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December 22, 2025

Dear TED Community,

We understand how important it is to keep the community informed about our efforts to develop potential new treatment options for people living with thyroid eye disease (TED). As requested by the community, we are writing with news that the U.S. Food and Drug Administration (FDA) has accepted for filing our Biologics License Application (BLA) for veligrotug*.

The BLA is a comprehensive submission of specific information about veligrotug to the FDA and a request for approval to market and distribute the treatment in the United States of America. At this time, veligrotug remains an investigational drug. It has not been shown to be safe and effective for any use by a regulatory agency nor approved for commercial use by any regulatory agency.

As part of the FDA's filing of our veligrotug BLA, the FDA granted veligrotug a Priority Review. Priority Review designation means the FDA's goal is to take action on the application within 6 months, as compared to approximately 10 months under standard review. This is reflected in the assigned Prescription Drug User Fee Act (PDUFA) date of June 30, 2026, the target date for the FDA to complete its review to determine if the benefits of the treatment outweigh the risks for the intended use and announce its decision.

We are grateful to the many people involved in our clinical trials, including those individuals living with TED who have participated, without whom this important milestone would not have been possible.

Below you will find answers to some anticipated questions around this announcement. If you have any additional questions, please reach out to the Viridian Patient Advocacy team via email patientadvocacy@viridiantherapeutics.com.

Thank you on behalf of Viridian Team,
Jennifer Helfer
Senior Director, Patient Advocacy & Engagement

**Veligrotug is an investigational drug, meaning it is available for use only in the setting of clinical trials. Veligrotug has not been determined to be safe and effective for any use by a regulatory agency nor approved for commercial use by any regulatory agency.*

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Q&A

Who can I contact for help or if I have any questions?

- For trial participants, we encourage you to reach out to the trial site at which you participated for more information.
- For members of the larger TED community, please speak with a healthcare professional for all medical questions or connect with a patient advocacy organization for more information.
- You can also contact the Viridian Patient Advocacy team via email patientadvocacy@viridiantherapeutics.com

What is veligrotug?

- Veligrotug is an insulin-like growth factor-1 receptor (IGF-1R) inhibitor under development for the potential treatment of TED. More specifically, it is a monoclonal antibody targeting the IGF-1R that is administered through an intravenous (IV) infusion. In clinical trials a full treatment course was five IV infusions, given three weeks apart with an approximate infusion time of 30-45 minutes.
- Veligrotug is an investigational drug, and its safety and efficacy have not been determined by any regulatory agency, including the FDA, nor approved for commercial use by any regulatory agency.

What is a (Biologics License Application) BLA?

A BLA is a comprehensive submission of specific information about a studied potential treatment to the FDA and a request for approval to market and distribute the treatment in the United States of America.

What does 'accepted' for filing mean?

A BLA application that has been accepted for filing means that the FDA has determined the submitted application is sufficiently complete and the regulatory agency can move forward with a full review.

What is Priority Review?

- A Priority Review designation means FDA's goal is to take action on an application within 6 months.
- A Priority Review designation will direct FDA resources to the evaluation of applications for drugs that, if approved, would be significant improvements in the safety or effectiveness of the treatment, diagnosis, or prevention of serious conditions when compared to standard applications.
- Designation of a drug as "Priority" does not alter the scientific standards or the quality of evidence the FDA requires for approval of a drug.

- Additional background on this designation can be found on the FDA's website - https://www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/priority-review

At the end of the FDA's review, what are the possible decisions they can make?

- By the assigned PDUFA date, the FDA will review the BLA application and determine if the treatment under review is safe and effective for the intended use, and that it can be manufactured to federal quality standards.
- If the treatment is determined to provide benefits that outweigh its known and potential risks for the intended population, the FDA will approve the treatment for commercial use. Commercial use means that the treatment can be marketed, distributed, and sold for use in the United States of America.
- If FDA needs more information or believes there are problems with the BLA, it may issue a Complete Response Letter (CRL). A CRL is not a rejection of the application, but a way of FDA informing a company that it needs more information before it can analyze the application. The company can submit new information or withdraw the application
- Additional background on the FDA review process: https://www.fda.gov/drugs/development-approval-process-drugs and https://www.fda.gov/drugs/information-consumers-and-patients-drugs/fdas-drug-review-process-ensuring-drugs-are-safe-and-effective

How is today's announcement different from the October 2025 BLA submission announcement?

- In late October we announced the submission of the veligrotug BLA to FDA. This submission started the FDA's initial review of the application, which typically lasts 60 days.
- Today's announcement indicates that FDA found that the BLA is sufficiently complete and therefore they have begun their full review of the application.

Will the FDA convene an advisory committee for veligrotug?

- It is not yet known if the FDA will convene an Advisory Committee meeting during its review of veligrotug.

What does this mean for people outside the United States?

- The Viridian team is working towards submitting a Marketing Authorization Application (MAA) for veligrotug to the European Medicines Agency's (EMA) in the first quarter of 2026. The MAA is a request for approval to market a medicine in European Union member countries.
- We will also consider other submissions in additional countries and regions with the aim of bringing new treatment options to as many individuals living with TED as possible.