PRESS RELEASE

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Ascelia Pharma Updates Timeline for Submission of the Orviglance NDA

Ascelia Pharma AB (publ) (ticker: ACE), a biotech focused on improving the life of people living with rare cancer conditions, today provided additional information regarding the submission of the New Drug Application (NDA) for Orviglance® to the US Food and Drug Administration (FDA).

The NDA file is essentially complete. The final electronic configuration of the file, required to meet FDA submission standards ("publishing"), is currently ongoing. This will be completed in two to three weeks after which the NDA will be submitted *.

'We are almost at the finishing line, and I look forward to sharing the news of our Orviglance NDA submission soon', says Magnus Corfitzen, CEO of Ascelia Pharma.

* It was previously communicated that the NDA submission was 'expected mid-year 2025, most likely during the first half of August'.

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.

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About Orviglance
Orviglance (manganese chloride tetrahydrate) is a novel oral contrast agent for MR-imaging developed to improve the detection and visualization of focal liver lesions (including liver metastases and primary tumors) in patients with reduced kidney function. These patients are at risk of serious side effects from the currently available class of gadolinium-based contrast agents. Orviglance, has been granted an Orphan Drug Designation by the US Food and Drug Administration (FDA). A clinical program of nine studies, including the pivotal global Phase 3 study SPARKLE, has successfully been completed with strong and consistent efficacy and safety results.

Attachments

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