Horizon Therapeutics plc to Present MIRROR Randomized Controlled Trial Primary Endpoint Data at The EULAR 2022 European Congress of Rheumatology

May 24, 2022

-- Oral presentation on KRYSTEXXA® (pegloticase injection) plus methotrexate to be held June 2, 2022 at 11:35 a.m. CEST--

-- Additional data presentations provide new insights on psychosocial and comorbidity impact of gout to help inform evolving treatment strategies --

DUBLIN--(BUSINESS WIRE)--May 24, 2022-- Horizon Therapeutics plc (Nasdaq: HZNP) today announced a series of data presentations during The EULAR 2022 European Congress of Rheumatology, June 1 – 4 in Copenhagen.

As part of Horizon's efforts to continually improve the understanding and treatment of gout, the company will present data on KRYSTEXXA ® (pegloticase injection), including six-month results from the MIRROR randomized controlled trial, as well as data from the PROTECT trial. The company will also present data on the experiences of people with gout, including comorbidities, complications and the potential impact of stigma on treatment considerations.

"The EULAR congress provides an important opportunity to discuss our findings with leading global experts in rheumatology and to understand how new insights can improve patient care," said Theresa Podrebarac M.D., MSc., senior vice president, clinical development, Horizon. "Importantly, we look forward to sharing data on the MIRROR randomized controlled trial, which demonstrated a significant improvement in response rate and overall safety. We believe data like this will reset the current standard of care for uncontrolled gout patients."

Key presentation details:

- **Title:** A Randomized, Double Blind, Placebo Controlled, Multicenter Study of Methotrexate Combined with Pegloticase in Patients with Uncontrolled Gout

Presenting Author: John Botson, M.D., R.Ph., C.C.D., rheumatologist, Orthopedic Physicians Alaska

Oral presentation: OP0171, June 2, 11:35-11:45 a.m. CEST, Auditorium 15

- **Title:** Does a Gout Stigma Among Rheumatologists Influence Perceptions of Patients and Treatment Decisions?

Presenting Author: Brian LaMoreaux, M.D., M.S., senior medical director, Horizon

Poster Tour: POS0283, June 4, 11:13-11:21 a.m. CEST, Auditorium 13

Additional poster presentations and published abstracts on KRYSTEXXA:

- **Title:** PROTECT: Pegloticase Treatment for Uncontrolled Gout in Kidney Transplanted Patients; Results From a Phase 4 Trial

Poster: POS1160, Poster View 8

- **Title:** Pharmacokinetics of Pegloticase and Methotrexate Polyglutamate(s) in Patients with Uncontrolled Gout Receiving Pegloticase and Co-treatment with Methotrexate

Poster: POS1163, Poster View 8

- **Title:** Pegloticase Use in Renal Transplant Recipients with Gout: An Insurance Claims Study

Published Abstract: AB1042

- **Title:** Pegloticase Urate-Lowering Response Following COVID-Related Gap in Therapy: Experiences of One Rheumatologist

Published Abstract: AB1038

- **Title:** Patient Reported Outcomes Among Patients Receiving Treatment from the Pegloticase Phase 3 Clinical Trials for Uncontrolled Gout

Published Abstract: AB1039

- **Title:** Clinical Outcomes and Healthcare Resource Utilization of Uncontrolled Gout Prior to Pegloticase Therapy

Published Abstract: AB1051

- **Title:** Estimated Glomerular Filtration Rate Changes in Uncontrolled Gout Patients Co-Treated with Pegloticase and Methotrexate: A Retrospective Case Series

Published Abstract: AB1048

- **Title:** Real-World Reporting of Gout Flares in Uncontrolled Gout Patients Co-Treated with Pegloticase and Methotrexate

Published Abstract: AB1041

Please see Important Safety Information for KRYSTEXXA below.

Additional gout-related posters and published abstracts:

- **Title:** Characteristics of Patients with Coincident Gout and Advanced Chronic Kidney Disease

Published Abstract: AB1050

- **Title:** Characterization of Gout in US Patients Undergoing Hemodialysis (HD) and Peritoneal Dialysis (PD)

Poster: POS1158, Poster View 8

- **Title:** Gout and Serious Kidney Disease in the US: A National Perspective

Poster: POS1166, Poster View 8

- **Title:** Prevalence and Impact of Dermatologic Conditions in Patients with Gout

Poster: POS1162, Poster View 8

- **Title:** Comparison of Patients with Early-Onset Gout and Common Gout: A Claims-Based Analysis

Poster: POS1164, Poster View 8

Sclerosis-related posters:

- **Title:** Comorbidity and Complications Prior to Systemic Sclerosis Diagnosis: A Retrospective Cohort Analysis

Poster: POS0867, Poster View 5

About KRYSTEXXA

INDICATION 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 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 Horizon

Horizon is focused on the discovery, development and commercialization of medicines that address critical needs for people impacted by rare, autoimmune and severe inflammatory diseases. Our pipeline is purposeful: We apply scientific expertise and courage to bring clinically meaningful therapies to patients. We believe science and compassion must work together to transform lives. For more information on how we go to incredible lengths to impact lives, visit www.horizontherapeutics.com and follow us on Twitter, LinkedIn, Instagram and Facebook.

Forward Looking Statements

This press release contains forward-looking statements, including statements regarding the potential benefits of KRYSTEXXA plus methotrexate for uncontrolled gout, Horizon's research and development plans and strategy and potential changes in the standard of care for uncontrolled gout. These forward-looking statements are based on management's expectations and assumptions as of the date of this press release and actual results may differ materially from those in these forward-looking statements as a result of various factors. These factors include, but are not limited to, risks regarding whether or on what terms the FDA may approve Horizon's supplemental Biologic License Application related to the use of KRYSTEXXA with methotrexate, whether additional data from clinical trials or other analyses will be required or consistent with prior data or Horizon's expectations and risks related to the adoption of co-treatment of KRYSTEXXA plus methotrexate for uncontrolled gout. For a further description of these and other risks facing Horizon, please see the risk factors described in Horizon's filings with the United States Securities and Exchange Commission, including those factors discussed under the caption "Risk Factors" in those filings. Forward-looking statements speak only as of the date of this press release and Horizon undertakes no obligation to update or revise these statements, except as may be required by law.

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