

Abstract for Orviglance comparison study to gadolinium accepted at the world's largest radiology conference RSNA

Ascelia Pharma AB (publ) (ticker: ACE) today announced that the study where Orviglance® (manganese chloride tetrahydrate, former working name Mangoral) was compared against a gadolinium-based specific contrast agent has been accepted as an oral paper presentation at the world's largest radiology conference RSNA. The conference will be held November 28 – December 3 in Chicago, Illinois.

In December 2020, Ascelia Pharma announced the results of a comparison study versus a gadolinium contrast agent. The results showed that Orviglance enhanced MRI was as effective as the gadolinium contrast agent gadobenate dimeglumine (Multihance) in terms of visualization of lesions and number of detected lesions detection. In fact, 2 out of the 3 independent readers reported higher scores for Orviglance enhanced MRI. The results also showed that Orviglance enhanced MRI provides improved diagnostic efficacy compared to MRI without a contrast agent using identical endpoints as in the ongoing pivotal Phase 3 study SPARKLE.

"We are very pleased that the study has been selected as an oral paper presentation at the prestigious radiology conference RSNA. The study provides a robust evidence of the diagnostic value that Orviglance can offer once available to patients and physicians. Orviglance is being developed to address the unmet medical need of patients with poor kidney function, and it is encouraging that Orviglance* is as effective as a gadolinium contrast agent, said Carl Bjartmar, Chief Medical Officer at Ascelia Pharma.

**Trademark is registered in Europe and several other markets and submitted for registration in the US.*

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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 (previously referred to as Mangoral) 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 (previously referred to as Mangoral)

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, which has been granted an Orphan Drug Designation by the US Food and Drug Administration (FDA), is currently in Phase 3 development, including the global multi-center SPARKLE study.

About Oncoral

Oncoral is a novel irinotecan chemotherapy tablet developed initially for the treatment of gastric cancer. Irinotecan chemotherapy has an established potent anti-tumor effect. Oncoral is a daily tablet with the potential to offer better patient outcomes with improved safety following the daily dosing at home compared to intravenous high-dose infusions at the hospital. Following successful Phase 1 results, Oncoral is now prepared for Phase 2 clinical development.

Attachments

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