptomatic albumin reductions observed
  - At day 28, mean albumin levels were 37.5 g/L in the 340 mg cohort, and 32.4 g/L in 680 mg cohort
- 2 SAEs observed in two separate SAD cohorts, both ruled unrelated to treatment by study investigator (cancer, appendicitis)
- Treatment-emergent ADA confirmed in 8% of IMVT-1401-treated subjects and 6% of placebo-treated subjects
  - No subject in MAD cohorts has developed a confirmed ADA response to IMVT-1401

Adverse events reported in Phase 1

Preliminary results from Phase 1 SAD/MAD cohorts

	Single-Ascending Dose													Multiple-Ascending Dose		
	Intravenous Infusion						Subcutaneous Injection							Subcutaneous Injection		
	0.1 mg/kg	100 mg	340 mg	765 mg	1530 mg	Placebo	0.5 mg/kg	1.5 mg/kg	5 mg/kg	340 mg	500 mg	765 mg	Placebo	340 mg	680 mg	Placebo
	n=4	n=6	n=6	n=6	n=6	n=8	n=3	n=6	n=6	n=6	n=6	n=6	n=10	n=8	n=8	n=4
MedDRA Preferred Term																
Abdominal pain									1					1		
Abdominal pain upper													2	1		
Abnormal sensation in eye					1					1						
Back pain						2					1		1	1		
Constipation						1								1		
Cough											1		2			
Diarrhea														2		
Dizziness						1							1			1
Dry skin													1		1	
Erythema							1								1	
Fatigue	1			1	1	1	1			1			1			
Headache	1	1	1	1	1			1	1	4	1		1	2		
Injection site erythema									5	1	5	6	7	8	7	4
Injection site pain											1			2		1
Injection site swelling									3		2	4	3	7	6	2
Insomnia									1					4		
Myalgia														1	1	
Nasal congestion									1		1		1	1		
Nausea									1	1			1		1	1
Ocular hyperaemia															2	
Oropharyngeal pain	1			1	2				1		1		1	2		
Pain in extremity						1							1			
Procedural complication								1		1						
Procedural dizziness					2						1					
Pyrexia			1	1					1							
Rash					2				2				2		1	
Rhinorrhea									1				2			
Sinusitis			1										1			
Somnolence		1							1							
Upper respiratory tract infection	1	1	1				3		1	1				1		
Vision blurred					1					1						

