Xspray Pharma's HyNap-Dasa Shows Formal Bioequivalence

STOCKHOLM, SWEDEN – October 10, 2018. Xspray Pharma (Nasdaq First North: XSPRAY) can today present data confirming formal bioequivalence for the company's lead product candidate, HyNap-Dasa, compared to Sprycel® (dasatinib).

"It has taken us three years of work to come to these encouraging results and the excitement in the company is clearly present today. We will now take serious steps in order to develop the business and as our technology is now proven we will seek partners for the commercial launch of HyNap-Dasa", says Per Andersson, CEO of Xspray Pharma.

Xspray Pharma today presents the final results of the completed analysis of full data from the clinical bioequivalence study with the company's lead product candidate HyNap-Dasa. The study results confirm bioequivalence for an optimized formulation of HyNap-Dasa and strengthen the conclusions based on preliminary data early September this year.

The confirmed study results will be instrumental in the design of the company's planned registration study and the U.S. ANDA-application (*Abbreviated New Drug Application*) for HyNap-Dasa.

"I am pleased to see that the study results so firmly support our technology, creating a solid ground for our other product candidates to reach the market." says Per Andersson.

The clinical results in summary:

- Total bioavailability of dasatinib from the two studied formulations of HyNap-Dasa, measured as the area under the curve (AUC), was 9 and 8% higher compared to Sprycel, respectively (AUC-ratio was 1.09 and 1.08 and the confidence intervals C.I. 95-126% and 94-124%, respectively).
- Maximal concentration of dasatinib in plasma, Cmax, was 4% lower for one formulation of HyNap-Dasa and 2% higher for the other compared to Sprycel (Cmax-ratio was 0.96 and 1.02 and the confidence intervals C.I. 81-114% and 86-120%, respectively)
- The results show that formal bioequivalence (Cmax and AUC in the range 80-125% of the original drug) has been achieved for one formulation, even though the study was not dimensioned for this. Therefore, in a forthcoming registration study with an adequate number of subjects, the probability of achieving formal bioequivalence will be very high.

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

For further information, please contact:
Per Andersson, CEO, Xspray Pharma AB

Mobile: +46 (0) 706 88 23 48

Email: per.andersson@xspray.com

Xspray Pharma in short

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 drugprices 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 six-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. The company's Certified Adviser is Redeye AB, www.redeye.se.