PRESS RELEASE

17 August 2026 11:50:00 CEST

Ascelia Pharma Announces FDA Has Scheduled Type A Meeting for Orviglance NDA on September 9, 2026

Ascelia Pharma AB (publ) (STO: ACE), a biotech company focused on improving the lives of people living with rare cancer conditions, today announced that the U.S. Food and Drug Administration (FDA) has scheduled a Type A meeting for September 9, 2026 to discuss the Complete Response Letter (CRL) issued on July 2, 2026 regarding the New Drug Application (NDA) for Orviglance®.

The meeting follows FDA's acceptance of the Company's Type A meeting request and provides an opportunity for Ascelia Pharma and FDA to review the Company's response to the issues outlined in the CRL, including statistical/clinical, product quality and regulatory considerations supporting the Orviglance NDA.

Ascelia Pharma remains confident that the Orviglance NDA is supported by substantial evidence demonstrating the efficacy and safety of Orviglance in its intended patient population. The Company believes the totality of the clinical, safety, and imaging data generated across the development program supports approval and looks forward to discussing these data and the regulatory path forward with FDA at the upcoming Type A meeting.

Following receipt of the CRL, Ascelia Pharma conducted a thorough review of the Agency's comments and prepared a detailed briefing package addressing each topic raised by FDA.

Regarding product quality, the Company has aligned with FDA's recommendations and implemented the actions requested by the Agency.

The briefing package also addresses FDA's comments related to the re-read of the “SPARKLE” Phase 3 study (ASC-Man-P016), including the scientific justification for the re-read, the training of new readers, and the demonstration of clinical utility. The briefing package further clarifies the Company's scientific rationale supporting the design, conduct, and interpretation of the study, including the use of T1-weighted imaging as the basis for assessing improvement of focal liver lesion visualization for a T1-enhancing agent.

"The scheduling of this Type A meeting represents an important step in our ongoing dialogue with FDA regarding the Orviglance NDA," said Magnus Corfitzen, Chief Executive Officer of Ascelia Pharma. "We have worked diligently to address the points raised in the Complete Response Letter and have submitted a comprehensive briefing package that clearly presents the

scientific, clinical, and regulatory foundation supporting the application. We remain confident in the strength of the Orviglance data package and look forward to a productive discussion with FDA on the path forward for bringing Orviglance to patients with severe kidney impairment who currently have limited liver imaging options."

FDA's acceptance of the Type A meeting request does not indicate any position by the Agency regarding the outcome of the review process or the matters to be discussed at the meeting. Ascelia Pharma intends to provide an update following receipt of the official meeting minutes.

Contacts

Magnus Corfitzen, CEO
Email: moc@ascelia.com
Tel: +46 735 179 118

Anton Hansson, CFO
Email: anton.hansson@ascelia.com
Tel: +46 735 179 113

This information was submitted for publication, through the agency of the contact persons set out above.

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

Ascelia Pharma Announces FDA Has Scheduled Type A Meeting for Orviglance NDA on September 9, 2026