IMVT-1401 has been given as a SC injection

Subcutaneous Injection

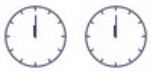
<10 seconds

Subcutaneous Infusion

30-60 minutes

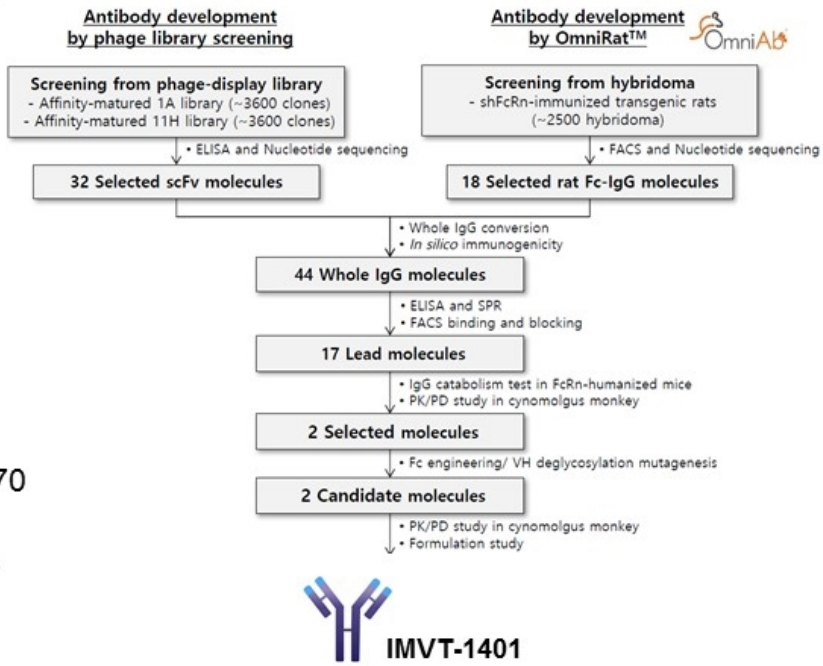
Intravenous Infusion

Potentially Hours



IMVT-1401 designed from inception to be a potentially class-leading SC injection

- Fully human monoclonal antibody
- Generated from Ligand/OMT's OmniAb transgenic rat platform
  - >400 antibody campaigns ongoing that use OmniAb technology[1]
  - 12 clinical-stage antibodies in development[1]
- IgG1 backbone Fc-engineered to reduce effector function
- Optimized for SC delivery
  - Current clinic formulation is 170 mg/mL
  - Delivered by 27-gauge needle



1. Ligand 2019 Analyst Day presentation, presented March 12, 2019

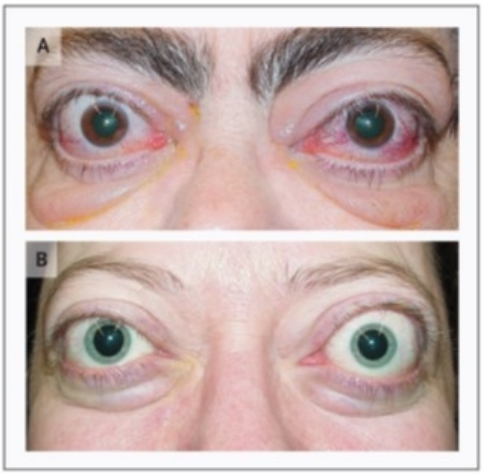
IMVT-1401 has the potential to deliver a class-leading profile

IMVT-1401 attribute	Potential patient benefit
Clinically meaningful IgG reductions	• 680 mg SC weekly: 78% reduction after four doses • 340 mg SC weekly: 63% reduction after four doses
SC injection	• Fast and minimally invasive
Simple dosing schedule	• No requirement for IV induction doses or lengthy SC infusions • Provides option for at-home administration • Fixed dosing, vs. weight-based, reduces potential for dose miscalculations
Fully human antibody	• Low risk of immunogenicity
Fc-engineered to reduce effector function	• Low potential for unintended immune responses

IMVT-1401 for Thyroid Eye Disease

Thyroid Eye Disease (TED): the clinical features

- Also called Graves' orbitopathy or ophthalmopathy (GO)
- 15,000-20,000 patients with active TED in the United States per year
- Clinical features[1]:
  - Eye bulging ("Proptosis")
  - Eye pain
  - Double vision ("Diplopia")
  - Light sensitivity
- Can be sight-threatening[2]
- Caused by autoantibodies that activate cell types present in tissues surrounding the eye[2]
- Close temporal relationship with Graves' disease

