Horizon Therapeutics plc Announces First Patient Enrolled in Phase 2 Trial Evaluating Daxdilimab for the Treatment of Lupus Nephritis

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DUBLIN--(BUSINESS WIRE)--May 2, 2023-- Horizon Therapeutics plc (Nasdaq: HZNP) today announced the first patient has enrolled in a Phase 2 randomized placebo-controlled trial to evaluate its development-stage medicine daxdilimab, a potentially first-in-class, fully human monoclonal antibody targeting immunoglobulin-like transcript 7 (ILT7) that depletes certain dendritic cells, to treat people with active proliferative lupus nephritis (LN).

LN is a rare, autoimmune and inflammatory condition of the kidney and represents a common organ manifestation of systemic lupus erythematosus (SLE), a multisystem autoimmune disease. Between 31 and 60 percent of SLE patients live with LN[1] and in the United States, Horizon estimates that approximately 60,000 patients with LN are appropriate for treatment with novel therapies, including biologics. The disease is more prevalent in certain ethnic groups such as African American, Asian and Hispanic populations.[2]

“For individuals living with LN, evaluating a safe and effective treatment that can prevent worsening kidney damage and decrease the risk of kidney failure and end-stage renal disease is a key objective,” said Kenneth Kalunian, M.D., professor of medicine, division of rheumatology, allergy and immunology, University of California, San Diego. “Current treatment regimens include intensive immunosuppressive therapy that can be associated with several adverse events. There is a need to identify a more specific medicine for those with proliferative LN.”

Approximately 210 participants who meet trial eligibility are expected to be enrolled. The primary endpoint is the proportion of participants who achieve a sustained complete renal response (CRR) between Week 48 and Week 52. This is a composite endpoint defined as a reduction in proteinuria and preservation or improvement of renal function.[3] Secondary endpoints include the proportion of participants achieving overall renal response (ORR), which is defined as CRR combined with partial renal response (PRR). To evaluate the steroid-sparing effects of daxdilimab, the proportion of participants who are able to effectively taper oral corticosteroids by Week 24 and maintain a low dose through Week 52 will also be evaluated.

“LN is a serious manifestation of SLE and requires urgent treatment to avoid chronic kidney disease, dialysis or kidney transplantation,” said Theresa Podrebarac, M.D., M.Sc., senior vice president, clinical development, Horizon. “Early studies point to the role of plasmacytoid dendritic cells (pDCs) and type 1 interferons in its pathogenesis. As a part of our commitment to addressing better treatment options for autoimmune diseases, we are currently evaluating daxdilimab in SLE as well as a variety of other conditions.”

About Daxdilimab

Daxdilimab is an anti-ILT7 human monoclonal antibody that depletes certain dendritic cells. Depleting these cells may interrupt the cycle of inflammation that causes tissue damage in a variety of autoimmune conditions. Horizon is also investigating daxdilimab in alopecia areata, discoid lupus erythematosus, systemic lupus erythematosus and plans to investigate it in dermatomyositis or anti-synthetase inflammatory myositis.

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.

Forward-Looking Statements

This press release contains forward-looking statements, including, but not limited to, statements related to the potential benefits of daxdilimab; the expected scope, endpoints and timing of Horizon’s Phase 2 clinical trial of daxdilimab in proliferative lupus nephritis and other statements that are not historical facts. These forward-looking statements are based on Horizon’s current expectations and inherently involve significant risks and uncertainties. Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of these risks and uncertainties, which include, without limitation, risks related to clinical trials, including the fact that prior results may not predict future clinical trial outcomes; impacts of pandemics and geopolitical conflicts and related disruptions to healthcare activities, including potential delays in clinical trials; regulatory obligations and oversight, including any changes in the legal and regulatory environment in which Horizon operates and those risks detailed from time-to-time under the caption "Risk Factors" and elsewhere in Horizon’s filings and reports with the SEC. Horizon undertakes no duty or obligation to update any forward-looking statements contained in this press release as a result of new information.

References

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