Horizon Therapeutics plc Announces First Patient Enrolled in Phase 2 Trial Evaluating HZN-7734 for the Treatment of Systemic Lupus Erythematosus

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DUBLIN--(BUSINESS WIRE)--Jun. 29, 2021-- Horizon Therapeutics plc (Nasdaq: HZNP) today announced the first patient has enrolled in a Phase 2 trial to evaluate its development-stage medicine HZN-7734 (formerly VIB7734), a first-in-class, fully human monoclonal antibody targeting immunoglobulin-like transcript 7 (ILT7), to treat people with moderate to severely active systemic lupus erythematosus (SLE). SLE, which accounts for 70 percent of lupus cases[1], is an autoimmune disease in which the immune system mistakenly attacks healthy cells and tissues. The Lupus Foundation of America estimates at least 5 million people worldwide are living with a form of lupus, 90 percent of whom are women.[2,3]

“Systemic lupus erythematosus has many manifestations, its severity can negatively impact a patient’s quality of life and there are limited treatment options,” said Victoria Werth, MD, professor of medicine at the Perelman School of Medicine at the University of Pennsylvania and chief of dermatology at the Corporal Michael J. Crescenz Veteran’s Administration Medical Center. “This trial will help determine the safety and efficacy of Horizon’s ILT7 antagonist in reducing overall disease activity for patients who live with moderate to severely active SLE.”

The initiation of the Phase 2 trial follows encouraging efficacy and safety data from a Phase 1b trial in patients with cutaneous lupus erythematosus, a form of lupus affecting the skin.[4] The Phase 1b study showed HZN-7734 decreased plasmacytoid dendritic cells (pDCs) and reduced Type 1 Interferon both in circulation, as well as the skin of people with cutaneous lupus, demonstrating that this molecule has activity in specific tissues where the disease occurs. HZN-7734 also improved Cutaneous Lupus Erythematosus Disease Area and Severity Index-Activity (CLASI-A) scores, a clinical measure of cutaneous lupus, versus placebo.

The composite primary endpoint of the Phase 2 trial is change in the British Isles Lupus Assessment Group (BILAG)-based Combined Lupus Assessment (BICLA) and reduction in oral glucocorticoid dose after 48 weeks. BICLA is a composite measure of overall SLE disease activity. Additional trial endpoints include other measures of both lupus disease activity and oral glucocorticoid reduction.

“Research suggests pDCs, a type of immune cell that produces Type 1 Interferon and causes inflammation, play a critical role in the pathogenesis of lupus and possibly other autoimmune diseases related to the interferon pathway,” said Elizabeth H.Z. Thompson, Ph.D, executive vice president, research and development, Horizon. “Early studies indicate that HZN-7734 can deplete pDCs in blood and tissue thereby reducing Type 1 Interferon and the resulting inflammation, potentially addressing an unmet treatment need for patients with lupus. The enrollment of the first patient in this study represents an important milestone for these patients.”

About HZN-7734

HZN-7734 is a fully human monoclonal antibody that targets ILT7 and, in early studies, has been shown to promote the destruction of plasmacytoid dendritic cells (pDCs). pDCs are thought to play a critical role in the pathogenesis of lupus and other autoimmune diseases through their capacity to produce rapid and robust quantities of Type 1 IFN as well as through IFN-independent mechanisms.

About Systemic Lupus Erythematosus (SLE)

SLE is marked by inflammation that can affect joints, skin and multiple organs. Symptoms can vary and may change over time, but skin rashes, swelling or pain in various parts of the body, extreme fatigue and low fevers are common. In some people, SLE can progress to more serious complications such as kidney damage, nervous system dysfunction and heart attack. The disease often occurs as periods of active disease, known as flares, alternating with periods where symptoms subside, known as remission.

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, please 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 HZN-7734; the expected scope, endpoints and timing of Horizon’s Phase 2 clinical trial of HZN-7734 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 the COVID-19 pandemic and actions taken to slow its spread, 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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4. Karnell JL, et al. Depleting plasmacytoid dendritic cells reduces local type I interferon responses and disease activity in subjects with cutaneous lupus. *Sci Trans Medicine.* 2021;13(595): eabf8442.

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