Xspray Pharma announces positive clinical data for the drug candidate HyNap-Sora

STOCKHOLM – February 18, 2019. Xspray Pharma AB today announced the results of a clinical Phase I pilot study with its HyNap-Sora drug candidate. The study examined HyNap-Sora's bioavailability compared to the sorafenib cancer drug, currently marketed as Nexavar® for the treatment of unresectable hepatocellular carcinoma and advanced renal cell carcinoma. Both investigated HyNap compositions demonstrated significantly increased bioavailability. The variability between subjects in AUC and Cmax was reduced to half compared to Nexavar for one of the HyNap-Sora formulations.

In the completed Phase I clinical trial in 14 healthy subjects, bioavailability of two different formulations of HyNap-Sora was assessed in comparison with Nexavar. The results are positive and the study achieved its primary purpose to show increased bioavailability compared to the originator product. In addition, and as shown in earlier studies with Xspray's lead product candidate, HyNap-Dasa, the study also showed reduced between subject variability.

"Sorafenib has a very different pharmacokinetic profile than our product candidates based on nilotinib and dasatinib. Therefore, I'm very pleased that we achieved the primary purpose of this study with sorafenib which enables continuation of the development program. It confirms and strengthens our belief that HyNap formulations of PKIs have the potential to improve both present and upcoming products with poor solubility, improving efficacy and safety enhancing patients' quality of life during this type of therapy," says Per Andersson, CEO of Xspray.

The clinical results in summary:

• The HyNap formulations were administered at half the dose compared to Nexavar to account for expected increase in bioavailability

• Area under the curve (AUC) was approximately 80 % for the HyNap-Sora formulations compared to Nexavar, indicating that the bioavailability of Sorafenib from HyNap-Sora was 1.6-fold higher

• The maximum concentration of Sorafenib in plasma (Cmax) was approximately 95 % compared to Nexavar.

• The variability between subjects in AUC and Cmax was reduced to half compared to Nexavar for one of the HyNap-Sora formulations.

Sorafenib is a compound with low aqueous solubility and low bioavailability from the sorafenib tablet (Nexavar). The present study demonstrates that the HyNap technology can increase the extent of absorption of sorafenib and reduce between subject variability by improving the solubility.

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About Xspray Pharma

Xspray Pharma AB (publ) is a product development company with several product candidates in clinical development. Xspray Pharma uses its innovative patented RightSize technology to develop improved generic versions of marketed drugs, primarily protein kinase inhibitors (PKIs) for the treatment of cancer. The segment is the second-largest in the field of oncology and drug prices are high. Through its innovative technology, Xspray Pharma's strategy is, through outlicensing to an appropriate pharmaceutical company, to enter the market as first competitor to the original drugs before the exclusivity from secondary patents expires. Three PKIs have been identified as the initial product candidates (HyNap-Dasa, HyNap-Sora and HyNap-Nilo). Xspray Pharma's goal is to have up to seven products ready for launch in the US market, where the first product to launch in 2021 will be HyNap-Dasa. The substance patents for Sprycel®(dasatinib)*, expire in 2020 and the secondary patents expire in 2026, which can give Xspray Pharma's HyNap-Dasa a five-year period of special position before other competitors get access to the market. The company has patented manufacturing technology, equipment and the resulting products. The shares in Xspray Pharma are traded on Nasdaq First North Stockholm.

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