PRESS RELEASE

18 March 2025 22:05:00 CET

Ascelia Pharma Announces Positive Outcomes of FDA Meeting and Confirms Plan to Submit the NDA for Orviglance mid-2025

Ascelia Pharma AB (publ) (ticker: ACE), a biotech focused on improving the life of people living with rare cancer conditions, today announced that the Company has received final minutes from the meeting with the FDA, providing positive guidance for the Orviglance NDA to progress with the submission mid-2025 as planned.

Ascelia Pharma has now received the final minutes from a meeting held with the US Food and Drug Administration (FDA) to discuss the planned New Drug Application (NDA) for Orviglance.

The FDA provided clear and concrete guidance for the proposed NDA for Orviglance. The meeting discussion and final minutes support the finalization of the NDA submission according to plan.

“We are very pleased with the outcome of our meeting with the FDA and look forward to advancing the NDA submission for Orviglance in order to submit in the middle of the year, as planned. This meeting with the FDA is another significant step forward in bringing Orviglance to market,” said Magnus Corfitzen, CEO of Ascelia Pharma.

As previously communicated, Ascelia Pharma plans to submit the NDA for Orviglance to the FDA by mid-2025 to obtain regulatory approval.

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 clinical 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.

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About Oncoral

Oncoral is a novel irinotecan chemotherapy tablet developed initially for the treatment of gastric cancer. Irinotecan chemotherapy has an established potent anti-tumor effect. Oncoral is a daily tablet with the potential to offer better patient outcomes with improved safety following the daily dosing at home compared to intravenous high-dose infusions at the hospital. Following successful Phase 1 results, Oncoral is now prepared for Phase 2 clinical development.

This information is information that Ascelia Pharma is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact persons set out above, at 2025-03-18 22:05 CET.

Attachments

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