**PRESS RELEASE**

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# Orviglance Review Article Published in Investigative Radiology

**Ascelia Pharma AB (publ) (ticker: ACE), a biotech company focused on improving the life of people living with rare cancer conditions, today announced that the scientific review article on its orphan drug candidate Orviglance® has been published in the scientific journal Investigative Radiology in a special issue "A new era in MR contrast media".**

The scientific review article, titled *Oral manganese chloride tetrahydrate, a novel magnetic resonance liver imaging agent for patients with renal impairment: efficacy, safety and clinical implication*, reviews and discusses liver imaging in patients with severely impaired kidney function as well as the development of Orviglance and its potential role in clinical practice. The review article is published in Investigative Radiology in a special issue "A new era in MR contrast media" and is now available ahead of the printed issue on their website (link).

"The publication of this review article in one of the leading journals in radiology shows that the scientific community sees a need for novel contrast agents without gadolinium. This strengthens our confidence in the unmet need for patients and clinicians as we approach headline data from our Phase 3 study and progress Orviglance towards regulatory approval." said Andreas Norlin, CSO of Ascelia Pharma.

Professor Dominik Geisel of Charité University in Berlin says: "In this review, we revisit the properties of manganese as a contrast agent and the key findings on the novel agent (ref. ACE-MBCA, Orviglance) and how this may allow high-quality liver MRIs that are comparable to GBCA and superior to unenhanced MRI. We offer our insights on the potential advancements in the field of liver imaging with the new agent being a beneficial and well-tolerated tool for radiologists. While current data show promise for patients with focal liver lesions and severe renal impairment, it could have applications for wider medical use pending further investigations".

Ascelia Pharma is thankful to Dominik Geisel, MD, Professor (Charité Universitätsmedizin Berlin) and the other experts and authors including Beatrice L. Madrazo, MD, Professor (University of Miami/Miller School of Medicine, Miami, Florida), Nikolaos Kartalis, PhD, Associate Professor (Karolinska University, Stockholm), and Torkel B Brismar, MD PhD, Professor (Karolinska Institutet, Stockholm).

Orviglance has been granted an Orphan Drug Designation by the US Food and Drug Administration (FDA) for liver imaging in patients with severely impaired kidney function. With Orviglance, these patients can gain access to effective liver imaging without gadolinium-related safety risks. The unmet need for these patients represents an addressable market potential of USD 800 million globally; almost half of which is in the US.

Headline results from the Phase 3 clinical study, SPARKLE, with Orviglance are expected by May 2024.

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## About us

### About Ascelia Pharma

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® (Mangoral) and Oncoral – in clinical development. Ascelia Pharma has its global headquarters in Malmö, Sweden, and is listed on Nasdaq Stockholm (ticker: ACE). For more information, please visit www.ascelia.com.

### About Orviglance

Orviglance (manganese chloride tetrahydrate) is a novel oral contrast agent for magnetic resonance imaging (MRI) 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 been completed. Results from the Phase 3 study are not yet available.

## Attachments

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