

Malmö, 23 October 2018

Oncoral demonstrates encouraging results in clinical phase I

Ascelia Pharma has presented results of the Phase I study for Oncoral at the European Society for Medical Oncology (ESMO) Annual Congress in Munich, Germany, 19-23 October 2018.

The poster presentation contains data from a dose escalating study in adult patients with solid tumors to assess safety, tolerability and pharmacokinetics of Oncoral, an oral irinotecan formulation, given as single agent. An abstract (# 433P) for the presentation is published online via the EMSO website (<https://www.esmo.org/Conferences/ESMO-2018-Congress>).

The data demonstrated that Oncoral was well tolerated; side effects were generally mild to moderate, manageable and similar in type to those observed with intravenous irinotecan. Furthermore:

- Hematological toxicities were few and all were mild to moderate
- Pharmacokinetic (PK) data showed consistent daily exposures during treatment at days 1 and 14 with no drug accumulation
- The active metabolite, SN-38, interpatient variability was in the same range as after infusion of irinotecan
- In this heavily pre-treated patient population, Oncoral demonstrated activity even among patients previously treated with irinotecan

"We are encouraged by these clinical data on Oncoral, and we look forward to presenting results from further clinical investigations next year where Oncoral is administered in combination with capecitabine thus enabling a potential attractive all-oral chemotherapy combination" states Carl Bjartmar, MD, PhD, Chief Medical Officer of Ascelia Pharma.

About the Phase I study:

Oncoral has been evaluated in an investigator sponsored Phase I trial at the Department of Oncology at Herlev Hospital in Denmark. The study was a dose-escalating safety, tolerability and pharmacokinetics study of orally administered Oncoral in 25 adult patients with advanced solid tumours. The objectives of the study were to determine the safety, tolerability and maximum tolerated dose of Oncoral given as single agent and when administered in combination with the oral chemotherapeutic drug capecitabine. Additional objectives were to determine any objective tumour response or stable disease, and to describe the pharmacokinetics of Oncoral given as single agent.

PRESS RELEASE



For further information contact:

Magnus Corfitzen, CEO, +46 735 179 110

About Ascelia Pharma

Ascelia Pharma is a specialty pharmaceutical company dedicated to the development of novel medicines to improve the life expectancy and quality of life for people living with cancer. The company is located at Medeon Science Park in Malmö, Sweden in the middle of Medicon Valley, a leading European life science cluster. For more information, please visit www.ascelia.com