

## Results from Orviglance comparison study to gadolinium presented at RSNA 2021

Ascelia Pharma AB (publ) (ticker: ACE) today presented results at the world's largest radiology conference, RSNA, in Chicago, Illinois from the study in which the investigational contrast agent Orviglance® was compared against a gadolinium-based contrast agent.

As communicated earlier, the comparison study versus the gadolinium contrast agent showed that MRI enhanced with the contrast agent Orviglance (former working name Mangoral) was as effective as the gadolinium contrast agent gadobenate dimeglumine (Multihance) in terms of visualization of lesions and number of detected lesions in the liver. The results also showed that Orviglance-enhanced MRI provides improved efficacy in terms of lesion detection and visualization compared to MRI without a contrast agent.

The presentation today at RSNA shows specifically the results of the efficacy parameters in the study including:

- Number of lesions detected
- Size of the detected lesions
- Lesion border delineation
- Lesion contrast compared to liver

The results showed that a higher number of liver lesions was detected by all three independent readers for Orviglance compared to gadolinium. All three readers were also able to see smaller lesions with Orviglance compared to gadolinium.

With respect to lesion border delineation and lesion contrast to liver, two out of three readers reported higher scores to Orviglance compared to gadolinium.

While the efficacy parameters show higher scores for Orviglance, it is important to notice that this crossover study was comprised only of 20 patients with liver metastases and the higher scores for Orviglance vs. gadolinium are not statistically sufficient to conclude that Orviglance is superior to gadolinium.

"We are very pleased to have presented the study as an oral paper presentation at the prestigious Radiological Society of North America's radiology conference, RSNA. The study provides robust evidence of the diagnostic value that Orviglance can offer once it is available to

patients and physicians. Orviglance is being developed to address the unmet medical need of patients with poor kidney function who require liver imaging, and it is very encouraging that Orviglance is as effective as a gadolinium contrast agent, said Carl Bjartmar, Chief Medical Officer at Ascelia Pharma.

## About us

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### 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](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.

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

## Contacts

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## Attachments

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