



Press release
Solna, 21 December, 2017

Xspray Pharma enters Manufacturing Agreement with NerPharMa for its lead product candidate; HyNap-Dasa

Xspray Pharma AB, a specialty pharmaceutical company, today announced that it has signed a Manufacturing and Supply Agreement with NerPharMa S.r.l., a pharmaceutical manufacturing company in Milan, Italy, to manufacture its lead product candidate HyNap-Dasa. The agreement covers the clinical and world-wide commercial supply of HyNap-Dasa, and includes production of both drug substance and the finished product. HyNap-Dasa is one of three product candidates that Xspray currently has under development. The company's goal is to launch HyNap-Dasa in the US-market in 2021.

Under the terms of the agreement, Xspray has contracted NerPharMa to manufacture drug substance and the finished product to supply material for clinical programs and for future world-wide commercial sales. Xspray is developing HyNap-Dasa both as a completely interchangeable variant of Sprycel to be registered in the United States by the Abbreviated New Drug Application (ANDA) route or as an improved product by the 505(b)(2) procedure. NerPharMa is a pharmaceutical manufacturing company and a subsidiary of Nerviano Medical Sciences S.r.l., Milan, Italy.

NerPharMa's GMP manufacturing facility is approved by both the Italian Medicines Agency (AIFA), the national authority responsible for drug regulation in Italy, and the U.S. Food and Drug Administration (FDA).

"This contract is a significant step in our development of HyNap-Dasa," said Per Andersson, CEO of Xspray Pharma. "We are pleased to have secured access to GMP production of drug substance and finished product for our continued clinical program as well as to GMP quantities of HyNap-Dasa for future commercial activities in an US FDA approved manufacturing facility."

"We are pleased to be working with Xspray Pharma to manufacture and provide finished product for their investigational and commercial needs," said Angelo Colombo, CEO of NerPharMa.

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About Xspray Pharma

Xspray Pharma AB (publ) is a product development company with several product candidates under clinical development. Xspray uses its innovative RightSize-technology in order to develop improved and generic versions of already marketed cancer drugs, primarily protein kinase inhibitors (PKI), for treating cancer. The segment is the second largest within the oncology department and the drug prices are very high. Through its innovative technology, Xspray can enter the market as first competitor to the original drugs available today without the hindrance of secondary patents. Xspray's goal is to have three products ready for launch on the American market during the period 2020-2023, with a first product launched at the latest by 2021. The company has patents on production technology, equipment and the resulting products. The shares in Xspray Pharma (publ) are traded on Nasdaq First North Stockholm and Redeye is the Certified Adviser for the company.

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