TODAY! FDA advisors convene to discuss exa-cel (Watch live)

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On Tuesday, October 31, the FDA will hold a Cellular, Tissue, and Gene Therapies Advisory Committee (Ad Comm) meeting to discuss exa-cel as we await the upcoming regulatory decision for approval.

> **Join the livestream here at 9 a.m. ET, Tuesday, October 31 or watch with us in The Leiden Center auditorium. We'll be livestreaming the Ad Comm all day for anyone who wishes to stop by!**

Though decidedly spooky timing, the decision to convene an Ad Comm meeting is not. The FDA only requests this type of meeting when a truly innovative therapy is up for final regulatory decision.

The advisors on this committee are considered experts in their respective fields — drawing from diverse basic science backgrounds, physicians and other specialists. Members of the Ad Comm are tasked with discussing topics chosen by the agency. This gives us an opportunity to showcase the transformative potential benefit of exa-cel and the positive risk-benefit we've seen in our clinical trials. They'll hear perspectives from leading experts, Vertexians and people living with this condition.

If approved, exa-cel will be the first of its kind to hit the market. The CRISPR/Cas9 technology behind our approach netted a Nobel Prize in 2020 for founding scientists Jennifer Doudna and Emmanuelle Charpentier. Now, after much hard work from Vertex scientists, it's on the precipice of a landmark decision that could bring a functional cure to people living with SCD.

The PDUFA date for exa-cel is currently scheduled for SCD on December 8 and beta thalassemia on March 30.

A huge shout out to the team involved in preparing for this meeting as we continue to go #fullstHEMEahead to potentially deliver the first CRISPR-based therapy to those who are

waiting.

To stay up-to-date on all exa-cel related news, visit our exa-cel launch readiness hub here.

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