PRESS RELEASE

Malmö, 2 December 2020

New study shows Mangoral's lesion visualization as effective as gadolinium contrast agent

Ascelia Pharma AB (publ) (ticker: ACE) today announced the results from an independent reader study where Mangoral was compared against a gadolinium-based liver specific contrast agent. The results showed that Mangoral was as effective as the gadolinium-based contrast agent gadobenate dimeglumine for visualization of focal liver lesions. The results also showed that Mangoral-enhanced MRI provides improved diagnostic efficacy compared to MRI without a contrast agent using identical endpoints as in Ascelia Pharma's ongoing pivotal Phase 3 study SPARKLE.

The blinded re-read study was performed on the images from a previously conducted clinical trial at Karolinska University Hospital in Stockholm, Sweden. The study included 20 patients with colorectal cancer and suspected liver metastases who underwent both Mangoral- and gadolinium-based enhanced liver MRI in a cross-over design with each patient as their own control. The purpose of the re-read study was to apply the assessment methodology recommended by regulatory guidelines for contrast agent development. The endpoints and evaluation criteria in the re-read study were therefore the same as in the current ongoing SPARKLE study.

In the re-read study, the liver MRI scans were assessed by three independent radiologists who were blinded to the drug and other clinical information, whereas the original data was assessed by a single on-site radiologist. The results show that Mangoral enhanced MRI has similar efficacy compared to the liver contrast agent gadobenate dimeglumine (Multihance) in terms of visualization of lesions and number of detected lesions detection with 2 out of 3 readers reporting higher scores for Mangoral enhanced MRI.

"We are very pleased that the study provides a robust evidence of the diagnostic value that Mangoral offers and the clear unmet medical need it fills. Mangoral is being developed to address the unmet medical need in patients with poor kidney function, and it is encouraging to note that Mangoral is as effective as a gadolinium liver-specific contrast agent. The re-read further strengthens the data package to the regulatory authorities", said Carl Bjartmar, Chief Medical Officer at Ascelia Pharma.

The second part of the re-read study was to evaluate the diagnostic efficacy of Mangoral-enhanced liver MRI compared to unenhanced liver MRI (i e liver MRI without a contrast agent). In this comparison all three readers concluded that Mangoral provided improved lesion detection and lesion visualization compared to unenhanced liver MRI.

"The results from the re-read study demonstrates the value of Mangoral to our target population where unenhanced MRI is the standard of care today. It also supports our expectations of positive outcome of the ongoing SPARKLE study", said Magnus Corfitzen, CEO at Ascelia Pharma.

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This information is such information as Ascelia Pharma AB (publ) is obliged to make public pursuant to the EU Market Abuse Regulation.The information was submitted for publication, through the agency of the contact person set out above, at 8.00 am CET on 2 December 2020.

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 – 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 www.ascelia.com.

About Mangoral
Mangoral (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. Mangoral, 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.