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PRESS RELEASE

Two studies finalized in Oasmia Pharmaceutical's Docecal programme

Oasmia Pharmaceutical AB (NASDAQ: OASM) reports on the results from the two clinical studies using Docecal in patients with metastatic breast cancer.

Docecal is a newly developed formulation of docetaxel – the active substance in the well established cancer drug Taxotere®. Docecal is free from ethanol as well as from polysorbate. Polysorbate is an additive that has been connected to serious adverse events.

Oasmia Pharmaceutical AB has since 2016 been conducting two clinical studies with Docecal; a pharmacokinetic phase I study and a first Phase II-/safety study. Both studies compare Docecal and Taxotere® and the treatment of total 230 patients was done at 17 clinical sites in five countries.

In the pharmacokinetic phase I study, all patients received one dose of Docecal and one dose of Taxotere® in a cross-over-design. The study indicates that Docecal is bioequivalent with Taxotere ® (AUC0-last and Cmax) with regards to the total fraction of docetaxel in plasma.
The fraction of docetaxel not bound to plasma proteins was low already during the infusion for both Docecal and Taxotere®. Generally, this fraction was often below detection limit at timepoints later than half an hour after end of infusion. No unexpected adverse events were reported in the study.

In parallel with this phase I study, Oasmia conducted the phase II/safety study in 200 patients with metastatic breast cancer in order to evaluate the comparability between Docecal and Taxotere® with regard to safety and anti-cancer efficacy measured as objective tumor response. The patients were treated with doses of 100 mg/m2 for six cycles of either Docecal without premedication or Taxotere® with standard mandated premedication.

Safety: There were fewer side effects as well as serious side effects reported for Docecal compared to Taxotere® during the study. The nature of the serious side effects was as expected, these were mainly; neutropenia (Docecal, 52%; Taxotere®, 83%), leukopenia (Docecal, 15%; Taxotere®, 27%) and febrile neutropenia (Docecal, 14%; Taxotere®, 23%). Infusion site reactions were more common in the Docecal group where approximately 28% of the patients experienced this side effect and no

patients in the Taxotere® group. The majority of these infusion site reactions were not serious.

Efficacy: The results from the main analysis, where the best overall objective tumor response during the study has been compared, show that non-inferiority with respect to efficacy could not be determined for Docecal. Additional statistical analyses have been performed to compare the efficacy between the drugs after finalization of the treatment for the patients that completed all six cycles. The result from this additional analysis shows that Docecal met non-inferiority compared to Taxotere within the pre-defined limits. This profile indicates that a dose adjustment can be motivated to extract the optimal benefit/risk profile for this new nanoparticle formulation of docetaxel. It should be noted that the measure of tumor response provides a first indication of drug efficacy but does not always conform with progression-free or total survival.

In summary, the results from the studies show that Docecal has a bioequivalent pharmacokinetic profile to Taxotere®, that Docecal causes less side effects and that the efficacy measured as objective response rate is comparable at a later timepoint than defined in the main analysis in the study protocol.

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About Docecal
Docecal is a novel formulation of the best selling cytostatic product through all times, Taxotere®, marketed by Sanofi. The main indications are breast-, head and neck-, stomach, prostate- and non-small cell lung cancer. Docecal is a nanoparticle and water-soluble formulation whis is free from ethanol and polysorbate and does not require pre-medication. The composition of the excipient that has been used in the development of Docecal differs from the composition used in Oasmia's other drug candidates including the market approved Apealea. The excipient in Docecal contains only one component (XMeNa) instead of two (XMeNa/13XMeNa) used in other products. XMeNa alone has been shown to be as efficient for solubilisation of docetaxel via micell formation as the previously developed two component composition.

About Oasmia Pharmaceutical AB
Oasmia Pharmaceutical AB develops, manufactures, markets and sells new generations of drugs in the field of human and veterinary oncology. The company's product development aims to create and manufacture novel nanoparticle formulations and drug-delivery systems based on well-established cytostatics which, in comparison with current alternatives, show improved properties, reduced side-

effects, and expanded applications. The company’s product development is based on its proprietary in-house research and company patents. Oasmia is listed on NASDAQ Capital Markets (OASM.US), Frankfurt Stock Exchange (OMAX.GR, ISIN SE0000722365) and NASDAQ Stockholm (OASM.ST).