PRESS RELEASE

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Ascelia Pharma receives FDA acceptance of IND application for Oncoral clinical trial

Ascelia Pharma AB (publ) (ticker: ACE) today announced that the U.S. Food and Drug Administration (FDA) has accepted the company's Investigational New Drug (IND) application for the upcoming global Phase 2 clinical study in gastric cancer with the daily oral chemotherapy candidate drug Oncoral.

"We are very happy that the FDA has accepted our IND application to start our Phase 2 study with Oncoral in the US, which is an important step forward for Ascelia Pharma. We believe this daily oral tablet formulation of irinotecan has the potential to provide both better efficacy and improved safety to patients suffering from this very aggressive cancer form where there is a large unmet medical need", said Carl Bjartmar, Chief Medical Officer of Ascelia Pharma.

In this combination study, Ascelia Pharma's irinotecan chemotherapy tablet Oncoral (ASC-201) will be evaluated in combination with Taiho Oncology's LONSURF® (trifluridine and tipiracil) film-coated tablets for oral use. The all-oral combination of Oncoral and LONSURF is investigational at this time and not approved for use in gastric cancer or any other disease.

Following an initial dose-finding part, the Phase 2 study will be a randomized controlled multicenter study of Oncoral added to LONSURF compared to LONSURF alone. The primary endpoint will be progression-free survival, with secondary endpoints including response rate, overall survival, pharmacokinetics, safety, and tolerability.

The study will include approximately 100 patients with metastatic gastric cancer and first patient visit is planned for H1 2022. The initial portion of the planned global study will be conducted at hospitals in Europe, whereas the subsequent randomized part will also include US sites.

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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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