Horizon Pharma plc Announces Agreement to License Pre-Clinical Uricase Derivative (MEDI4945) from MedImmune

January 8, 2018

Agreement Aims to Further Expand Growing Gout Franchise

DUBLIN, Ireland, Jan. 08, 2018 (GLOBE NEWSWIRE) -- Horizon Pharma plc (NASDAQ:HZNP), today announced that it has licensed the global rights to MEDI4945, a pre-clinical, genetically engineered uricase derivative combined with site-specific PEGylation, from MedImmune, the global biologics research and development arm of AstraZeneca. Under the terms of the agreement, Horizon Pharma will provide MedImmune an upfront cash payment and future payments contingent on MEDI4945 development and sales milestones.

“In addition to our ongoing development of KRYSTEXXA, the licensing of MEDI4945 gives us the potential to extend the future of our gout franchise,” said Timothy P. Walbert, chairman, president and chief executive officer, Horizon Pharma plc. “MEDI4945 provides us with a pre-clinical candidate that, based on initial studies, has the potential for subcutaneous dosing and reduced immunogenicity, which may benefit more patients living with uncontrolled gout.”

About Horizon Pharma plc
Horizon Pharma plc is focused on researching, developing and commercializing innovative medicines that address unmet treatment needs for rare and rheumatic diseases. By fostering a growing pipeline of medicines in development and exploring all potential uses for currently marketed medicines, we strive to make a powerful difference for patients, their caregivers and physicians. For us, it’s personal: by living up to our own potential, we are helping others live up to theirs. For more information, please visit www.horizonpharma.com. Follow @HZNPplc on Twitter, like us on Facebook or explore career opportunities on LinkedIn.

About KRYSTEXXA®
INDICATIONS AND USAGE
KRYSTEXXA® (pegloticase injection) is a PEGylated uric acid specific enzyme indicated for the treatment of chronic gout in adult patients refractory to conventional therapy.

Gout refractory to conventional therapy occurs in patients who have failed to normalize serum uric acid and whose signs and symptoms are inadequately controlled with xanthine oxidase inhibitors at the maximum medically appropriate dose or for whom these drugs are contraindicated.

Important Limitations of Use: KRYSTEXXA is not recommended for the treatment of asymptomatic hyperuricemia.

IMPORTANT SAFETY INFORMATION
WARNING: ANAPHYLAXIS AND INFUSION REACTIONS

Anaphylaxis and infusion reactions have been reported to occur during and after administration of KRYSTEXXA. Anaphylaxis may occur with any infusion, including a first infusion and generally manifests within 2 hours of the infusion. However, delayed-type hypersensitivity reactions have also been reported. KRYSTEXXA should be administered in healthcare settings and by healthcare providers prepared to manage anaphylaxis and infusion reactions. Patients should be premedicated with antihistamines and corticosteroids. Patients should be closely monitored for an appropriate period of time for anaphylaxis after administration of KRYSTEXXA. Serum uric acid levels should be monitored prior to infusions and healthcare providers should consider discontinuing treatment if levels increase to above 6 mg/dL, particularly when 2 consecutive levels above 6 mg/dL are observed.

The risk of anaphylaxis and infusion reactions is higher in patients who have lost therapeutic response.

Concomitant use of KRYSTEXXA and oral urate-lowering agents may blunt the rise of sUA levels. Patients should discontinue oral urate-lowering agents and not institute therapy with oral urate-lowering agents while taking KRYSTEXXA.

In the event of anaphylaxis or infusion reaction, the infusion should be slowed or stopped and restarted at a slower rate.

Patients should be informed of the symptoms and signs of anaphylaxis and instructed to seek immediate medical care should anaphylaxis occur after discharge from the healthcare setting.

CONTRAINDICATIONS: G6PD DEFICIENCY ASSOCIATED HEMOLYSIS AND METHEMOGLOBINEMIA
Patients should be screened patients for G6PD deficiency prior to starting KRYSTEXXA. Hemolysis and methemoglobinemia have been reported with KRYSTEXXA in patients with G6PD deficiency. KRYSTEXXA should not be administered to these patients.

GOUT FLARES
An increase in gout flares is frequently observed upon initiation of anti-hyperuricemic therapy, including treatment with KRYSTEXXA. If a gout flare occurs during treatment, KRYSTEXXA need not be discontinued. Gout flare prophylaxis with a non-steroidal anti-inflammatory drug (NSAID) or colchicine is recommended starting at least 1 week before initiation of KRYSTEXXA therapy and lasting at least 6 months, unless medically contraindicated or not tolerated.

CONGESTIVE HEART FAILURE
KRYSTEXXA has not been studied in patients with congestive heart failure, but some patients in the clinical trials experienced exacerbation. Caution should be exercised when using KRYSTEXXA in patients who have congestive heart failure and patients should be monitored closely following infusion.

ADVERSE REACTIONS
The most commonly reported adverse reactions in clinical trials with KRYSTEXXA were gout flares, infusion reactions, nausea, contusion or ecchymosis, nasopharyngitis, constipation, chest pain, anaphylaxis and vomiting.

Forward-Looking Statements
This press release contains forward-looking statements, including, but not limited to, statements related to the potential benefits of Horizon Pharma's license of MEDI4945, Horizon Pharma's strategy, plans, objectives, expectations and intentions, including with respect to the development of MEDI4945, the timing of a planned Phase 1 clinical trial of MEDI4945; the potential for MEDI4945 to benefit patients with uncontrolled gout and other statements that are not historical facts. These forward-looking statements are based on Horizon Pharma's current expectations and inherently involve significant risks and uncertainties. Actual results and the timing of events could differ materially from those anticipated in such forward looking statements as a result of these risks and uncertainties, which include, without limitation, risks related to Horizon's ability to maintain its license rights with respect to MEDI4945; risks associated with pre-clinical and clinical development, such as the risk that future studies and trials are not initiated or completed on time and the fact that prior pre-clinical results may not predict the outcome of future studies or trials, as well as other risks related to Horizon's business detailed from time-to-time under the caption "Risk Factors" and elsewhere in Horizon Pharma'sSEC filings and reports, including in its Annual Report on Form 10-K for the year ended December 31, 2016 and subsequent quarterly reports on Form 10-Q. Horizon Pharma undertakes no duty or obligation to update any forward-looking statements contained in this press release as a result of new information, future events or changes in its expectations.

Contacts:
Tina Ventura
Senior Vice President, Investor Relations
Investor-relations@horizonpharma.com

Ruth Venning
Executive Director, Investor Relations
Investor-relations@horizonpharma.com

U.S. Media Contact:
Geoffrey Curtis
Senior Vice President, Corporate Affairs and Chief Communications Officer
media@horizonpharma.com

Ireland Media Contact:
Ray Gordon
Gordon MRM
ray@gordonmrm.ie

Primary Logo

Source: Horizon Pharma plc