



## Successful production start for HyNap-Dasa in Xspray's unique full-scale production line

STOCKHOLM – June 27, 2019. Xspray Pharma (Nasdaq First North: XSPRAY) today announced that the first of two full-scale production lines, producing the company's amorphous formulation on a commercial scale, is now installed and tested in Milan, Italy. This means that the development of the company's first product candidate HyNap-Dasa, an amorphous version of Sprycel® (dasatinib), is proceeding according to plan.

Xspray Pharma's production process at NerPharma in Milan, Italy, is developed for commercial production of drugs formulated with the company's HyNap technology. The production facility is expected to receive official approval from the Italian pharmaceutical authority, AIFA, during the fourth quarter of 2019, which means that the material produced can be used in the company's pivotal studies.

"The new production line in Milan is an important scale-up that represents a significant milestone for Xspray. In addition to being the first in the world to be able to run full-scale commercial production of HyNap material, right now with a focus on HyNap-Dasa, the cost of future products is reduced considerably as we now can produce material for clinical studies directly on a full scale", said Per Andersson, CEO of Xspray.

The now installed production line will initially be used for GMP production of amorphous material for pivotal studies with HyNap-Dasa. The produced amorphous material and the finished tablets will be evaluated in stability studies according to the regulatory requirements. All in all, this means that the company expects to submit a so-called ANDA (Abbreviated New Drug Application) application for HyNap-Dasa to the US Food and Drug Administration (FDA) in mid 2020. Market launch is expected to take place during 2021, according to plan.

"It is very gratifying that we run according to plan production-wise and that we are continuously taking the steps required to prepare our ANDA application. The second production line will be installed during the autumn. It will be used for our product candidates HyNap-Sora and HyNap-Nilo and to prepare for upcoming product candidates developed from our unique platform technology," said Per Andersson.

### For further information, please contact:

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### About Xspray Pharma

Xspray Pharma AB (publ) is a product development company with multiple product candidates in clinical development. Xspray uses its innovative, patented RightSize technology to develop improved and generic versions of marketed drugs, primarily protein kinase inhibitors (PKIs) for the treatment of cancer. The segment is the second largest in oncology, and drug prices are very high.

The company's innovative technology allows Xspray Pharma to gain entry as the first competitor to today's original drugs before the secondary patents expire. Xspray's goal is to become the leader in the development of improved drugs or generic versions of PKIs already marketed for the treatment of cancer, which numbered 39 in 2018. The company's leading product candidates, HyNap-Dasa, HyNap-Sora and HyNap-Nilo, are stable amorphous versions of the three blockbuster cancer drugs Sprycel® (dasatinib), Nexavar® (sorafenib) and Tassigna® (nilotinib), respectively. The launch of the first product candidate, HyNap-Dasa, is planned to take place in 2021. The substance patent for the original drug Sprycel® (dasatinib) expires at the end of 2020, and the secondary patents in 2026, which offers Xspray's HyNap-Dasa a period of five years of semi-exclusivity before other competitors gain 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.

[www.xspraypharma.com](http://www.xspraypharma.com)

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