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

January 4, 2023

DUBLIN--(BUSINESS WIRE)--Jan. 4, 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 anti-ILT7 depletes certain dendritic cells to treat people with moderate-to-severe primary discoid lupus erythematosus (DLE).

DLE is a rare, chronic, inflammatory skin condition characterized by lesions that result in scarring, irreversible hair loss and skin discoloration with no approved therapies. The localized form of primary DLE is characterized by limited cutaneous involvement of the head and scalp and usually accounts for 70 percent of primary DLE. The generalized form is characterized beyond this and includes the head-body area and usually accounts for about 30 percent of primary DLE.[1] In the United States, approximately 30,000 patients with DLE are appropriate for treatment with novel therapies, including biologics.[2] Primary DLE incidence rates are approximately four times higher among women compared with men and the disease has a higher prevalence among non-Latino Black and Latino populations.[3]

“DLE is one of the most challenging scarring skin diseases because there is no curative treatment. It causes round, inflammatory lesions that favor the scalp, face and ears and is associated with a diminished quality of life in patients,” said Benjamin Chong, M.D., associate professor, department of dermatology, University of Texas Southwestern Medical Center. “There is a tremendous unmet medical need for safe treatments for DLE. This trial will help evaluate the potential of daxdilimab to meet this need.”

Horizon expects to enroll approximately 100 participants in the trial. The primary endpoint is the mean change in Cutaneous Lupus Erythematosus Disease Area and Severity Index-Activity (CLASI-A) score from baseline to Week 24. This endpoint is used to measure activity in inflammatory lupus skin disease and ranges from 0 to 70 with higher scores indicating more active and skin damaging disease.[4]

Key inclusion criteria include a diagnosis of moderate-to-severe DLE for more than six months prior to screening supported by a biopsy and/or a clinical feature score of ≥ 7 on the DLE Classification Criteria (DLECC) scale. This score is used to specifically validate and classify DLE across several clinical variables including atrophic scarring, disease location on the body and dyspigmentation.[5]

“Plasmacytoid dendritic cells, or pDCs, are reported to be abundant in DLE skin lesions while interferon levels are elevated and daxdilimab has been shown to deplete pDCs,” said Theresa Podrebarac, M.D., M.Sc., senior vice president, clinical development, Horizon. “DLE can lead to alopecia or permanent hair loss and skin dyspigmentation. Daxdilimab is also being investigated in other autoimmune conditions that are driven by high levels of interferon, including alopecia areata, dermatomyositis, lupus nephritis and systemic lupus erythematosus.”

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 systemic lupus erythematosus and alopecia areata and plans to investigate it in dermatomyositis and lupus nephritis.

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 and primary endpoint of Horizon’s Phase 2 clinical trial of daxdilimab in discoid lupus erythematosus; Horizon’s plans to evaluate daxdilimab in other indications 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 development, including potential challenges in patient enrollment; 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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Source: Horizon Therapeutics plc