PRESS RELEASE

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Ascelia Pharma completes FDA Type A meeting on Orviglance NDA

Ascelia Pharma completed the previously scheduled Type A meeting with the U.S. Food and Drug Administration (FDA) on September 9, 2026, regarding the Complete Response Letter (CRL) for the Orviglance® New Drug Application (NDA).

The meeting provided an opportunity to discuss the issues raised by the FDA in the CRL and to gain further clarity regarding obtaining regulatory approval for Orviglance in the US. Ascelia will provide an update on the regulatory path forward after receiving the FDA's official meeting minutes. The minutes are expected within approximately 30 days.

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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

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