Press Release
Stockholm June 17, 2022

Dasynoc granted Orphan Drug Designation in the US for the treatment of chronic myeloid leukemia

Xspray Pharma (Nasdaq Stockholm: Xspray) today announced that the US Food and Drug Administration (FDA) has granted Dasynoc Orphan Drug Designation (ODD) in the US for the treatment of chronic myeloid leukemia (CML).

The FDA decision to grant the designation is based on the plausible hypothesis that Dasynoc may be clinically superior to the same drug(s) already approved for the same indication because Xspray Pharmas product candidate may provide a major contribution to patient care due to the gastric pH-resistant qualities of its formulation and in the context of significant concomitant use of acid reducing agents in the CML population.

“We are very pleased that our product candidate Dasynoc has been granted this orphan drug designation. This is our second product candidate to be granted this designation and it confirms both our technology and the unmet medical need that Xspray Pharma can address. This strengthens us in our goal to work with improved oncology pharmaceuticals and to provide patients a better quality of life”, said Per Andersson, CEO of Xspray Pharma.

Dasynoc is Xspray Pharmas first product candidate and is currently under FDA review for approval. The FDA grants ODD status to medicines and potential new medicines intended for the treatment, diagnosis or prevention of rare diseases or disorders that affect fewer than 200,000 people in the US.

Chronic myeloid leukemia – CML
CML is a type of blood cancer where the body produces malignant white blood cells. Almost all patients with CML have an abnormality known as the "Philadelphia chromosome," which produces a protein called BCR-ABL. This protein aids the proliferation of malignant white blood cells in affected patients. About 15% of all leukemia is CML. In 2020 it was projected that 8,450 people in the US would be diagnosed with CML and in 2017, there were an estimated 58,000 people living with the disease in the US.

For further information, please contact:

Christina Malmberg Hägerstrand
Senior Vice President Communications & Investor Relations
Xspray Pharma AB
Mob: +46 (0) 72 855 93 29
E-mail: christina.malmberg.hagerstrand@xspray.com

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About Xspray Pharma

Xspray Pharma AB (publ) is a pharmaceutical company with several product candidates in clinical development. Xspray Pharma uses its innovative, patented RightSize™ technology to develop improved 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 of PKIs already marketed for the treatment of cancer, which numbered to 72 in the end of 2021.

The company has patented manufacturing technology, equipment, and the resulting products. The shares in Xspray Pharma are traded on Nasdaq Stockholm (Nasdaq Stockholm: XSPRAY). 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 2022-06-17 08:50 CEST.

Attachments

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