

Written Comments Guide

FDA Advisory Committee Meeting for exagamglogene autotemcel (exa-cel)

October 31st, 2023, 9:00 a.m. – 5:00 p.m. ET

On **October 31st, 2023**, the U.S. Food and Drug Administration (FDA) will convene the **Cellular, Tissue, and Gene Therapies Advisory Committee** to discuss exagamglogene autotemcel (exa-cel), a gene therapy for the treatment of Sickle Cell Disease (SCD) for patients between the ages of 12 and 35. The Advisory Committee Meeting will be used by FDA to obtain independent expert advice on scientific, technical, and policy matters. The meeting is public and includes an opportunity for voluntary community participation through written and oral comments.

Submissions

All submissions for both [Oral Comments](#) and [Written Comments](#) must include the following information:

Docket No. FDA-2023-N-1190 for Cellular, Tissue, and Gene Therapies Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments-Sickle Cell Disease, Meeting Date: October 31, 2023

[Oral Comments](#) from the public will be scheduled between approximately **12:35 p.m. and 1:35 p.m. Eastern Time** for approximately 3-5 minutes each for each speaker. Speakers should **submit a brief statement** along with the above items and the following information: name, e-mail address, and direct contact phone number, with an indication of the approximate time requested to make their presentation **by 12 p.m. Eastern Time on October 16, 2023**. Speakers will receive a confirmation to speak **by October 18, 2023 6 p.m. ET**.

For Speaker Registration, please contact Cicely Reese or Marie DeGregorio CBERCTGTAC@fda.hhs.gov

[Written comments must be submitted online \[Here\]\(#\)](#). All submissions must include the items listed above.

Comments received **on or before October 24th** will be provided to the committee to be read during the meeting. Comments received **after that date until October 30th** will go to the FDA and will be taken into consideration. All submissions are public

Suggested Topics

The question to consider to guide your writing process: *How do you see this therapy benefiting the lives of people living with SCD, ages 12-35 years old?* We suggest focusing on the following information:

- Does it improve or reduce the quality of life for people and families living with SCD?
- Will it reduce or increase your interactions with the healthcare systems in the long term?
- How does or could gene therapy impact your ability to live your life to the fullest?
- Will it reduce the economic burden on you and your family?
- What would access to gene therapy mean to you and/or your family?

This is a monumental moment for the sickle cell community, and we look forward to your engagement. Would it be possible to add these announcements of our webinar and the FDA Advisory Committee convening to your newsletter this week, please? Please do not hesitate to contact me for questions. For additional information, please contact Mariah Scott (mescott@sickcells.org).