Horizon Therapeutics plc Announces New Development Programs at Virtual R&D Day

-- Announcing Five Total New Development Programs for Daxdilimab (HZN-7734) and Dazodalibep (HZN-4920); Expect to Initiate New Phase 2 Trials in 2022, Bringing Total Development Programs to 27 --

--Positioned for Growth with Expanding R&D Team, New Disease Areas and Manufacturing Capability--

-- 10 Data Readouts Across Development Programs Expected Through 2023 --

-- Robust Pipeline and Diversified Portfolio Represent Potential ~$10B in Total Peak Annual Net Sales –

-- Event Begins at 9 a.m. ET--

DUBLIN – Sept. 29, 2021 – Horizon Therapeutics plc (Nasdaq: HZNP) will present an overview of its pipeline, including five new development programs for investigational medicines, daxdilimab (HZN-7734) and dazodalibep (HZN-4920), in new disease areas today during its first virtual R&D Day for investors and analysts.

The virtual event will be held from 9 a.m. to approximately 12:30 p.m. Eastern Time and may be accessed at https://horizonrdinvestorday.stagepro.io/. Please connect at least 15 minutes prior to the live webcast to register and ensure adequate time for any software download that may be needed to access the event. Details about the agenda can be found here.

"Horizon's unique combination of commercial execution, proven and disciplined business development and strong R&D capabilities transformed us into one of the fastest growing, profitable biotechnology companies in the industry," said Tim Walbert, chairman, president and chief executive officer, Horizon. "Today's announcement of new development programs, new disease areas and increased investment in our drug discovery activity further diversifies our portfolio and positions us for long-term growth."

New Development Programs

With the addition of five new development programs, Horizon now has 27 development programs across its pipeline. Daxdilimab (HZN-7734), an investigational, fully human monoclonal antibody targeting immunoglobulin-like transcript 7 (ILT7) promoting the destruction of plasmacytoid dendritic cells (pDCs), is currently in a Phase 2 clinical trial for systemic lupus erythematosus. It will also be studied in four new disease areas:

- Alopecia areata
    - An autoimmune disorder characterized by nonscarring hair loss. There are no FDA-approved treatments for alopecia areata.
- Dermatomyositis
    - A rare, autoimmune disorder characterized by rashes, debilitating muscle weakness and interstitial lung disease. There are no FDA-approved treatments for dermatomyositis.
- Discoid lupus erythematosus
    - A rare, chronic, inflammatory skin condition characterized by lesions that result in scarring. There are no FDA-approved treatments for discoid lupus erythematosus.

- Lupus nephritis
    - A rare, autoimmune and inflammatory condition of the kidney.

Dazodalibep (HZN-4920), an investigational fusion protein binding CD40L on T cells, blocking their interaction with CD40-expressing B cells, is currently in Phase 2 clinical trials for Sjögren's syndrome, rheumatoid arthritis and kidney transplant rejection. It will also be studied in one new disease area:

- Focal segmental glomerulosclerosis
    - A rare kidney disorder characterized by scarring of glomeruli, or small filters in the kidney, which leads to kidney damage and failure.

All five programs are Phase 2 trials that are expected to begin in 2022.

"Our mission is to serve patients with rare, autoimmune and severe inflammatory diseases and in R&D, we are doing that by putting our focus on understanding and impacting the critical biological pathways underlying these diseases," said Elizabeth H.Z. Thompson, Ph.D., executive vice president, research and development, Horizon. "The new development programs we've announced with daxdilimab and dazodalibep not only each represent an intriguing biological approach, but more importantly, the potential to develop new treatment options for diseases with significant unmet need."

About Daxdilimab (HZN-7734)
Daxdilimab is a fully human monoclonal antibody that targets ILT7 and has been shown in early studies to promote the destruction of plasmacytoid dendritic cells (pDCs). These cells 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 Interferons (IFN) as well as through IFN-independent mechanisms.

About Dazodalibep (HZN-4920)
Dazodalibep is a novel, non-antibody fusion protein that blocks CD40 ligand (CD40L) activity that has been shown to reduce B cell activation and autoantibody production, potentially halting inflammation and autoimmunity. CD40 is a well-established receptor pathway that contributes to autoimmune and inflammatory disease when it binds to the CD40L, causing B cell and T cell interaction that creates inflammation and disease. This can lead to conditions such as Sjögren's syndrome and other autoimmune diseases.

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 Horizon's clinical development plans; timing of clinical data; potential peak net sales of Horizon's medicines and medicine candidates; expected financial performance and operating results in future periods, including potential growth; the potential benefits of Horizon's medicine candidates; and business 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 that Horizon's actual future financial and operating results may differ from its expectations or goals; impacts of the COVID-19 pandemic and actions taken to slow its spread, including impacts on supplies and net sales of Horizon's medicines and potential delays in clinical trials; risks associated with the manufacture of biologic medicines; risks relating to Horizon's ability to successfully implement its business strategies, including its development, manufacturing and global expansion strategies; risks inherent in developing novel medicine candidates and existing medicines for new indications, including the risk that future clinical trials are not successful or are delayed; risks associated with regulatory approvals; risks in the ability to recruit, train and retain qualified personnel; competition, including potential generic competition; the ability to protect intellectual property and defend patents; 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.

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