Horizon Pharma plc Announces Poster Presentation on KRYSTEXXA® (pegloticase injection) at the American Society of Nephrology Kidney Week 2017

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DUBLIN, Ireland, Nov. 03, 2017 (GLOBE NEWSWIRE) -- Horizon Pharma plc (NASDAQ:HZNP), a biopharmaceutical company focused on improving patients' lives by identifying, developing, acquiring and commercializing differentiated and accessible medicines that address unmet medical needs, today presented a post-hoc analysis of data from two randomized, placebo-controlled clinical trials of KRYSTEXXA® (pegloticase injection) in adults living with chronic gout refractory to conventional therapies, also known as uncontrolled gout. In the post-hoc analysis, nearly two-thirds of patients who were serum uric acid (sUA) responders to KRYSTEXXA experienced reductions in mean arterial blood pressure (MAP) throughout the trials. The analysis (*Pegloticase, a Mammalian Uricase, Significantly Decreases Mean Arterial Blood Pressure in Patients with Chronic Gout;* abstract FR-PO582*)* was presented at the American Society of Nephrology (ASN) Kidney Week 2017, Oct. 31 – Nov. 5, in New Orleans.

“People living with uncontrolled gout often have other health conditions that are closely associated with high blood pressure, including chronic kidney disease,” said Richard J. Johnson, M.D., one of the authors of the poster presentation and Professor, Division of Renal Diseases and Hypertension, University of Colorado Denver - Anschutz Medical Campus. “This analysis provides valuable insights into the connections between sUA levels and blood pressure in people living with uncontrolled gout treated with KRYSTEXXA.”

Summary of Study Results
This post-hoc analysis included data from two pivotal, six-month clinical trials in which patients were randomized to treatment with KRYSTEXXA 8 mg every two weeks or placebo. A total of 29 patients who received KRYSTEXXA every two weeks were characterized as sUA responders by the prespecified primary endpoint. MAP for this responder group at baseline was 94.9 + 9.6 mm Hg.

- An assessment of the 29 sUA responders indicated a reduction in MAP throughout the six-month trials and was noted within two weeks of the first KRYSTEXXA dose.
- Of the 29 sUA responders, 18 (62.1 percent) had decreases in MAP throughout the trials.
- Blood pressure reductions seen in sUA responders were independent of changes in renal function (as measured by estimated glomerular filtration rate, or eGFR).
- There were no significant differences in baseline age, gender, race, body mass index (BMI), history of hypertension, gout duration, MAP, baseline sUA, cholesterol, eGFR or urinary uric acid/creatinine ratio between those who experienced persistent decreases in MAP and those who did not.
- There were no significant changes in eGFR in sUA responders and no significant correlation between changes from baseline MAP and eGFR in these patients.

While the studies utilized for this analysis were not designed to evaluate change in MAP as a clinical endpoint, these data support further investigation of KRYSTEXXA in blood pressure reduction.

“These findings add to the growing body of evidence on how the burden of urate may impact people living with uncontrolled gout, including those with other health conditions such as chronic kidney disease and hypertension,” said Jeffrey W. Sherman, M.D., FACP, executive vice president, research and development and chief medical officer, Horizon Pharma plc. “We are committed to continuing to research the full potential of KRYSTEXXA and expand awareness of this innovative treatment option for those suffering from uncontrolled gout.”

Gout is a type of chronic inflammatory arthritis in which uric acid builds up in the blood and can lead to severe pain and joint destruction. Patients with uncontrolled gout continue to have abnormally high levels of uric acid and continued symptoms despite the use of conventional therapies. KRYSTEXXA is the only medicine approved by the U.S. Food and Drug Administration (FDA) for the treatment of uncontrolled gout in adult patients. For more information please visit www.KRYSTEXXAHCP.com.

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.

Horizon Pharma plc
Horizon Pharma plc is a biopharmaceutical company focused on improving patients' lives by identifying, developing, acquiring and commercializing differentiated and accessible medicines that address unmet medical needs. The Company markets 11 medicines through its orphan, rheumatology and primary care business units. For more information, please visit www.horizonpharma.com. Follow @HZNPplc on Twitter, like us on Facebook or view careers on our LinkedIn page.

Forward-Looking Statements
This press release contains forward-looking statements, including, but not limited to, statements related to the potential benefits of KRYSTEXXA, Horizon Pharma's plans to continue research of KRYSTEXXA, 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, the fact that results in future clinical trials may not support better patient outcomes from the use of KRYSTEXXA or be consistent with post-hoc analysis from prior clinical trials, as well as other risks related to Horizon Pharma'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:
Amanda Phraner
Senior Manager, Public Relations and Social Media
media@horizonpharma.com

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

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