Topline Data for Dazodalibep (HZN-4920) Meets Primary Endpoint in Rheumatoid Arthritis

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Detailed results to be presented at upcoming medical congress

DUBLIN--(BUSINESS WIRE)--May 3, 2022-- Horizon Therapeutics plc (Nasdaq: HZNP) today announced that its Phase 2, randomized, double-blinded, placebo-controlled trial of dazodalibep (HZN-4920) in rheumatoid arthritis (RA) met the primary endpoint.

“It is promising to see that the dazodalibep Phase 2 rheumatoid arthritis trial not only met the primary endpoint, but that the observed treatment effect was consistently maintained,” said Theresa Podrebarac, M.D., M.Sc., senior vice president, clinical development, Horizon. “Horizon’s scientific strategy is to maximize each of our molecule’s scientific impact and these results serve as the first proof-of-concept that our mechanism of action is effective in addressing a central pathway that has the potential to help patients across many autoimmune diseases. It also serves as the first of what we hope will be many clinical validations of the value we see in our growing pipeline.”

In this dazodalibep Phase 2 trial, approximately 75 subjects with active, moderate-to-severe, adult-onset RA were randomized into four different dosing regimens or a placebo arm. The study met its primary endpoint of change from baseline in DAS28-CRP at Day 113 in all four dazodalibep dosing arms. This endpoint is a standardized measure that is used in RA clinical trials to measure disease activity.[1] Dazodalibep was well tolerated.

The pharmacokinetic and the pharmacodynamic parameters observed after dosing will also inform the dosing regimen for other studies with dazodalibep.

The dazodalibep Phase 2 trial follows the Phase 1b, multiple ascending dose study in patients with active moderate-to-severe RA. In the Phase 2 trial, the last dose of dazodalibep was given at Day 85 and follow-up data at Day 169 showed a prolonged and sustained benefit on disease activity.

Data from the trial will be presented at an upcoming medical congress.

About Dazodalibep (HZN-4920)

Dazodalibep (HZN-4920) 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 is also investigating dazodalibep in Sjögren’s syndrome and kidney transplant rejection and plans to investigate it in focal segmental glomerulosclerosis.

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 dazodalibep (HZN-4920) in treating rheumatoid arthritis and other autoimmune diseases, as well as Horizon’s future development plans. 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 future data analyses or clinical evidence will be consistent with the analysis from the Phase 2 clinical trial or Horizon’s expectations. 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.

References

1. Prevoo ML, van’t Hof MA, Kuper HH, van Leeuwen MA, van de Putte LB, van Riel PL. Modified disease activity scores that include twenty-eight-joint counts. Development and validation in a prospective longitudinal study of patients with rheumatoid arthritis. *Arthritis Rheum*. 1995;38(1):44-8.

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