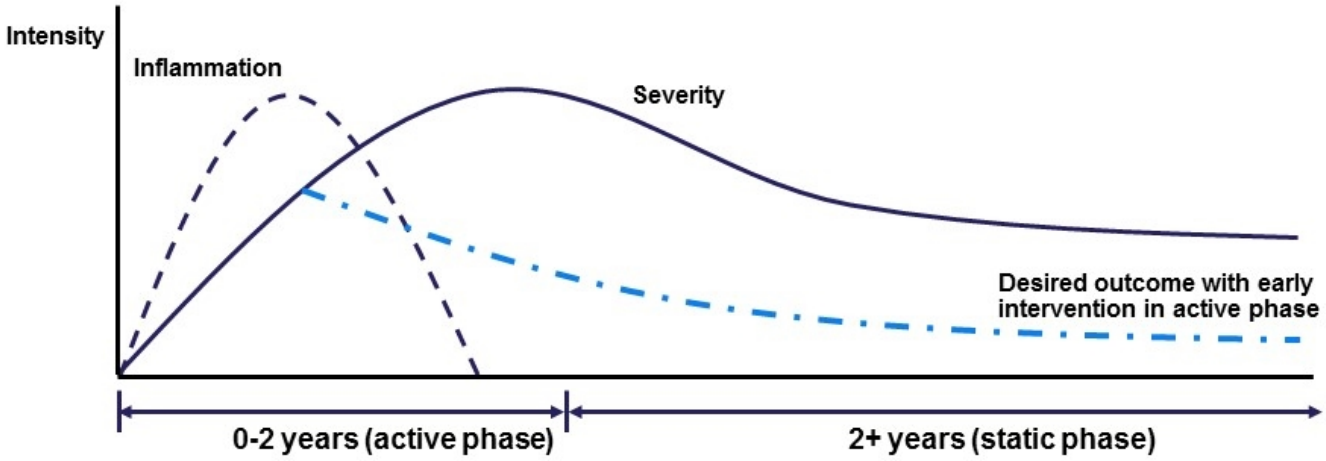


Bahn, 2010
Figure 1. Patients with Thyroid Eye Disease
Panel A shows a 59-year-old woman with excess proptosis, moderate eyelid edema, and erythema with moderate eyelid retraction affecting all four eyelids. Conjunctival chemosis (edema) and erythema with bilateral edema of the caruncles, with prolapse of the right caruncle, are evident. Panel B shows a 40-year old woman with excess proptosis, minimal bilateral injection, and chemosis with slight erythema of the eyelids. She also had evidence, on slit-lamp examination, of moderate superior limbic keratoconjunctivitis.

1. Davies T. and Burch H.B. Clinical features and diagnosis of Graves' orbitopathy (ophthalmopathy), UpToDate, 2018
2. McAlinden C. An overview of thyroid eye disease. Eye and Vision, 2014

Thyroid Eye Disease characterized by an active phase, followed by a static phase

Rundle's Curve describes natural history of disease[1]



- Orbital tissue actively inflamed
- Steroids and other immunosuppressive treatments can be effective

- Inflammatory tissue replaced by fibrotic tissue
- Steroids and immunosuppression no longer effective
- Patients to be evaluated for surgery

1. Adapted from Hiromatsu Y., et al. Graves' ophthalmopathy: epidemiology and natural history. Internal Medicine, 2014

Limited treatment options for Thyroid Eye Disease

Current treatment paradigm[1]

1st Line	2nd Line	3rd Line	Inactive disease
• Corticosteroids	• Orbital radiotherapy • Immunosuppressive agents	• Rituximab[2]	• Orbital surgery

Unmet need

- Only one approved therapy for Thyroid Eye Disease (Tepezza)
- Corticosteroids are not effective in all patients, and approximately one-third of patients will relapse
- Sight-threatening disease may occur in 3-5% of patients with Graves' disease[3]
  - Medical emergency requiring immediate hospitalization and evaluation for surgery[3]
- Up to 20% of TED patients require surgical invervention[3]

1. Bothun E.D., et al. Update on thyroid eye disease and management. Clinical Ophthalmology, 2009
2. Rituximab is not approved by the FDA for Thyroid Eye Disease
3. Bartalena L., et al. Management of Graves' Ophthalmopathy: Reality and Perspectives. Endocrine Reviews, 2000

Clinical program includes a lower dose proof of concept study and a multi-dose randomized trial

ASCEND GO-1

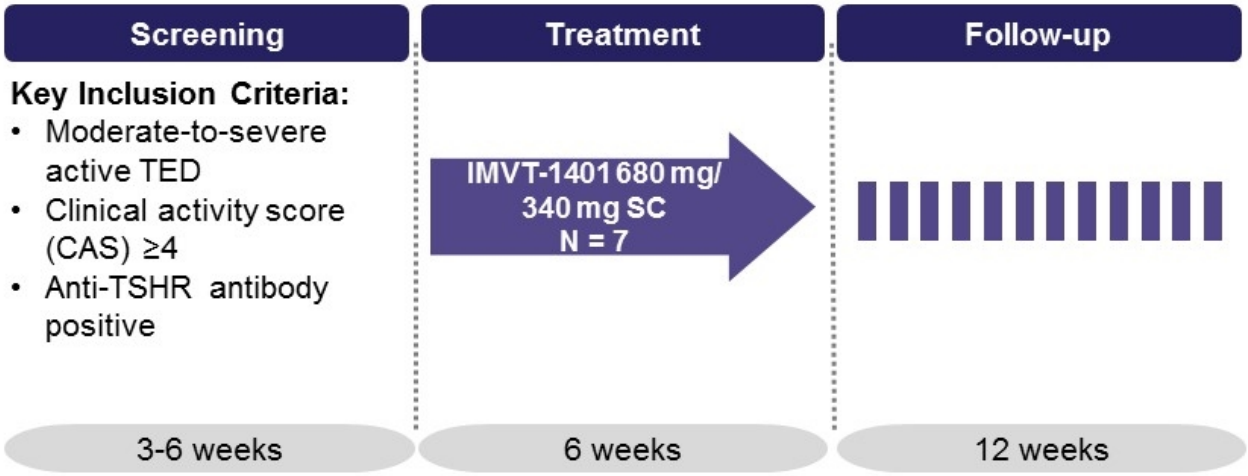
- **Phase 2a**
  - Trial ongoing in Canada
  - Subcutaneous dosing
  - Single arm, open label
  - N=7*
  - 6 weeks of dosing
    - 680 mg weekly x 2 doses
    - 340 mg weekly x 4 doses

