

Ascelia Pharma provides Orviglance® update following FDA Type A meeting

Ascelia Pharma AB (publ) today announces that it has received the official minutes from its Type A meeting with the U.S. Food and Drug Administration (FDA) regarding the Complete Response Letter (CRL) issued for the Orviglance® New Drug Application (NDA). While the FDA maintains that approval would require additional clinical evidence from a new clinical study, the Agency also acknowledged that clinical evidence to support approval may potentially be generated through a prospective analysis of images from the Phase 3 SPARKLE study using a different primary endpoint.

In the Type A meeting the FDA acknowledged several important aspects of the Orviglance program, including:

- Orviglance addresses a significant unmet medical need
- No major safety concerns have been identified
- Existing clinical studies provide evidence supporting Orviglance's technical performance as a T1-weighted MRI contrast enhancement agent

Based on the FDA's feedback, Ascelia will evaluate the most efficient path forward for Orviglance in the U.S. and does not plan to conduct another clinical study of Orviglance. Other key priorities for Ascelia will be to advance regulatory activities in Europe and continue the partnering process. The company remains confident that the totality of evidence generated throughout the development program supports Orviglance's efficacy and safety and remains committed to bringing Orviglance to patients with severely impaired kidney function.

"While we are disappointed that the FDA continues to request additional clinical evidence, the Type A meeting has provided greater clarity on the potential paths forward. We remain confident in the strength of our data and will evaluate the most efficient regulatory path forward in the U.S., focusing on alternatives that build on the existing SPARKLE dataset, while continuing our partnering activities to bring Orviglance to patients," said Magnus Corfitzen, CEO of Ascelia.

The FDA acknowledged the rationale for the image re-read study conducted by Ascelia, while noting its general policy regarding post hoc re-read analyses. Ascelia maintains that the re-read was performed according to the SPARKLE study protocol and specifically designed to address reader-related issues identified in the original image assessment.

The quality-related issues raised in the Complete Response Letter (CRL) have been thoroughly discussed with the FDA, and agreement has been reached on an appropriate path to resolution. Importantly, these issues relate to the product specifications and proposed analytical procedures, rather than to the manufacturing process itself.

Investor webcast

Ascelia will host a webcast and conference call today, Monday, October 12, 2026, at 08.30 am CEST here: <https://events.inderes.com/ascelia-pharma/2026-investor-update>

To participate by telephone, please register in advance here: <https://events.inderes.com/ascelia-pharma/2026-investor-update/dial-in>

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About us

Ascelia Pharma is a biotech company focused on orphan oncology treatments. We develop and commercialize novel drugs that address unmet medical needs and have a clear development and market pathway. The company has two drug candidates – Orviglance and Oncoral – in development. Ascelia Pharma has global headquarters in Malmö, Sweden, and is listed on Nasdaq Stockholm (ticker: ACE). For more information, please visit <http://www.ascelia.com>.

Attachments

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