Xeris Biopharma Enters Into an Exclusive Worldwide License Agreement for Xerijject® Formulation of Teprotumumab

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CHICAGO--(BUSINESS WIRE)--Jan. 10, 2024-- Xeris Biopharma Holdings, Inc. (Nasdaq: XERS), a growth-oriented biopharmaceutical company committed to improving patient lives by developing and commercializing innovative products across a range of therapies, today announced that it has entered into an exclusive worldwide license agreement for Amgen to develop, manufacture, and commercialize a subcutaneous formulation of teprotumumab using Xeris' XeriJect® technology in Thyroid Eye Disease (TED) - a serious, progressive and potentially vision-threatening rare autoimmune disease. Teprotumumab-trbw is known as TEPEZZA® in the United States.

"We are very excited that our partner is moving forward with licensing the XeriJect technology to further the development of the XeriJect subcutaneous teprotumumab to potentially enhance the patient experience and delivery of the treatment for Thyroid Eye Disease. This agreement to license XeriJect further validates the potential value of our technology to enable large molecule subcutaneous injections that provide a more patient friendly regimen that is effective, safe, and more convenient, with potential for improved adherence," said Paul R. Edick, Chairman and CEO of Xeris. "We will move quickly to support our partner in this important development program."

Under the terms of the License Agreement, Xeris has the potential to receive $75 million in development and regulatory milestones, plus sales-based milestones, as well as escalating single-digit royalties based on future sales of TEPEZZA using the XeriJect technology.

About XeriJect®

XeriJect formulations are innovative, ready-to-use, viscoelastic pharmaceutical suspensions that have the potential to improve drug delivery, lower treatment burden and improve patients' lives across a broad range of therapeutic categories. XeriJect suspensions maximize drug loadings at >400mg/mL, enable small volume subcutaneous injections and do not settle on storage. The suspensions use FDA-approved excipients and leverage known manufacturing processes. XeriJect formulation technology is well suited for drugs and biologics including large molecules such as proteins, monoclonal antibodies, and vaccines. The technology is protected by an extensive patent estate, trade secrets and know-how, and it is available for licensing.

About Xeris

Xeris (Nasdaq: XERS) is a growth-oriented biopharmaceutical company committed to improving patients' lives by developing and commercializing innovative products across a range of therapies. Xeris has three commercially available products; Gvoke®, a ready-to-use liquid glucagon for the treatment of severe hypoglycemia, Keveyis®, for a proven therapy for primary periodic paralysis, and Recorlev® for the treatment of endogenous Cushing's syndrome. Xeris also has a robust pipeline of development programs to extend the current marketed products into important new indications and uses and bring new products forward using its proprietary formulation technology platforms, XeriSol™ and XeriJect®, supporting long-term product development and commercial success.

Xeris Biopharma Holdings is headquartered in Chicago, IL. For more information, visit www.xerispharma.com, or follow us on X, LinkedIn, or Instagram.

Forward-Looking Statements

Any statements in this press release other than statements of historical fact are forward-looking statements. Forward-looking statements include, but are not limited to, statements about future expectations, plans and prospects for Xeris Biopharma Holdings, Inc., including the development and potential of XeriJect® subcutaneous TEPEZZA®, the expectations regarding future product development efforts between Xeris and Amgen, Xeris' potential entitlements to milestone and royalty payments from Amgen, the potential utility of its formulation platforms such as XeriJect, the market and therapeutic potential of its products and product candidates, and other statements containing the words "will," "would," "continue," "expect," "should," "anticipate" and similar expressions, constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. These forward-looking statements are based on numerous assumptions and assessments made in light of Xeris' experience and perception of historical trends, current conditions, business strategies, operating environment, future developments, geopolitical factors and other factors it believes appropriate. By their nature, forward-looking statements involve known and unknown risks and uncertainties because they relate to events and depend on circumstances that will occur in the future. The various factors that could cause Xeris' actual results, performance or achievements, industry results and developments to differ materially from those expressed in or implied by such forward-looking statements, include, but are not limited to, its financial position and need for financing, including to fund its product development programs or commercialization efforts, whether its products will achieve and maintain market acceptance in a competitive business environment, its reliance on third-party suppliers, including single-source suppliers, its reliance on third parties to conduct clinical trials, the ability of its product candidates to compete successfully with existing and new drugs, and its and collaborators' ability to protect its intellectual property and proprietary technology. No assurance can be given that such expectations will be realized and persons reading this communication are, therefore, cautioned not to place undue reliance on these forward-looking statements. Additional risks and information about potential impacts of financial, operational, economic, competitive, regulatory, governmental, technological, and other factors that may affect Xeris can be found in Xeris' filings, including its most recently filed Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission, the contents of which are not incorporated by reference into, nor do they form part of, this communication. Forward-looking statements in this communication are based on information available to us, as of the date of this communication and, while we believe our assumptions are reasonable, actual results may differ materially. Subject to any obligations under applicable law, we do not undertake any obligation to update any forward-looking statement whether as a result of new information, future developments or otherwise, or to conform any forward-looking statement to actual results, future events, or to changes in expectations.

About TEPEZZA

INDICATION

TEPEZZA is indicated for the treatment of Thyroid Eye Disease regardless of Thyroid Eye Disease activity or duration.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Infusion Reactions: TEPEZZA may cause infusion reactions. Infusion reactions have been reported in approximately 4% of patients treated with TEPEZZA. Reported infusion reactions have usually been mild or moderate in severity. Signs and symptoms may include transient increases in blood pressure, feeling hot, tachycardia, dyspnea, headache, and muscular pain. Infusion reactions may occur during an infusion or within 1.5 hours after an infusion. In patients who experience an infusion reaction, consideration should be given to premedicating with an antihistamine, antipyretic, or corticosteroid and/or administering all subsequent infusions at a slower infusion rate.

Preexisting Inflammatory Bowel Disease: TEPEZZA may cause an exacerbation of preexisting inflammatory bowel disease (IBD). Monitor patients with IBD for flare of disease. If IBD exacerbation is suspected, consider discontinuation of TEPEZZA.

Hyperglycemia: Increased blood glucose or hyperglycemia may occur in patients treated with TEPEZZA. In clinical trials, 10% of patients (two-thirds of whom had preexisting diabetes or impaired glucose tolerance) experienced hyperglycemia. Hyperglycemic events should be controlled with medications for glycemic control, if necessary. Assess patients for elevated blood glucose and symptoms of hyperglycemia prior to infusion and continue to monitor while on treatment with TEPEZZA. Ensure patients with hyperglycemia or preexisting diabetes are under appropriate glycemic control before and while receiving TEPEZZA.

Hearing Impairment Including Hearing Loss: TEPEZZA may cause severe hearing impairment including hearing loss, which in some cases may be permanent. Assess patients' hearing before, during, and after treatment with TEPEZZA and consider the benefit-risk of treatment with patients.

ADVERSE REACTIONS

The most common adverse reactions (incidence ≥5% and greater than placebo) are muscle spasm, nausea, alopecia, diarrhea, fatigue, hyperglycemia, hearing impairment, dysgeusia, headache, dry skin, weight decreased, nail disorders, and menstrual disorders.

Please see Full Prescribing Information or visit TEPEZZAhcp.com for more information.

View source version on businesswire.com: https://www.businesswire.com/news/home/20240109335095/en/

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