*Planned 8th patient enrolled in ASCEND GO-2 instead of ASCEND GO-1

ASCEND GO-2

- **Phase 2b**
  - Trial ongoing in USA, Canada, and Europe
  - Subcutaneous dosing
  - Double masked, placebo controlled, randomized
  - N=77
  - 3 drug arms vs placebo
    - 680mg x 12 doses
    - 340mg x 12 doses
    - 255mg x 12 doses

ASCEND GO-1: the first proof of concept study of an anti-FcRn in Thyroid Eye Disease



Primary Endpoints:

- Safety & tolerability
- Change from baseline levels of anti-TSHR antibodies, total IgG, and IgG by subclasses

Secondary Endpoints:

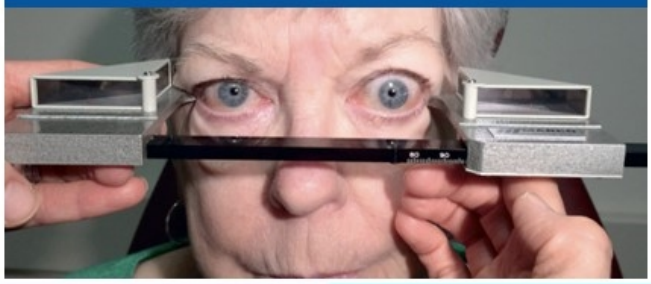
- Change in proptosis
- PK/PD
- Anti-drug antibody levels

Exploratory Endpoints:

- CAS, Diplopia
- Biomarkers (gene expression, serum pro-inflammatory markers, receptor occupancy)

Three clinical measures of disease activity used to measure response in trials

Proptosis Measured By Exophthalmometer



Clinical Activity Score (CAS, 0-7)	Diplopia Score (1-4)
• Spontaneous orbital pain (+1) • Gaze evoked orbital pain (+1) • Eyelid swelling that is considered to be due to active TED (+1) • Eyelid erythema (+1) • Conjunctival redness that is considered to be due to active TED (+1) • Chemosis (+1) • Inflammation of caruncle OR plica (+1)	1. No diplopia 2. Intermittent, i.e., diplopia in primary position of gaze, when tired or when first awakening 3. Inconstant, i.e., diplopia at extremes of gaze 4. Constant, i.e., continuous diplopia in primary or reading position

Source: Bartalena, et al. Eur Thyroid J 2016; 5: 9–26.
Chemosis: Swelling of conjunctiva, which is the mucous membrane that covers the front of the eye and lines the inside of the eyelids.
Caruncle: Small, pink, globular nodule at the inner corner (the medial canthus) of the eye.
Plica: A small fold of bulbar conjunctiva on the medial canthus of the eye.
Diplopia: Double vision.
Image Credit: www.sciencedirect.com/topics/medicine-and-dentistry/hypoglobus

ASCEND GO-1: Patient baseline characteristics

Variable	Mean ± SD (N =7)
CAS (0-7)	5.0 ± 1.0
Proptosis (mm)	23.1 ± 3.3
Diplopia (1-4)	2.3 ± 0.8
IgG (g/L)	11.3 ± 1.7
Albumin (g/L)	48.3 ± 3.7

IMMUNOVANT **Note:** SD = standard deviation. Proptosis values are for study eye.

