Horizon Therapeutics plc Highlights Expanding R&D Efforts with Data Presentations at the EULAR European Congress of Rheumatology

May 21, 2021

-- Key presentations feature investigational programs in rheumatoid arthritis and data evaluating KRYSTEXXA® (pegloticase injection) for people with uncontrolled gout who received a kidney transplant --

DUBLIN--(BUSINESS WIRE)--May 21, 2021-- Horizon Therapeutics plc (Nasdaq: HZNP) today announced data presentations at the EULAR European Congress of Rheumatology, June 2 – 5, 2021.

At this year's meeting, Horizon will present data on HZN-4920 (VIB4920), the company's investigational compound under evaluation for rheumatoid arthritis in an oral session. Additional presentations will include an update on the PROTECT trial evaluating the use of KRYSTEXXA (pegloticase injection) in people with chronic gout refractory to conventional therapies – also known as uncontrolled gout – who have received a kidney transplant, as well as pharmacokinetic data regarding the concomitant use of KRYSTEXXA and the immunomodulator methotrexate.

"The EULAR congress provides an important opportunity to engage with the rheumatology community on evolving approaches to treating these challenging diseases," said Jeffrey D. Kent, M.D., FACG, FACP, executive vice president, medical affairs and outcomes research, Horizon. "We are energized by the expansion of our R&D efforts into additional areas of rheumatic disease and continue our commitment to fuel productive and collaborative research to inform physicians' decision-making and improve patient outcomes."

Presentation Details:

- **Title:** Duration of Clinical Efficacy Following Treatment with VIB4920 in Subjects with Moderate to Severe Rheumatoid Arthritis
  Oral presentation: OP0120, 10:15 CEST, June 3, 2021
- **Title:** Preliminary Findings of The PROTECT Clinical Trial: Pegloticase Efficacy and Safety in Kidney Transplant Recipients
  Abstract: POS1122
- **Title:** Pharmacokinetics of Pegloticase and Methotrexate Polyglutamate(s) in Patients with Uncontrolled Gout Receiving Pegloticase and Co-treatment of Methotrexate
  Abstract: POS1136
- **Title:** Demographics, Comorbidities, and Renal Function of Uncontrolled Gout Patients Who Received Pegloticase: Finding From A Large US Claims Database
  Abstract: POS1121
- **Title:** Dual Energy CT Has Prognostic Value in Gout Beyond Standard Clinical Measures: A Best Evidence Synthesis
  Abstract: POS1125

Additional data will be presented as part of the online publication for EULAR.

- **Title:** Pegloticase/Methotrexate Co-Therapy Improved Joint and Patient-Reported Health Assessments in Patients With Uncontrolled Gout: 12-Month Exploratory Outcomes of the MIRROR Open-Label Trial
  Abstract: AB0630
- **Title:** Pre-Infusion Glucocorticoid Elimination in Patients with Uncontrolled Gout Treated with Pegloticase: a Case Series
  Abstract: AB0628

About HZN-4920 (VIB4920)

This investigational compound is a CD40 ligand antagonist that blocks T cell interaction with the CD40-expressing B cells, disrupting the overactivation of the CD40 ligand co-stimulatory pathway. Several autoimmune diseases are associated with the overactivation of this pathway.

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 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, please visit www.horizontherapeutics.com and follow us on Twitter, LinkedIn, Instagram and Facebook.

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Tina Ventura
Senior Vice President, Investor Relations
Investor-relations@horizontherapeutics.com

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

U.S. Media Contact:
Amanda Phraner
Director, Product Communications
media@horizontherapeutics.com

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

Source: Horizon Therapeutics plc