Xeris Biopharma Announces Research Collaboration and Option Agreement With Horizon Therapeutics plc for XeriJect™ Formulation of Teprotumumab

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Xeris to develop an ultra-concentrated, ready-to-use, subcutaneous injection of teprotumumab

CHICAGO--(BUSINESS WIRE)--Nov. 23, 2022-- 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 a research collaboration and option agreement with Horizon Therapeutics plc (Nasdaq: HZNP). Under the terms of the agreement, Xeris will use its proprietary formulation technology platform, XeriJect™, to develop an ultra-concentrated, ready-to-use, subcutaneous injection of teprotumumab and Horizon will have an option to license the Xeris technology. Teprotumumab is the first and only medicine approved by the U.S. Food and Drug Administration (FDA) for the treatment of Thyroid Eye Disease (TED) – a serious, progressive and potentially vision-threatening rare autoimmune disease. Teprotumumab-trbw is known as TEPEZZA® in the United States. Xeris will receive an upfront payment, and may be entitled to receive development milestones, regulatory milestones, and sales-based milestones, as well as royalties based on future sales if the commercial license option is exercised. Specific financial terms of the agreement were not disclosed.

“We are excited to announce our collaboration with Horizon for the development of a subcutaneous formulation of teprotumumab using our XeriJect technology to potentially enhance the patient experience and delivery of the treatment for Thyroid Eye Disease,” said Paul R. Edick, Chairman and CEO of Xeris. “This partnership demonstrates 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.”

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®, the first and only FDA-approved 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 Twitter, LinkedIn, or Instagram.

Forward-Looking Statements

Any statements in this press release about future expectations, plans and prospects for Xeris Biopharma Holdings, Inc., including the development of a subcutaneous formulation of teprotumumab, the market and therapeutic potential of Xeris’ products and product candidates, expectations regarding clinical data or results from planned clinical trials, the timing of clinical trials, the timing or likelihood of regulatory approval and commercialization of its product candidates, the timing or likelihood of expansion into additional markets, the potential utility of its proprietary formulation technology platforms, the potential to receive milestone payments if Horizon exercises its option and other statements containing the words “will,” “would,” “continue,” 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, 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. Various factors 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, including the impact of COVID-19 on our business operations and clinical activities, our ability to fund our product development programs or commercialization efforts, and whether our products will achieve and maintain market acceptance. No assurance can be given that our expectations will be realized and persons reading this communication are, therefore, cautioned not to place undue reliance on these forward-looking statements. Additional information about economic, competitive, governmental, technological, and other factors that may affect Xeris is set forth in the "Risk Factors" section of the most recently filed Quarterly Report on Form 10-Q filed with the U.S. Securities and Exchange Commission, the contents of which are not incorporated by reference into, nor do they form a part of, this communication. Forward-looking statements in this communication are based upon information available to Xeris, as of the date of this communication and, while believed to be reasonable, actual results may differ materially. Subject to any obligations under applicable law, Xeris does 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.

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 managed with medications for glycemic control, if necessary. Monitor patients for elevated blood glucose and symptoms of hyperglycemia while on treatment with TEPEZZA. Patients with preexisting diabetes should be under appropriate glycemic control before receiving TEPEZZA.

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, 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/20221122005608/en/

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