Q32 Bio and Horizon Therapeutics plc Announce Dosing of First Patient in Phase 2 Trial of ADX-914 for Atopic Dermatitis

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WALTHAM, Mass. and DUBLIN, Oct. 27, 2022 /PRNewswire/ -- Q32 Bio, a clinical stage biotechnology company developing biologic therapeutics to restore immune homeostasis, and Horizon Therapeutics plc (Nasdaq: HZNP), today announced that the first patient has been dosed in a randomized, double-blind, placebo-controlled, Phase 2 multi-center proof-of-concept study in adult subjects to evaluate the safety and efficacy of ADX-914 in persistent, moderate-to-severe atopic dermatitis (AD). Q32 Bio and Horizon are developing ADX-914, a fully human anti-IL-7Rα antibody that re-regulates adaptive immune function, in collaboration.

"The dosing of the first patient in our Phase 2 trial of ADX-914 is an important milestone for both companies that underscores our commitment to delivering novel, disease-modifying treatments to individuals with autoimmune and inflammatory diseases," said Jodie Morrison, Board Member and Acting Chief Executive Officer of Q32 Bio. "We appreciate our close collaboration with Horizon as we advance ADX-914 in the clinic."

"We are excited to advance the development of ADX-914 in patients suffering from moderate to severe atopic dermatitis," added Jason Campagna, M.D., Ph.D., Chief Medical Officer of Q32 Bio. "Auto-reactive T cells that have escaped immune regulation have a central role in autoimmune skin diseases, including AD, and ADX-914 has the potential to attenuate this pathology and help restore immune homeostasis by targeting both the IL-7 and TSLP signaling pathways."

"ADX-914 represents a potential unique approach to correcting immune system dysregulation," said Elizabeth H.Z. Thompson, Ph.D., Executive Vice President, Research and Development, Horizon. "The start of this Phase 2 trial marks a significant moment in our collaboration with Q32 Bio, which we hope will result in meaningful advances for patients with autoimmune diseases such as atopic dermatitis."

AD is the most common type of eczema and affects more than 25 million people in the United States. In individuals with AD, the immune system is overactive, triggering inflammation that damages the skin barrier.

About ADX-914

ADX-914 is a fully human anti-IL-7Rα antibody that re-regulates adaptive immune function by blocking signaling mediated by both IL-7 and TSLP. Q32 has recently completed a biomarker-enabled Phase 1 study characterizing pharmacokinetics, pharmacodynamics and safety of ADX-914 that demonstrated pharmacological effect on T cells in healthy volunteers. Q32 Bio has initiated a Phase 2 trial in atopic dermatitis and is planning to initiate a Phase 2 trial in a second autoimmune disease in 2023.

About the Q32 Bio-Horizon Collaboration for ADX-914 in Autoimmune Diseases

In August 2022, Q32 Bio and Horizon announced that they had entered into a collaboration and option agreement to develop ADX-914 for the treatment of autoimmune diseases. Under the terms of the agreement, Horizon is obligated to fund development through completion of two Phase 2 trials of ADX-914, with Q32 being operationally responsible for the conduct of all program-related activities. Horizon received an option to acquire the ADX-914 program, exercisable through a period following completion of the Phase 2 trials.

About Q32 Bio

Q32 Bio is a clinical stage biotechnology company developing biologic therapeutics targeting powerful regulators of the innate and adaptive immune systems to re-balance immunity in autoimmune and inflammatory diseases. Q32 Bio's lead programs, focused on the IL-7 / TSLP receptor pathways and complement system, address immune dysregulation to help patients take back control of their lives.

The company's most advanced program, ADX-914, is a fully human anti-IL-7Rα antibody that re-regulates adaptive immune function and is being developed in collaboration with Horizon Therapeutics for the treatment of autoimmune diseases, including Phase 2 trials in both atopic dermatitis and an undisclosed indication. The IL-7 and TSLP pathways have been genetically and biologically implicated in driving several T cell-mediated

pathological processes in numerous autoimmune diseases.

Q32 Bio's lead program for innate immunity, ADX-097, is based on a novel platform enabling tissue-targeted regulation of the complement system without long-term systemic blockade – a key differentiator versus current complement therapeutics. Q32 Bio is currently conducting a first-in-human, Phase 1, ascending dose (SAD/MAD) clinical study of ADX-097 for the treatment of complement disorders. For more information, please visit www.Q32bio.com.

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.

Horizon Forward Looking Statements

This press release contains forward-looking statements, including, but not limited to, statements related to expected activities and payments under the collaboration between Horizon and Q32 and the potential benefits of ADX-914. These forward-looking statements are based on Horizon's and Q32'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 and uncertainties associated with development, regulatory approval and commercialization of novel therapeutic candidates, the timing of development activities under the collaboration; the fact that the collaboration is subject to early termination and the fact that Horizon has limited control over the development of the ADX-914 program prior to exercising its acquisition option. 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.

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