PRESS RELEASE

27 January 2025 07:30:00 CET

Ascelia Pharma Announces Acceptance of Three Scientific Abstracts with SPARKLE Phase 3 Data at the European Society of Gastrointestinal and Abdominal Radiology Annual Meeting

Ascelia Pharma AB (publ) (ticker: ACE), a biotech focused on improving the life of people living with rare cancer conditions, today announced that two oral presentations and one scientific poster with clinical data from the SPARKLE Phase 3 study with Orviglance have been accepted for presentation at the European Society of Gastrointestinal and Abdominal Radiology (ESGAR) Annual Meeting, taking place 13-16 May in Amsterdam, Netherlands.

"We are pleased to see the strong interest in Orviglance within the scientific community. ESGAR, a major congress dedicated to advancing the development of gastrointestinal and abdominal imaging, offers an excellent platform to showcase the promising results of the SPARKLE study", says Andreas Norlin, CSO of Ascelia Pharma.

All three abstracts outline data and conclusions from the SPARKLE Phase 3 study with Orviglance. In the study, Orviglance was shown to enhance the detection of suspected or known focal liver lesions, including small-sized lesions, and consistently shows positive results in visualizing lesions in both patients with hepatocellular carcinoma (HCC, primary liver cancer) and those with liver metastases. The study includes patients with severe renal impairment who currently lack an alternative to gadolinium-based contrast MRI.

The following abstracts have been accepted for the ESGAR 2025 conference:

- Liver metastases and HCC: Visualization with manganese-based orally administered contrast agent enhanced liver MRI in patients with severe kidney disease – evidence from the SPARKLE study Presenting author: N. Kartalis (Karolinska University, Stockholm, Sweden) - accepted as oral presentation taking place on Wednesday 14 May 2025 9.00 AM - 10.30 AM CET
- Improved detection of focal liver lesions with manganese-based contrast agent in patients with severe kidney impairment: evidence from the SPARKLE study: Presenting author V. Lucidi (Sant' Orsola University, Bologna, Italy) - accepted as oral presentation taking place on Thursday 15 May 2025 11.00 AM - 12.30 PM CET
- SPARKLE: A Multicenter, Open-label Study to Evaluate the Safety and Diagnostic Efficacy of ACE-MBCA in Patients with Known or Suspected Focal Liver Lesions and Severe Renal Impairment Presenting author D. Geisel (Charite' University, Berlin, Germany) - accepted as poster presentation

Ascelia Pharma expects to submit the New Drug Application (NDA) file for Orviglance to the US Food and Drug Administration (FDA) by mid-2025 to obtain regulatory approval.

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

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.

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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