



## Data on Multiple Immunomodulation Approaches with KRYSTEXXA® (pegloticase injection) to be Presented at the Annual European Congress of Rheumatology (EULAR 2020)

May 21, 2020

-- Additional data presented will highlight the effect of urate deposition and link between gout and serious comorbidities --

-- Two oral presentations will be given on Thursday, June 4, 2020 --

DUBLIN--(BUSINESS WIRE)--May 21, 2020-- Horizon Therapeutics plc (Nasdaq: HZNP) announced today that multiple case series and studies will be presented at the Annual European Congress of Rheumatology (EULAR 2020), being held virtually June 3 - 6, 2020. Several presentations of clinical trial data and in-practice cases will provide results on KRYSTEXXA® (pegloticase injection) with commonly used immunomodulators to help more people with chronic gout refractory to conventional therapies – also known as uncontrolled gout – potentially achieve complete and durable response to treatment.

Additional data to be featured during EULAR 2020 demonstrate the systemic impact of gout and potential kidney, cardiovascular and other risks associated with the disease.

“We look forward to presenting these data, which add to the to the growing body of evidence regarding the use of KRYSTEXXA with immunomodulators,” said Jeffrey D. Kent, M.D., FACG, FACP, executive vice president, medical affairs and outcomes research, Horizon. “Along with additional data linking uncontrolled gout to serious risks and complications, these presentations reflect the growing body of evidence and evolving approach to aggressively manage this disease and address its systemic impact.”

### Presentation Details:

Immunomodulation approaches combining KRYSTEXXA with commonly used immunomodulators to prevent the development of anti-drug antibodies with biologics:

- **Title:** *Pegloticase response improvement by co-treatment with methotrexate: results from the MIRROR open-label clinical trial in patients with uncontrolled gout*  
**Abstract:** [THU0416](#)
- **Title:** *Leflunomide co-therapy with pegloticase in uncontrolled gout*  
**Abstract:** [THU0434](#)
- **Title:** *Companion Immunosuppression with Azathioprine Increases the frequency of Persistent Responsiveness to pegloticase in patients with chronic refractory gout*  
**Abstract:** [THU0410](#)  
\*Investigator-initiated trial
- **Title:** *Pegloticase response rate in uncontrolled gout patients co-treated with methotrexate: experience in a community rheumatology practice*  
**Abstract:** [THU0431](#)
- **Title:** *Immunomodulation co-therapy with pegloticase: database trends 2014-2019*  
**Oral presentation:** [OP0173](#), 10:55 a.m. CET, June 4, 2020

Data on the link between hyperuricemia and non-alcoholic fatty liver disease (NAFLD):

- **Title:** *Treatment with Pegloticase Improves Hepatic Fibrosis Estimated by Fibrosis-4 Index in Subjects with Chronic Refractory Gout*  
**Abstract:** [THU0433](#)

Please see important safety information for KRYSTEXXA below.

Additional data showing associated complications for people living gout, furthering understanding of the disease:

- **Title:** *Amputation procedures in patients with gout compared to patients with diabetes*  
**Oral presentation:** [OP0169](#), 10:25 a.m. CET, June 4, 2020

- **Title:** *Effect of new-onset gout on kidney transplant outcomes: a retrospective cohort analysis of the United States Renal Data System*  
**Abstract:** [THU0408](#)
- **Title:** *Renal Urate Deposition: Summary of Published Evidence*  
**Abstract:** [THU0430](#)
- **Title:** *Gout and Heart Failure in the US: A National Perspective*  
**Abstract:** [THU0442](#)  
*\*\*Independent study, Horizon support and funding provided*

## 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 researching, developing and commercializing medicines that address critical needs for people impacted by rare and rheumatic 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](http://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](mailto:Investor-relations@horizontherapeutics.com)

**Ruth Venning**

Executive Director, Investor Relations

[Investor-relations@horizontherapeutics.com](mailto:Investor-relations@horizontherapeutics.com)

**U.S. Media Contact:**

**Amanda Phraner**

Director, Public Relations and Social Media

[media@horizontherapeutics.com](mailto:media@horizontherapeutics.com)

**Ireland Media Contact:**

**Gordon MRM**

Ray Gordon

[ray@gordonmrm.ie](mailto:ray@gordonmrm.ie)

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