



Q32 Bio and Horizon Therapeutics Announce Collaboration in Autoimmune Diseases

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WALTHAM, Mass. and DUBLIN, Aug. 15, 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 they have entered into a collaboration and option agreement to develop ADX-914 for the treatment of autoimmune diseases.



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ADX-914 is a fully human anti-IL-7R α 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 expects to initiate a Phase 2 trial in atopic dermatitis later this year and is planning to initiate a Phase 2 trial in a second autoimmune disease next year.

"Horizon is a leader in the autoimmune and inflammatory disease space and brings to this collaboration both the resources and experience of a pharmaceutical company and the speed and agility of a biotech," said Michael Broxson, chief executive officer of Q32 Bio. "We're very excited to combine our strengths and expertise to continue to advance ADX-914 for autoimmune diseases, an area that is underserved by existing therapeutics and one where we hope to deliver life-changing medicines for patients in need."

Under the terms of the agreement, Horizon will fund development through completion of the two Phase 2 trials of ADX-914, with Q32 being operationally responsible for the conduct of all program-related activities. Horizon will receive an option to acquire the ADX-914 program, exercisable through a period following completion of the Phase 2 trials. During the option period, Q32 will receive \$55 million in the form of initial consideration and staged development funding, of which Horizon expects to recognize as R&D expenses approximately \$32.5 million in the third quarter of 2022, and the remainder in 2023. These payments will be included in Horizon's non-GAAP financial measures, including adjusted EBITDA. If Horizon exercises the option, Q32 may be eligible to receive up to an additional \$645 million in closing and milestone payments, as well as tiered royalties on net sales, less certain amounts payable under a pre-existing license agreement.

"We are very pleased to begin our collaboration with Q32 to advance ADX-914 through the next phase of clinical development," said Elizabeth H.Z. Thompson, Ph.D., executive vice president, research and development, Horizon. "By targeting the IL-7 and TSLP pathways, which are biologically and genetically implicated as central mediators of T cell-mediated pathologies, ADX-914 represents a novel approach to targeting a number of autoimmune diseases with the potential to restore healthy immune regulation."

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 severe 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-7R α antibody that re-regulates adaptive immune function and is being initially developed to treat an immune-mediated dermatological disease. 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 pioneering approach 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](#).

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, the potential benefits of the collaboration and ADX-914 and expected recognition of expenses and impact on Horizon's financial results. 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, whether Horizon exercises its option to acquire the ADX-914 program, the timing of development activities and payments 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 the 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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