Horizon Pharma plc to Present KRYSTEXXA® (pegloticase injection) Data for the Management of Uncontrolled Gout at the 2017 ACR/ARHP Annual Meeting

October 23, 2017

-- Initial data from investigator-initiated TRIPLE study to be presented on Nov. 6 --

-- Horizon Pharma plc to host an investor call on Nov. 9 following the ACR/AHRP Annual Meeting --

DUBLIN, Ireland, Oct. 23, 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, will present data on KRYSTEXXA®(pegloticase injection) at the 2017 ACR/ARHP Annual Meeting, Nov. 3-8, in San Diego. This will be the first presentation of initial data from the investigator-initiated TRIPLE (**T**olerization **R**educes **I**ntolerance to **P**egloticase and Prolongs the Urate **L**owering **E**ffect) study of a KRYSTEXXA tolerizing regimen in patients with chronic gout refractory to conventional therapies, also known as uncontrolled gout. Findings from three additional analyses of KRYSTEXXA will also be presented, as well as a study of Horizon's RAYOS® (prednisone) Delayed-Release Tablets in patients with untreated polymyalgia rheumatic (PMR).

"Our clinical presence at the ACR/ARHP Annual Meeting this year underscores our ongoing commitment to patients suffering from painful and debilitating inflammatory conditions such as uncontrolled gout and polymyalgia rheumatica," said Jeffrey W. Sherman, M.D., FACP, executive vice president, research and development, and chief medical officer, Horizon Pharma plc. "We have participated in multiple follow-on trials with our medicines and continue to actively engage with the medical community to advance the science and ultimately help improve outcomes in people living with uncontrolled gout."

Horizon Pharma will be hosting an investor call on Thursday, Nov. 9, 2017, at 9 a.m. CT to discuss the initial data from the TRIPLE trial presented at the ACR/ARHP Annual Meeting, as well as provide an overview of the gout market, KRYSTEXXA and the Company's comprehensive clinical strategy for the medicine.

KRYSTEXXA is the only medicine approved by the U.S. Food and Drug Administration (FDA) for the treatment of uncontrolled gout in adult patients. In general, 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 gout symptoms despite the use of conventional therapies. For more information please visit www.KRYSTEXXAHCP.com.

Presentation Details:

KRYSTEXXA Data

- *Initial Results of a Clinical Study to Determine Whether a Tolerizing Regimen of Pegloticase Can Increase the Frequency of Subjects Having Sustained Lowering of Serum Urate*

Abstract #: 1141
Authors: K. Saag, M. Feinman, A.J. Kivitz, H.S.B. Baraf, R. Fleischmann, A. Kavanaugh, P.E. Lipsky
Date: Monday, Nov. 6, 2017
Time: 9 a.m.-11 a.m. PT

- **Title:** *Treatment with Pegloticase Significantly Decreases Mean Arterial Blood Pressure in Patients with Chronic Gout*

Abstract #: 2067
Authors: H.K. Choi, R. Johnson, A. Yeo, P. E. Lipsky
Date: Tuesday, Nov. 7, 2017
Time: 9 a.m.-11 a.m. PT

- **Title:** *Evidence-Based Development of Criteria for Complete Response in Patients with Chronic Refractory Gout*

Abstract #: 2070
Authors: N. Schlesinger, P. Khanna, A. Yeo, P. E. Lipsky
Date: Tuesday, Nov. 7, 2017
Time: 9 a.m.-11 a.m. PT

- **Title:** *Rapid Tophus Resolution in Chronic Refractory Gout Patients Treated with Pegloticase*

Authors: B.F. Mandell, H.S.B. Baraf, A. Yeo, P.E. Lipsky
Abstract #: 2054
Date: Tuesday, Nov. 7, 2017
Time: 9 a.m.-11 a.m. PT

RAYOS Data

- **Title:** *A Randomized, Open-Label, Dose-Ranging Study of Oral Delayed Release Prednisone in Patients with Untreated Polymyalgia Rheumatica*

Abstract #: 1176
Authors: J.A. Singh, L.S. Simon
Date: Monday, Nov. 6, 2017
Time: 9 a.m.-11 a.m. PT

About KRYSTEXXA
INDICATIONS AND USAGE
KRYSTEXXA® (pegloticase) is indicated for the treatment of chronic gout in adult 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.

Please see Full Prescribing Information and Medication Guide for more information.

About RAYOS
INDICATIONS AND USAGE
RAYOS® (prednisone) Delayed-Release Tablets is a corticosteroid indicated as an anti-inflammatory or immunosuppressive agent for certain allergic, dermatologic, gastrointestinal, hematologic, ophthalmologic, nervous system, renal, respiratory, rheumatologic, specific infectious diseases or conditions and organ transplantation; for the treatment of certain endocrine conditions; and for palliation of certain neoplastic conditions.

IMPORTANT SAFETY INFORMATION ABOUT RAYOS
CONTRAINDICATIONS
Known hypersensitivity to prednisone or any excipients in the formulation.

WARNINGS AND PRECAUTIONS

- Corticosteroids can cause hypothalamic-pituitary-adrenal (HPA) axis suppression, Cushing's syndrome and hyperglycemia. Monitor patients for these conditions with chronic use. Taper doses gradually for withdrawal after chronic use.
- RAYOS may increase susceptibility to new infection and increase risk of exacerbation, dissemination or reactivation of latent infection. RAYOS may mask signs and symptoms of infection. The rate of infectious complications increases with increasing doses of corticosteroids.
- Corticosteroids can cause elevated blood pressure, salt and water retention and hypokalemia. Monitor blood pressure and sodium, potassium serum levels. RAYOS should be used with caution in patients with a history of recent myocardial infarction, congestive heart failure, hypertension or renal insufficiency.
- There is an increased risk of gastrointestinal (GI) perforation in patients with certain GI disorders. RAYOS may mask signs and symptoms of GI perforation.
- Corticosteroid use may be associated with behavioral and mood disturbances, including euphoria, insomnia, mood swings, personality changes, severe depression and psychosis. Existing conditions may be aggravated.
- Corticosteroid use may lead to inhibition of bone growth in children and adolescents and the development of osteoporosis at any

age. Give special consideration to patients at increased risk of osteoporosis (eg, postmenopausal women) before initiating corticosteroid therapy, and bone density should be monitored in patients on long-term corticosteroid therapy.
- Prolonged use of corticosteroids may result in cataracts, infections and glaucoma. Monitor intraocular pressure if corticosteroid therapy is continued for more than 6 weeks.
- Do not administer live or attenuated vaccines to patients receiving immunosuppressive doses of corticosteroids.
- Long?term use of corticosteroids can have negative effects on growth and development in children. Monitor pediatric patients on long?term corticosteroid therapy.
- Fetal harm can occur with first trimester use of corticosteroids. Apprise women of potential harm to the fetus.

ADVERSE REACTIONS
Common adverse reactions for corticosteroids include fluid retention, alteration in glucose tolerance, elevation in blood pressure, behavioral and mood changes, increased appetite and weight gain

Please see Full Prescribing Information **for more information.**

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 benefits of KRYSTEXXA to patients with 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, the fact that results in on-going clinical trials may not support better patient outcomes from the use of KRYSTEXXA, 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.

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