ASCEND GO-1: Summary clinical observations

Clinical Activity Score (CAS):

- 4/7 patients (57%) improved by ≥ 2 points
- 3/7 patients (43%) were CAS responders (achieved a 0 or 1 score)

Proptosis:

- 3/7 patients (43%) were proptosis responders
  - Responders met standard criteria ≥ 2mm improvement study eye without significant deterioration in fellow eye
  - More impacted eye was selected as the study eye

Diplopia:

- 4/6 patients (67%) with baseline diplopia saw an improvement in diplopia
- 2 patients with baseline diplopia achieved a status of no diplopia

Note: Complete ASCEND GO 1 results are not yet available

ASCEND GO-1: Labs, safety, and tolerability were in-line with Phase 1 data

Total IgG:

- Average reduction of 65% from baseline to end of treatment
- Pharmacodynamic curves as expected

Safety and tolerability:

- No SAEs
- No withdrawals due to AEs
- All AEs were mild or moderate
- No headaches reported

Albumin:

- Average reduction of 24% from baseline to end of treatment
- Albumin changes asymptomatic

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Note: Complete ASCEND GO 1 results are not yet available
AE: Adverse event; SAE: Serious adverse event

ASCEND GO-1 results provide positive proof-of-concept for IMVT-1401 in Thyroid Eye Disease

Only subcutaneous therapy in clinical development for Thyroid Eye Disease (TED)

Positive clinical results after 6 weeks of treatment	Observed to be safe and generally well-tolerated
• 65% mean reduction in total IgG from baseline to end of treatment • 57% of patients improved by ≥ 2 points on clinical activity score (CAS) • 43% of patients were both proptosis responders* and CAS responders** • 67% of patients with baseline diplopia saw an improvement in diplopia	• Subcutaneous injection • No serious adverse events (SAEs) were reported • No withdrawals due to adverse events (AEs) • All reported AEs were mild or moderate • No headaches were reported

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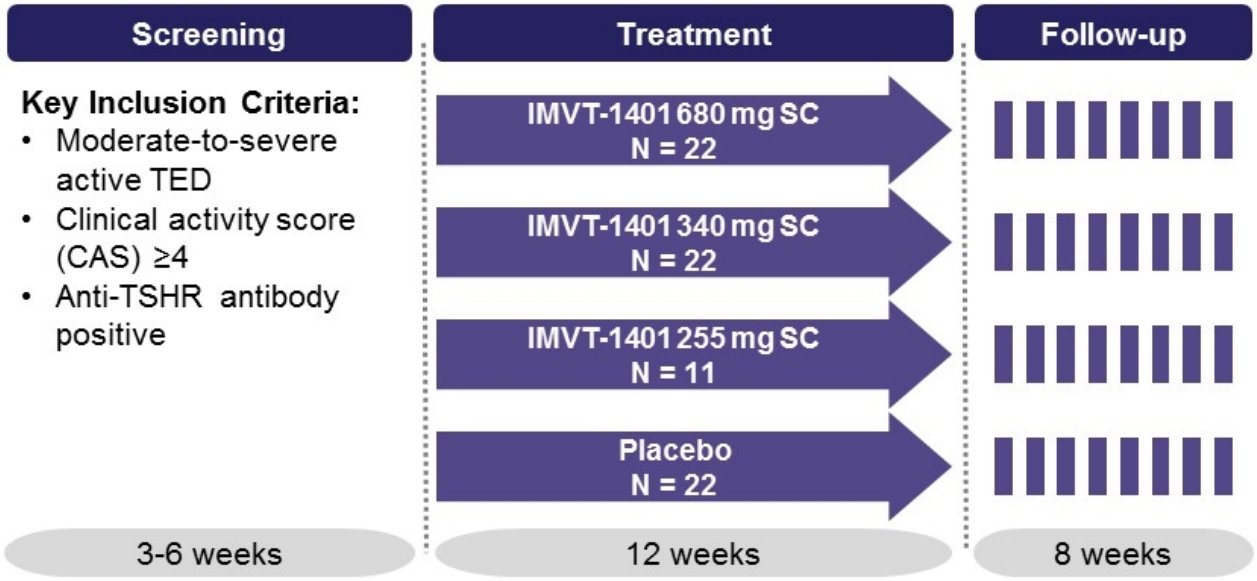
*Proptosis responders improved ≥ 2mm in study eye without significant deterioration in fellow eye
**CAS responders achieved a total CAS score of 0 or 1

