Horizon to Highlight Novel Insights in Gout Care During the American College of Rheumatology Convergence 2022

September 19, 2022

– Meeting plenary session to feature 12-Month data from MIRROR randomized controlled trial of KRYSTEXXA® (pegloticase) injection with methotrexate –

DUBLIN--(BUSINESS WIRE)--Sep. 19, 2022-- Horizon Therapeutics plc (Nasdaq: HZNP) today announced plans for a series of data presentations on its marketed and pipeline medicines, with a focus on continued efforts to advance the understanding and care of uncontrolled gout, during the American College of Rheumatology Convergence 2022 to be hosted in Philadelphia and online, Nov. 10-14, 2022.

Key results from the MIRROR randomized controlled trial will be presented as part of the American College of Rheumatology Convergence 2022 plenary session:

- **12-month Findings of the Randomized, Double-Blind, Placebo-Controlled, Multicenter, Efficacy and Safety Study of Methotrexate to Increase Response Rates in Patients with Uncontrolled Gout Receiving Pegloticase (MIRROR RCT)**

  Presenting Author: John K. Botson M.D., R.Ph., C.C.D., president, Alaska Rheumatology Alliance and rheumatologist, Orthopedic Physicians Alaska
  Abstract 0001 (plenary presentation): Saturday, Nov. 12; 11:45 – 11:55 a.m. EST

Poster presentations on KRYSTEXXA will include:

- **Reduction in Monosodium Urate Crystal Deposit Volume During the MIRROR RCT Trial in Patients Treated with Pegloticase Plus Methotrexate Co-therapy: A Serial Dual-Energy Computed Tomography (DECT) Analysis**
  Abstract 1807: Monday, Nov. 14
- **eGFR Changes in Uncontrolled Gout Patients Undergoing Pegloticase + Methotrexate Co-therapy**
  Abstract 1824: Monday, Nov. 14
- **Pegloticase for Uncontrolled Gout in Patients with History of Kidney Transplant: Pharmacokinetics and Immunogenicity in the PROTECT Clinical Trial**
  Abstract 1814: Monday, Nov. 14
- **Characteristics and Comorbidity Burden of Phase 3 Clinical Trial Participants Who Did and Did Not Experience Acute Gout Flares During Biweekly Pegloticase Dosing**
  Abstract 1806: Monday, Nov. 14
- **Neutrophil-to-lymphocyte Ratio Among Flaring and Non-flaring Uncontrolled Gout Patients Undergoing Pegloticase Therapy as Part of the Phase 3 Pivotal Trials**
  Abstract 1803: Monday, Nov. 14
- **Assessing Urate Deposition and Inflammation in the Vasculature of Gout Patients Using Dual Energy Computed Tomography and Positron Emission Tomography Pre and Post Pegloticase- a Pilot Study**
  Abstract 1816: Monday, Nov. 14 (*investigator-initiated trial)*

Additional presentations on the impact of uncontrolled gout will include:

- **Real-World Evidence from Social Media Provides Insights into Patient Mental Health Outcomes in the Management of Gout**
  Abstract 0201: Saturday, Nov. 12
- **Assessing the Role of the NLRP3 Inflammasome in Driving Inflammation in Affected Joints of Patients with Inter-critical Gout**
  Abstract 1808: Monday, Nov. 14 (*investigator-initiated trial)*

Horizon will also present new insights on an emerging pipeline program:

- **A Phase 2, Randomized, Double-Blind, Placebo-controlled, Mechanistic Insight and Dosage Optimization Study of the Efficacy and Safety of Dazodalibep (VIB4920/HZN4920) in Patients with Rheumatoid Arthritis Having Inadequate Response to Conventional / Biological DMARDs**
  Abstract 2008 (featured Ignite Talk): Sunday, Nov. 13; 2:35-2:40 p.m.

About KRYSTEXXA

INDICATION

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.

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

IMPORTANT SAFETY INFORMATION

WARNING: ANAPHYLAXIS AND INFUSION REACTIONS, G6PD DEFICIENCY ASSOCIATED HEMOLYSIS AND METHEMOGLOBINEMIA

- **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. Delayed 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 and closely monitored for anaphylaxis for an appropriate period after administration of KRYSTEXXA.**
- **Serum uric acid levels should be monitored prior to each infusion and treatment discontinued if levels increase to above 6 mg/dL, particularly when 2 consecutive levels above 6 mg/dL are observed.**
- **Patients at risk for glucose-6-phosphate dehydrogenase (G6PD) deficiency should be screened prior to starting KRYSTEXXA. Hemolysis and methemoglobinemia have been reported with KRYSTEXXA in patients with G6PD deficiency. KRYSTEXXA is contraindicated in patients with G6PD deficiency.**

CONTRAINDICATIONS:

- In patients with G6PD deficiency.
- In patients with history of serious hypersensitivity reactions, including anaphylaxis, to KRYSTEXXA or any of its components.

WARNINGS AND PRECAUTIONS

Gout Flares: An increase in gout flares is frequently observed upon initiation of anti-hyperuricemic therapy, including KRYSTEXXA. 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 formally studied in patients with congestive heart failure, but some patients in the pre-marketing placebo-controlled clinical trials experienced exacerbation. Caution should be exercised in patients who have congestive heart failure and patients should be closely monitored following infusion.

ADVERSE REACTIONS

The most commonly reported adverse reactions (≥5%) are:

- **KRYSTEXXA co-administration with methotrexate trial:** gout flares, arthralgia, COVID-19, nausea and fatigue; **KRYSTEXXA alone:** gout flares, arthralgia, COVID-19, nausea, fatigue, infusion reactions, pain in extremity, hypertension and vomiting.
- **KRYSTEXXA pre-marketing placebo-controlled trials:** gout flares, infusion reactions, nausea, contusion or ecchymosis, nasopharyngitis, constipation, chest pain, anaphylaxis and vomiting.

Please see Full Prescribing Information, **including Boxed Warning**.

About Horizon

Horizon is a global biotechnology company 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.

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Source: Horizon Therapeutics plc