PRESS RELEASE

11 March 2022 07:05:00 CET

Ascelia Pharma successfully completes Orviglance Hepatic Impairment Study

Ascelia Pharma AB (publ) (ticker: ACE) today announced that the last patient visit has been completed in the clinical study to evaluate the effect of liver impairment on the safety, pharmacokinetics and pharmacodynamics of the company's lead drug candidate Orviglance. Preliminary results show that Orviglance was well tolerated in patients with liver impairment. The study is part of the ongoing pivotal clinical program for Orviglance and will be included in the marketing authorization package to the regulatory authorities, including FDA and EMA.

Orviglance is Ascelia Pharma's oral investigational MRI imaging agent used in the visualization of cancer in the liver and is currently in Phase 3 development. The Hepatic Impairment Study evaluates if patients with different degrees of hepatic impairment can tolerate Orviglance since Orviglance is selectively taken up and excreted by the liver.

The study was performed at the Texas Liver Institute in the US in patients with mild, moderate and severe hepatic impairment, respectively. Each severity group had 6 volunteers which was matched to a control group with normal hepatic function. Preliminary data indicate that Orviglance was well tolerated with no serious adverse events. Final results of the Hepatic Study are expected in mid-2022.

"We are pleased to have completed the patient enrollment and it is encouraging to see preliminary results that Orviglance has been well tolerated by patients with different degrees of hepatic impairment. These data are solid step ahead in our preparations for regulatory submission and approval of Orviglance", said Carl Bjartmar, Chief Medical Officer of Ascelia Pharma.

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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