ASCEND GO-2: Phase 2b study design



Primary Endpoints:

- Proptosis responder rate
- Safety & tolerability

Secondary Endpoints:

- CAS responder rate
- Change from baseline levels of anti-TSHR antibodies, total IgG, and IgG by subclasses

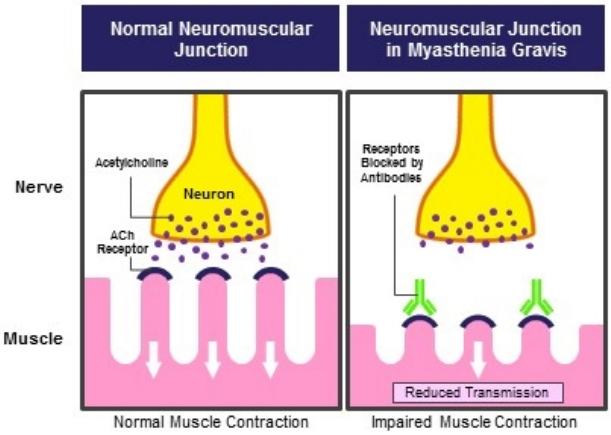
Exploratory Endpoints:

- Biomarkers (gene expression, serum pro-inflammatory markers, receptor occupancy)
- CT scans

IMVT-1401 for Myasthenia Gravis

Myasthenia Gravis overview

- Rare autoimmune disorder affecting an estimated 65,000 people in the US[1]
- Characterized by weakness of voluntary muscles including ocular, facial, oropharyngeal, limb, and respiratory muscles[1]
- 15-20% of MG patients will experience at least one myasthenic crisis over their lifetimes, a potentially life-threatening acute complication[2]
- Disease caused by autoantibodies targeting the neuromuscular junction[1]
- ~93% of patients have an identified autoantibody[1]
  - Anti-acetylcholine receptor (AChR) antibodies (~85%)
  - Anti-muscle-specific tyrosine kinase (MuSK) antibodies (~8%)



1. Meriggioli M.N. and Sanders D.B. Muscle autoantibodies in myasthenia gravis: beyond diagnosis? Expert Review Clinical Immunology, 2012
2. Sudulagunta S.R., et al. Refractory myasthenia gravis – clinical profile, comorbidities and response to rituximab. German Medical Science, 2016

Unmet need persists despite availability of treatment options

Current treatment paradigm[1]

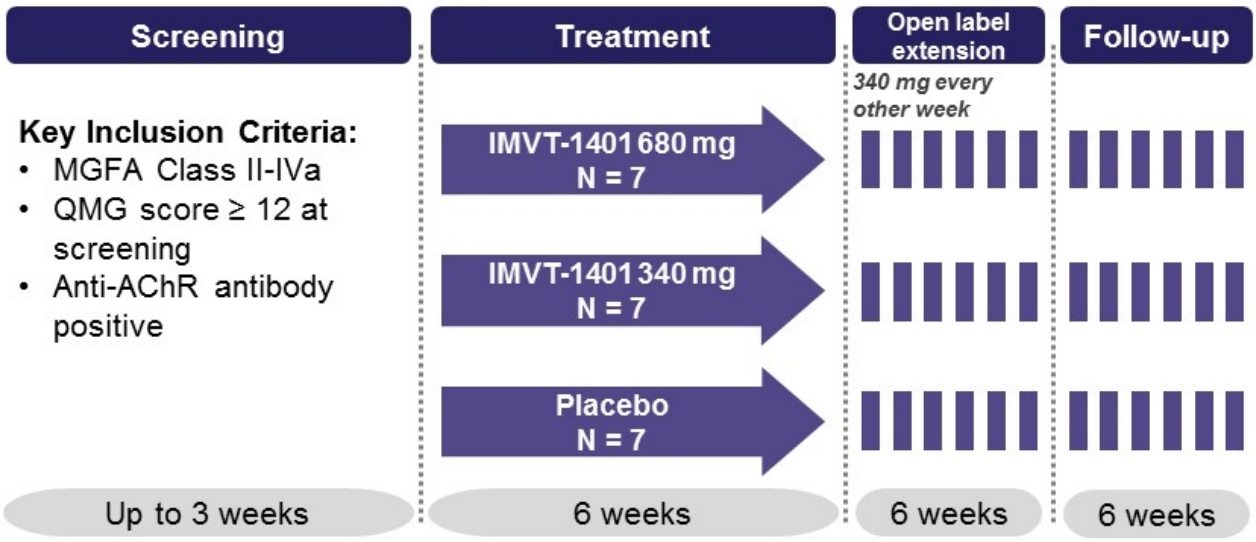
1st Line	2nd Line	3rd Line	4th Line
• Acetylcholinesterase inhibitors • Corticosteroids	• Immunosuppressive agents • Thymectomy	• IVIg • Plasma exchange • Immunoadsorption • Rituximab[1]	• Eculizumab

