

Xspray strengthens the value of the product portfolio with patent protection for tablet of dasatinib propylene glycol solvate

Xspray Pharma AB (Nasdaq Stockholm: XSPRAY) announces today that the Company has received a Notice of Allowance from the United States Patent and Trademark Office (USPTO) regarding its patent application for tablets containing dasatinib propylene glycol solvate (dasatinib PG). When issued this patent will significantly strengthen Xspray's IP rights and means that any possible future generic products based on dasatinib PG, must consider Xspray's patents before entering the market.

Xspray's patent application relates to a tablet formulation that contains dasatinib PG. The patent is significant in Xspray's commercialization strategy where all future launches of generic products in tablet form based on dasatinib PG, must consider Xspray's patent. Receipt of the "Notice of Allowance" means that the USPTO will issue a U.S. patent to Xspray based on its pending application once Xspray pays the issue fee. Once paid, Xspray expects issuance of the patent in September. The patent will be Xspray's eighth patent for dasatinib in the U.S.

"It is very gratifying that our patent strategy results in receiving this Notice of Allowance. The U. S. patent will cover tablet products containing dasatinib PG. We make the assessment that any company planning to launch a product based on this form of dasatinib must consider Xspray's patent. We are currently aware of at least one such company. This increases the value of our product portfolio and strengthens our negotiating position, both towards the original company and the generic companies, when seeking commercialization opportunities for HyNap-Dasa," comments Per Andersson, CEO of Xspray.

This patent concerning the tablet of dasatinib PG is the result from the work and know-how Xspray has gained from developing HyNap-Dasa, an amorphous form of dasatinib.

"We work continuously to secure the entire dasatinib market value as we do for all the products we develop. This has now resulted in a patent that potentially can change the generic landscape for dasatinib, and it adds substantial value to our two dasatinib product candidates in our product portfolio, HyNap-Dasa and HyNap-Dasa improved, that we are currently progressing", continues Per Andersson.

Xspray's HyNap-Dasa is a stable amorphous version of the anti-cancer drug Sprycel (dasatinib) that are currently being developed in two versions. First, a generic version for which the Company plans to file an ANDA, and thereafter an improved version which will follow the 505(b)(2) regulatory pathway. Bristol Meyer Squibb's Sprycel® (dasatinib) is today approved for treatment of chronic myeloid leukemia (CML) and acute lymphoblastic leukemia (ALL) with reported global sales of USD 2.1 billion in 2019 of which U.S. sales represented USD 1.2 billion.

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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 to 54 in December 2019. 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 Tasisign® (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 Stockholm.

www.xspraypharma.com

This information is information that Xspray Pharma AB is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact persons set out above, at 2020-08-18 15:50 CEST.

Attachments

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