PRESS RELEASE

12 July 2026 18:45:00 CEST

Ascelia Pharma Provides Orviglance Update

Ascelia Pharma AB (publ) (STO: ACE), a biopharmaceutical company focused on improving the lives of people living with rare cancer conditions, provides an update following the recent publication of the Complete Response Letter (CRL) by the U.S. Food and Drug Administration (FDA) regarding the New Drug Application (NDA) for Orviglance®.

As previously communicated, Ascelia Pharma ("Ascelia") is preparing for a Type A meeting with the FDA to obtain a detailed understanding of the matters outlined in the CRL and to find an expedited path forward for Orviglance.

Ascelia views the FDA concerns in the clinical section of the CRL as related to the image reading process and is providing additional factual context to clarify our position.

Ascelia considers the pivotal phase 3 study ASC-Man-P016 ("SPARKLE") to be an adequate and well-controlled study, and the SPARKLE dataset provides a comprehensive and robust basis for evaluating the clinical performance of Orviglance. The SPARKLE study was conducted in accordance with the study protocol and generated a comprehensive imaging dataset. Image acquisition included all planned MRI sequences, including T1-weighted, T2-weighted and diffusion-weighted imaging (DWI) sequences. Manganese, the active substance in Orviglance, is a T1 enhancing compound.[1]

As previously disclosed, issues in the initial image reading process meant that no conclusions on efficacy can be made based on the scoring by those image readers.

Based on a thorough analysis, a new image reading process was subsequently implemented using new independent, blinded image readers with no prior knowledge of the SPARKLE images or prior reading results. The image re-read was conducted under predefined procedures to support a consistent and rigorous assessment of the imaging data. The initial image reading issues and the resulting approach for evaluation were discussed with the FDA and the agency's feedback was incorporated into the NDA submission.

The Company also notes that certain questions raised by the FDA relate to product documentation. Ascelia expects to address these matters in the near term.

Ascelia intends to provide a further update following the planned meeting with the FDA and receipt of the official meeting minutes. The Company welcomes the opportunity to discuss the matters outlined in the Complete Response Letter with the FDA.

Footnote:
[1] Pan D *et al*. Manganese-based MRI contrast agents: past, present and future. Tetrahedron. 2011 Nov 4;67(44):8431-8444. doi: 10.1016/j.tet.2011.07.076. PMID: 22043109; PMCID: PMC3203535.

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.**

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.

Attachments

Ascelia Pharma Provides Orviglance Update