Unmet need

- ~10% of MG patients refractory to current treatments, while 80% fail to achieve complete stable remission[1]
- Existing therapies associated with significant side effects
  - Early line agents can lead to disease exacerbation and do not always prevent disease progression
  - Treatment for more advanced disease often requires invasive and burdensome infusions
- Patients with anti-MuSK antibodies more likely to become refractory[2]
  - ~50% of the refractory MG population, despite comprising <10% of the overall MG population
  - Newest treatment option, eculizumab, only indicated for anti-AChR positive patients

1. Rituximab is not approved by the FDA for myasthenia gravis
2. Mantegazza R. and Antozzi C. When myasthenia gravis is deemed refractory: clinical signposts and treatment strategies. Therapeutic Advances in Neurological Disorders, 2018

ASCEND MG: Phase 2a study design



Primary Endpoints:

- Safety & tolerability
- Change from baseline levels of anti-AChR antibodies, total IgG, and IgG by subclass

Secondary Endpoints:

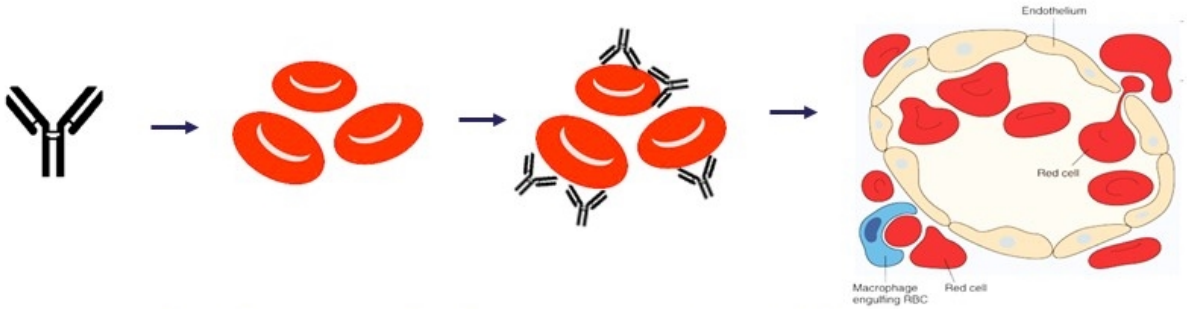
- IMVT-1401 pharmacokinetics
- Change from baseline in QMG, MG-ADL, quality of life measures

Exploratory Endpoints:

- Biomarkers (gene expression, serum pro-inflammatory markers, receptor occupancy)

IMVT-1401 for Warm Autoimmune Hemolytic Anemia

Warm Autoimmune Hemolytic Anemia overview



Anti-red blood cell autoantibody	Red blood cells (RBCs)	Anti-RBC autoantibodies bind to RBCs	Antibody-coated RBCs undergo extravascular hemolysis

