

Ascelia Pharma Announces Acceptance of Orvigance SPARKLE Study Primary Results as Oral Presentation in Cutting-Edge Research at the 2024 RSNA Annual Meeting

Ascelia Pharma AB (publ) (ticker: ACE) today announced that the primary results from the Orvigance® phase 3 SPARKLE Study have been accepted as an oral presentation at the world's largest radiology conference, RSNA. The conference will be held December 1-5 in Chicago.

The SPARKLE Study evaluates the safety and efficacy of Orvigance in patients with suspected or known liver lesions and severe kidney impairment. The results, originally announced in May 2024, showed that the primary endpoint was successfully met with high statistical significance and demonstrated that the company's magnetic resonance imaging (MRI) contrast agent, Orvigance significantly improved the visualization of focal liver lesions compared to unenhanced MRI.

The results have been accepted as an oral presentation at the 2024 annual conference of the Radiological Society of North America, the world's largest radiology conference. The presentation was accepted in the Cutting-Edge Research category and will be presented by Dr. Alvin Silva, SPARKLE Principal Investigator and Professor of Radiology, Mayo Clinic, Phoenix, United States and is co-authored by Dr. Beatrice L. Madrazo, SPARKLE Principal Investigator and Professor of Radiology, University of Miami, United States.

"I am very pleased that the study has been selected as an oral presentation at the prestigious radiology conference, RSNA. The results support the potential clinical value of a novel manganese based liver specific MR contrast alternative for patients with severe kidney disease" said Dr. Beatrice L. Madrazo.

- **Title of presentation:** 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
- **Timing of presentation:** 2 Dec, 13:30-14:00 CDT, local time Chicago

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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

[Ascelia Pharma Announces Acceptance of Orviglance SPARKLE Study Primary Results as Oral Presentation in Cutting-Edge Research at the 2024 RSNA Annual Meeting](#)