PRESS RELEASE

10 May 2022 07:30:00 CEST

Ascelia Pharma's Food Effect Study shows that Orviglance image enhancement of the liver is not reduced by light meal

Ascelia Pharma AB (publ) (ticker: ACE) today announced the results of the Food Effect Study that evaluated the effect of food intake on absorption and signal intensity of Orviglance®. The results showed that intake of a light meal prior to Orviglance administration provides similar image MRI enhancement of the liver compared to a fasting condition. In line with previous studies, the data also confirmed robust image enhancement of the liver after Orviglance administration compared to an MRI image without a contrast agent. A patent application has been filed on these new findings.

"We are very pleased to conclude that the intake of a light meal does not impact image enhancement of the liver compared to a fasting condition. This further improves the convenience and ease the administration of Orviglance in clinical practice. The results from the study also support our previous knowledge about the image enhancement that Orviglance provides to MRI scans", said Carl Bjartmar, Chief Medical Officer of Ascelia Pharma.

In this crossover study, Orviglance was administered to 24 healthy volunteers in fasting condition and in one of two conditions with food intake (either light meal or full meal). The image enhancement effect was measured as the change in the MR signal intensity before and after (1, 4, 8 and 24 hours) administration of Orviglance. The results showed that a light meal prior to Orviglance administration provided similar image enhancement when compared to a fasting condition, whereas the image enhancement was less pronounced for the group receiving a full meal. The strongest signal intensity occurred 4 hours after administration, which is in line with what has been observed in previous studies.

The Food Effect Study forms part of Orviglance ongoing pivotal clinical program and the results will be included in the marketing authorization submission package to the health authorities including FDA and EMA.

Ascelia Pharma has filed a patent application based on the results of the study.

Contacts

Magnus Corfitzen, CEO
Email: moc@ascelia.com
Tel: 46 735 179 118

Mikael Widell, IR & Communications
Email: mw@ascelia.com
Tel: +46 703 11 99 60

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 (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.

Attachments

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