PRESS RELEASE

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Ascelia Pharma provides update on the Orviglance NDA

Ascelia Pharma AB (publ) (ticker: ACE), a biotechnology company focused on improving the lives of people living with rare cancer conditions, today announced that it has received a Complete Response Letter (CRL) from the U.S. Food and Drug Administration (FDA) regarding the Company's New Drug Application (NDA) for Orviglance®. Ascelia will engage with the FDA to find an expedited path forward.

The FDA has informed the Company that it is currently unable to approve the NDA for Orviglance in its present form and has requested additional clinical data and product documentation.

We seek to understand the issues in detail and plan to request a Type A meeting with the FDA as soon as possible.

“We remain confident in Orviglance and are committed to making it available to patients.” said Magnus Corfitzen, CEO of Ascelia Pharma. “Our focus now is to work with the FDA to identify an expedited path forward. We will provide further updates when appropriate.”

The Company has a cash runway into 2027 and will assess potential cost saving initiatives.

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

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 2026-07-03 14:23 CEST.

Attachments

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