- Blood disorder marked by red blood cell destruction
- Estimated prevalence of 42,000 patients in US and 66,000 patients in EU[1]
- Presentation typically non-specific and occurs over several weeks to months
    - Fatigue, weakness, skin pallor, shortness of breath
- Severe cases can be fatal[2]

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1. Park S.H. Diagnosis and treatment of autoimmune hemolytic anemia: classic approach and recent advances. Blood Research, 2016
2. Roumier M., et al. Characteristics and outcome of warm autoimmune hemolytic anemia in adults: new insights based on a single-center experience with 60 patients. American Journal of Hematology, 2014

Limited options for treating WAIHA

Current treatment paradigm[1,2]

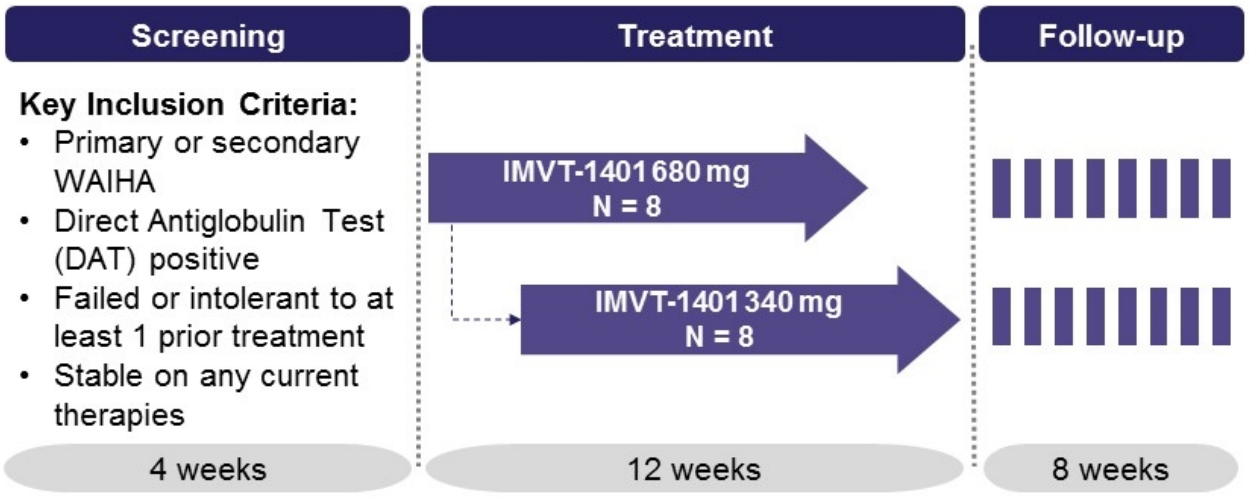
1st Line	2nd Line	3rd Line	4th Line
• Corticosteroids • RBC transfusion	• Immunosuppressive agents	• Rituximab[3]	• Splenectomy

Unmet need

- Currently no FDA-approved therapies for WAIHA
- Only one-third of all patients maintain sustained disease control once steroids are discontinued
  - Majority of patients will require either long-term steroid treatment or additional therapies[1]
- No clear guidelines on choice of treatment in patients failing treatment with corticosteroids
- RBC transfusions are indicated in patients who require immediate stabilization, despite the fact that autoantibodies present in WAIHA patients may react against RBCs in the transfusion product[1,2]

1. Salama A. Treatment Options for Primary Autoimmune Hemolytic Anemia: A Short Comprehensive Review. Transfusion Medicine and Hemotherapy, 2015
2. Park S.H. Diagnosis and treatment of autoimmune hemolytic anemia: classic approach and recent advances. Blood Research, 2016
3. Rituximab is not approved by the FDA for warm autoimmune hemolytic anemia

ASCEND WAIHA: Phase 2 study design



Primary Endpoints:

- Hemoglobin response rate*
- Safety & tolerability

Secondary Endpoints:

- Change in hemoglobin, LDH, bilirubin, & haptoglobin
- Time to response
- QOL measures
- PK/PD
- Anti-drug antibody levels

Exploratory Endpoints:

- Biomarkers (gene expression, serum pro-inflammatory markers, receptor occupancy)

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* Defined as hemoglobin level ≥10 g/dL with at least a ≥2 g/dL increase from baseline


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