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Encouraging results from clinical Phase I study of Oncoral presented in a new publication

In continuation of the previously published poster presentation at ESMO in Munich, 19-23 October 2018, Ascelia Pharma has announced the encouraging Phase I results in a new publication titled *Oral administration of irinotecan in patients with solid tumors: an open-label, phase I, dose escalating study evaluating safety, tolerability and pharmacokinetics*.

The publication, which is available on pubmed.gov, contains data from a dose escalation study in adult patients with solid tumors to assess safety, tolerability and pharmacokinetics of Oncoral, an oral irinotecan formulation, given as single agent.

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:

- In total 25 patients were included across four cohorts. The age range was 51-82 years and the majority of patients had Cholangiocarcinoma, Colon, Pancreas or Prostate as primary cancer
- 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 interpatient variability of the active metabolite, SN-38, was in the same range as after infusion of irinotecan
- Nine patients (36%) had stable disease, lasting median of 19 weeks (range 7-45 weeks), and five of those had previously been treated with i.v. irinotecan. Consequently, in this heavily pre-treated patient population, Oncoral indicated activity even among patients previously treated with irinotecan

“These clinical data on Oncoral are encouraging since they indicate a future potential safe and efficient oral administration route of irinotecan. 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”, said Carl Bjartmar, MD, PhD, Chief Medical Officer of Ascelia Pharma.

PRESS RELEASE

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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