



## Horizon Therapeutics plc Announces Presentation of Data that Advances the Understanding of Rheumatic Diseases at the 2023 EULAR European Congress of Rheumatology

May 23, 2023

-- Phase 2 results for dazodalibep in Sjögren's syndrome to be presented on June 1, 11:35-11:45 a.m. CEST and June 3, 9:35-9:45 a.m. CEST --

-- Planned presentations illustrate Horizon's momentum in raising standards of care for rheumatology conditions including Sjögren's syndrome and uncontrolled gout --

DUBLIN--(BUSINESS WIRE)--May 23, 2023-- Horizon Therapeutics plc (Nasdaq: HZNP) today announced plans for the first presentation of data from a Phase 2 study of dazodalibep, the company's investigational therapy for Sjögren's syndrome, during the [2023 EULAR European Congress of Rheumatology](#), May 31 - June 3, 2023, in Milan. The company will also present additional data on KRYSTEXXA® (pegloticase) injection, including new analyses from the MIRROR randomized clinical trial.

"Our pipeline continues to strengthen as we work to address challenging research questions and bring new thinking that can advance standards for patient care in the rheumatology field," said Elizabeth H.Z. Thompson, Ph.D., executive vice president, research and development, Horizon.

"We're looking forward to joining the world's experts as we share new data on our investigational Sjögren's treatment, dazodalibep, as well as presentations on KRYSTEXXA that are helping to shape approaches to treat uncontrolled gout."

### KEY PRESENTATIONS

#### Dazodalibep for Sjögren's Syndrome

- **Title:** [Efficacy and Safety of Dazodalibep \(VIB4920/HZN4920\) in Subjects with Sjögren's Syndrome: A Phase 2, Randomized, Double-Blind, Placebo-Controlled, Proof of Concept Study](#)  
**Presenting Author:** Wan-Fai Ng, Ph.D., Translational and Clinical Research Institute, Newcastle University, Newcastle, United Kingdom  
**Presentation Details:** OP0143, June 1, 11:35-11:45 a.m. CEST, South Hall, Session room 2
- **Title:** [Dazodalibep \(VIB4920/HZN4920\) in Sjögren's Subjects with an Unacceptable Symptom Burden: Safety and Efficacy from a Phase 2, Randomized, Double-Blind Study](#)  
**Presenting Author:** Chiara Baldini, M.D., Department of Clinical and Experimental Medicine, Rheumatology Unit, University of Pisa, Italy  
**Presentation Details:** LB0003, June 3, 9:35-9:45 a.m. CEST, Space 2
- **Title:** [CD40L Blockade with Dazodalibep \(VIB4920/HZN4920\) Reduces Blood Biomarkers of T and B Cell Co-stimulation in Subjects with Systemic Sjögren's Syndrome](#)  
**Poster:** POS0815, June 1, 2:45-3:45 p.m. CEST, Poster Hall

#### Sjögren's-related published abstract:

- **Title:** [The Mental Health Impact of Sexual Dysfunction in Sjögren's Disease: A Social Media Approach to Real-World Evidence](#)  
**Published Abstract:** AB0601

#### KRYSTEXXA

- **Title:** [Quality of life and clinical gout assessment changes in uncontrolled gout patients undergoing pegloticase therapy as part of the MIRROR randomized controlled trial](#)  
**Poster:** POS0513, May 31, 3:30-4:30 p.m. CEST, Poster Hall
- **Title:** [Bone erosion remodeling after depletion of monosodium urate deposition with intensive urate lowering with pegloticase in patients with uncontrolled gout: MIRROR RCT dual-energy CT findings](#)  
**Poster:** POS0514, May 31, 3:30-4:30 p.m. CEST, Poster Hall
- **Title:** [Pegloticase + Methotrexate Co-therapy in Uncontrolled Gout Patients with Prior Pegloticase Monotherapy Failure: Findings of the ADVANCE Open-Label Trial](#)  
**Published Abstract:** AB1255

#### Gout-related posters and published abstracts:

- **Title:** [Projecting the future health and economic burden of controlled and uncontrolled gout in the chronic kidney disease population in the US: preliminary results using microsimulation modelling methods](#)  
**Poster:** POS0509, May 31, 3:30-4:30 p.m. CEST, Poster Hall
- **Title:** [Using Social Media Conversations to Understand Patient Care: Factors Driving Proactive vs. Reactive Management of Gout](#)  
**Poster:** POS0529, May 31, 3:30-4:30 p.m. CEST, Poster Hall
- **Title:** [Gout and Venous Thromboembolism in the US: A National Perspective](#)  
**Published Abstract:** AB1242
- **Title:** [Perceptions of gout and its management patterns: findings from survey and structured interviews with primary care physicians and rheumatologists](#)  
**Published Abstract:** AB1240

#### About Dazodalibep

[Dazodalibep](#) is a CD40 ligand antagonist that blocks T cell interaction with 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. Horizon also plans to investigate dazodalibep in focal segmental glomerulosclerosis, a rare kidney disorder characterized by scarring of glomeruli.

#### About Sjögren's Syndrome

Sjögren's syndrome is a chronic, systemic autoimmune disease affecting exocrine glands, primarily the salivary and tear glands, with severe cases affecting multiple organs. Like other autoimmune diseases, Sjögren's syndrome primarily affects women. The disease also has an increased risk of non-Hodgkin's B-cell lymphoma and there is an unmet medical need for patients with extraglandular disease manifestations, as currently there is no therapy that can improve or slow the course of the disease. Disease manifestations include dry mouth, dry eyes, arthritis and kidney or lung dysfunction.

#### 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 ( $\geq 5\%$ ) 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](http://www.horizontherapeutics.com) and follow us on [Twitter](#), [LinkedIn](#), [Instagram](#) and [Facebook](#).

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### Investor Relations:

#### Tina Ventura

Senior Vice President, Chief Investor Relations Officer  
[Investor-relations@horizontherapeutics.com](mailto:Investor-relations@horizontherapeutics.com)

#### Erin Linnihan

Executive Director, Investor Relations  
[Investor-relations@horizontherapeutics.com](mailto:Investor-relations@horizontherapeutics.com)

### U.S. Media:

#### Amanda Phraner

Senior Director, Product Communications  
[media@horizontherapeutics.com](mailto:media@horizontherapeutics.com)

### Ireland Media Contact:

#### Eimear Rigby

Associate Director, Corporate Communications  
[media@horizontherapeutics.com](mailto:media@horizontherapeutics.com)

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