Press release
Stockholm, 9 September 2018

Xspray Pharma announces positive clinical data for its lead product candidate HyNap-Dasa

STOCKHOLM – September 9, 2018. Xspray Pharma AB (Nasdaq First North: XSPRAY) today announces positive data from a clinical bioequivalence study with the company's lead product candidate HyNap-Dasa. The study results confirmed its primary aim to show bioequivalence of an optimized formulation of HyNap-Dasa compared to Sprycel®. The data will be instrumental in the design of the planned registration study for an ANDA application.

The completed clinical Phase I study examined HyNap-Dasa's bioavailability compared to the dasatinib cancer drug, currently marketed as Sprycel for the treatment of chronic myeloid leukemia (CML). In the study, bioavailability of two different tablet formulations of HyNap-Dasa was tested in comparison with Sprycel tablets in 16 healthy subjects. The results are very positive and confirm the validity of Xspray's patented formulation technology. The planned studies required to take HyNap-Dasa to final registration studies will now be performed as planned. The results also strengthen the potential for additional product candidates in the pipeline being developed with the same technology to reach the market.

"I am happy to see that the data so strongly confirm our technology. The outcome of this study represents an important milestone for Xspray Pharma as it means that we now can initiate the preparation of the pivotal phase of the clinical program, taking us closer to a commercial launch of HyNap-Dasa. Furthermore, the results pave the way also for additional product candidates in our pipeline. It signifies a new and important step in our development as a company" said Per Andersson, CEO of Xspray Pharma.

The clinical results in summary:
The study compared the pharmacokinetic parameters Cmax and AUC for the originator product Sprycel® and two different HyNap tablet formulations of dasatinib. Sixteen healthy volunteers received single doses of each product in a cross-over design. Although this study was not powered to demonstrate formal bioequivalence, an analysis of preliminary data indicate that bioequivalence with Sprycel was achieved for one of the HyNap formulations. The results demonstrate a high likelihood that formal bioequivalence will be achieved in an adequately powered study.

Sprycel® is a registered trademark of Bristol-Myers Squibb.

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About Xspray Pharma

Xspray Pharma AB (publ) is a product development company with several product candidates in clinical development. Xspray uses its innovative patented RightSize technology to develop improved as well as generic versions of marketed cancer 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 very high. Through its innovative technology, Xspray may 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) where the first product (HyNap-Dasa). Xspray's goal is to have up to seven products ready for launch in the US market, with a first product launch by 2021. The company has patented manufacturing technology, equipment and the resulting products. The company's Certified Adviser is Redeye AB, www.redeye.se.

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