Press release

# Xspray Pharma announces positive clinical data for its HyNap-dasatinib product candidate, HyNap-Dasa

**STOCKHOLM – June 16, 2017. Xspray Pharma AB today released the results of a clinical study in which its product candidate, HyNap-Dasa, demonstrated the ability to eliminate the clinically relevant pH-dependency of an important anti-cancer drug, dasatinib. The drug is currently being marketed for treatment of chronic myeloid leukemia (CML).**

Xspray Pharma AB today announced that its lead product candidate, HyNap-Dasa, demonstrated the ability to eliminate the clinically relevant pH dependent of dasatinib in a Phase I clinical trial.

Xspray Pharma AB is a clinical stage product development company that utilizes its innovative HyNap technology to develop improved and generic versions of marketed anti-cancer products. Xspray's lead product candidate, HyNap-Dasa, is being developed as an improved version of a leading dasatinib product indicated for treatment of CML. HyNap-Dasa has the potential to reach the US market in 2020.

One of the drugs being marketed for treatment of CML – SPRYCEL® – reported global sales in 2016 exceeding 1.8 billion USD of which US sales were close to 1 billion USD. As disclosed in SPRYCEL® labelling, one of the challenges is that the uptake is dependent on the patient's gastric acidity. Reduced gastric acidity (increased pH) dramatically decreases dasatinib´s solubility and absorption. Previous studies with acid reducing agents (ARAs) have shown that dasatinib's absorption measured as area under the curve (AUC), decreased by 61% and 43% using leading ARAs famotidine and omeprazole, respectively. SPRYCEL® is a trademark of Bristol-Meyers Squibb Company. Xspray Pharma AB is not affiliated with, sponsored by, or endorsed by Bristol-Meyers Squibb Company.

In the completed Phase I clinical trial in 16 healthy subjects, HyNap-Dasa given with or without the acid reducing agents omeprazole demonstrated bioequivalence by showing less than 2% difference in absorption measured as AUC.

Highlights from the clinical data include:

- Absorption of dasatinib from HyNap-Dasa was equal before and after omeprazole treatment measured as area under the curve, AUC (AUC-ratio was 0.98 and C.I. 87 - 120%).
- Dasatinib´s maximum concentration (Cmax) was equal before and after omeprazole treatment (Cmax-ratio was 0.98 and C.I. 81 - 128%).
- The PK profile of HyNap-Dasa was shown not to be influenced by omeprazole treatment.

"We are extremely pleased with the clinical results obtained and believe that these data will support our further development of HyNap-Dasa as a product with clinically relevant benefits compared to available dasatinib products," stated Per Andersson, Chief Executive Officer. Mr. Andersson continued, "The results of this clinical trial also confirmed that our HyNap technology may not only address the food effect as shown in the previous clinical study with HyNap-Nilo (nilotinib) but also the important pH

dependent absorption frequently encountered for orally administered PKI drugs in targeted cancer therapy."

Mikael von Euler, clinical advisor to Xspray, who has held leading clinical positions for 4 of today's marketed PKIs at 3 different big pharma companies said: "I am impressed with the results of this study showing the ability of the HyNap technology to eliminate the clinically important drug-drug interaction between PKIs and omeprazole. There are currently 34 PKI anti-cancer products on the market, and more than 300 in clinical development. I believe HyNap formulations of PKIs have the potential to improve both present and upcoming products´ profiles improving safety and enhancing patients' quality of life during this type of therapy."

**ABOUT PKIs:**
Protein kinase inhibitors (PKI) is a break-through class of compounds commonly used in the treatment of cancer. However, since many PKIs exhibit pH-dependent solubility, concomitant use of acid-reducing agents (ARAs) that suppress gastric acidity can impair their absorption. Acid-reducing agents, most notably proton pump inhibitors (PPIs) such as e.g. omeprazole, are the most commonly prescribed medications in North America and Western Europe and are also readily available over-the-counter.

On average one third of all cancer patients and two thirds of patients with gastrointestinal tumors frequently take ARAs to alleviate symptoms of gastroesophageal reflux disease. Such co-administration raises the risk of decreasing the absorption of their anticancer medication leading to undesirable clinical consequences including subsequent failure of therapy.

According to the drug label for SPRYCEL®, the concomitant use of H2 antagonists such as e.g. famotidine or PPIs such as e.g. omeprazole is not recommended as it significantly decreases dasatinib absorption.

**For more information, please contact**:
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