PRESS RESELASE

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Encouraging results from the Phase I combination study with Oncoral and oral capecitabine published in the journal Cancer Chemotherapy and Pharmacology

Ascelia Pharma AB (ticker: ACE), announces results from the Phase I investigator-sponsored extension study (ClinicalTrials.gov Identifier: NCT03295084) demonstrating reassuring tolerability of the oral chemotherapy tablet Oncoral (oral irinotecan) administered in combination with oral capecitabine. These results are published in Cancer Chemotherapy and Pharmacology, a peer reviewed medical journal covering oncological pharmacotherapy.

The Phase I study for Oncoral consisted of two parts. The first, where Oncoral was given as a single agent, was published last fall showing promising results. The second, extension, part of the study evaluated combination with another oral chemotherapy, capecitabine, which could enable an all-oral chemotherapy combination. The aim of this investigator-initiated combination study conducted at Copenhagen University Hospital in Herlev, Denmark, was to evaluate the safety, tolerability, and Maximum Tolerated Dose of Oncoral given in together with capecitabine.

Irinotecan (the active ingredient in Oncoral) and capecitabine is a widely used intravenous combination in the treatment of various cancer forms, and the opportunity to dose both drugs perorally offers several advantages in comparison to intravenous administration. Among these are easier administration, the possibility of home treatment including health-economic benefits and the facilitation of continuous treatment regimens.

The study included 14 adult patients with metastatic or unresectable solid tumors for which no standard curative or palliative therapies existed. Tolerability issues usually associated with chemotherapy, such as altered blood values, were mild and manageable, confirming the favorable safety profile of Oncoral. The study was not designed to assess efficacy, although 5 patients had stable disease lasting median 14 weeks.

“Oncoral in combination with oral capecitabine could become a more convenient and patient friendly treatment option compared to the intravenous formulations of these compounds. The encouraging tolerability profile justifies further clinical studies to assess the efficacy of this treatment regimen”, said Dr. Carl Bjartmar, Chief Medical Officer at Ascelia Pharma.

The scientific article – titled ‘*An open label phase 1 study evaluation safety, tolerability and maximum tolerated dose of oral administration of irinotecan in combination with capecitabine’* –is available through the Cancer Chemotherapy and Pharmacology via:
https://link.springer.com/article/10.1007/s00280-019-03819-0

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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 10.30 p.m. CET on 8 April 2019.

About Ascelia Pharma
Ascelia Pharma is an oncology-dedicated orphan drug development company located in Malmö, Sweden. The company's strategy is to develop drugs, which target unmet medical needs, have an established mode of action and a relatively low development risk. Ascelia Pharma has two drug candidates – Mangoral® and Oncoral – currently under development.

Mangoral is a novel contrast agent for MR-scans and is ready for Phase III clinical studies. Mangoral is developed to improve the visualization of focal liver lesions (liver metastases) in patient with impaired kidneys that cannot tolerate current gadolinium contrast agents on the market. Oncoral is an oral chemotherapy tablet ready for Phase II for the treatment of gastric cancer. Ascelia Pharma is listed on Nasdaq Stockholm (ticker: ACE). For more information, please visit www.ascelia.com.

About Oncoral
Oncoral is a novel tablet formulation of the topoisomerase I inhibitor irinotecan, a chemotherapeutic drug with a well-established role and high anti-tumor activity for treatment of cancer. Oncoral is intended for the treatment of advanced gastric cancer in combination with other anti-cancer treatments. Gastric cancer is a serious disease with a large unmet medical need and is the third leading cause of cancer death worldwide.

Oncoral enables patients to take their chemotherapy at home, which improves the quality of life for cancer patients. The daily dosing of Oncoral could also mitigate the side-effects associated with intravenous treatment where the doses of irinotecan are very high. For clinicians and payors, Oncoral can offer reduced hospital stays and bills as well as less risk of adverse effects associated with intravenous chemotherapy and hospital-acquired infections.

Since the mechanism of action of irinotecan is inhibition of topoisomerase I, a validated anti-cancer concept, Oncoral also has the potential to fulfil unmet medical needs in selected patient segments in various other cancer indications. The additional indications to be considered for Oncoral will be based on several factors, including the results of the clinical development in gastric cancer.