Press Release
Stockholm November 30, 2022

Xspray Pharma's drug candidate XS004 granted orphan drug designation in the US for the treatment of acute lymphoblastic leukemia

Xspray Pharma (Nasdaq Stockholm: Xspray) has today received a decision from the US Food and Drug Administration (FDA) granting drug candidate XS004 (dasatinib) Orphan Drug Designation (ODD) for the treatment of acute lymphoblastic leukemia (ALL).

The FDA decision is based on the potential that XS004 may be clinically superior to other drugs already approved for the same indication. Xspray Pharma's product candidate may provide a major contribution to patient treatment due to the gastric pH-resistant qualities of the formulation and the significant frequency of concomitant use of acid-reducing agents in the ALL population.

“We are pleased that our product candidate XS004 has now been granted orphan drug designation for ALL. It is the second indication where XS004 has been granted this status, further validating our technology and the unmet medical need that Xspray Pharma can address. This strengthens us in our objective to work with improved oncology pharmaceuticals that can give cancer patients a better quality of life," says Per Andersson, CEO of Xspray Pharma.

In June of this year, the FDA granted orphan drug designation status for XS004 (dasatinib) for the treatment of chronic myeloid leukemia (CML). XS004 is Xspray Pharma's first product candidate currently undergoing FDA review for market approval. The FDA grants orphan drug designation status to potential new drug candidates intended for the treatment, diagnosis, or prevention of rare diseases or disorders that affect fewer than 200,000 people in the United States.

"It is very gratifying that the FDA has recognized the potential for improvement in XS004 as a significant improvement in patients' quality of life. Xspray will attend the annual international hematology congress organized by the American Society of Hematology (ASH) this year and will present two scientific posters that may be relevant to the treatment of patients with ALL and CML” says Thomas Walz, CMO of Xspray Pharma.

Acute lymphocytic leukemia - ALL
ALL is an acute form of cancer caused by rapid growth of immature lymphocytes (lymphoblasts) in the bone marrow due to various genetic changes. In 2022, it was estimated that 6,660 people in the United States would be diagnosed with ALL and it is estimated that approximately 100,000 people in the United States have this diagnosis.

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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

Attachments

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