Q32 Bio to Present Tissue-Targeted Complement Inhibitor ADX-097 Positive Phase 1 Clinical Trial Results at the American Society of Nephrology Kidney Week 2024

October 14, 2024

-- Poster presentation to highlight data from completed first-in-human, Phase 1 ascending dose clinical trial of ADX-097 in healthy volunteers; results support Phase 2 dose selection and continued clinical advancement of ADX-097 --

WALTHAM, Mass., Oct. 14, 2024 /PRNewswire/ -- Q32 Bio Inc. (Nasdaq: QTTB) ("Q32 Bio"), a clinical stage biotechnology company focused on developing biologic therapeutics to restore immune homeostasis, today announced that it will present clinical data supporting its program for innate immunity, ADX-097, at the American Society of Nephrology (ASN) Kidney Week 2024, taking place October 24-27, 2024, in San Diego, Calif. Abstracts are available here. ADX-097, Q32 Bio's lead product candidate from its tissue-targeted complement inhibitor platform, is a humanized anti-C3d mAb fusion protein being evaluated for the treatment of patients with renal diseases associated with increased complement activation.

"We look forward to presenting our promising clinical data at ASN Kidney Week 2024 that supports the continued advancement of ADX-097, our novel tissue-targeted inhibitor of complement activation designed to inhibit complement in the diseased tissue and minimize systemic complement blockade," said Shelia Violette, Ph.D., Chief Scientific Officer of Q32 Bio. "In our Phase 1 clinical trial, ADX-097 was observed to be generally well-tolerated with desirable pharmacokinetics and pharmacodynamics (PK/PD) properties. We believe ADX-097 has the potential to achieve relevant complement inhibition directly in the tissue while sparing systemic activity, with the goal of addressing limitations of the currently available systemic approaches, including infection risk and the need for high drug doses and frequent administration to achieve therapeutic levels of complement inhibition."

"These first-in-human data for ADX-097 that we will share at Kidney Week demonstrate the potential of our novel and differentiated approach to inhibiting the complement system, a validated biologic target," said Jodie Morrison, Chief Executive Officer of Q32 Bio. "We remain focused on advancing our pipeline of programs targeting the immune system for the treatment of autoimmune and inflammatory diseases, including ADX-097 in two Phase 2 clinical trials."

Presentation Details:

Abstract Title: ADX-097, a Tissue-Targeted Complement Inhibitor for the Treatment of Renal Diseases: Phase 1 Results in Healthy Participants and Model-Informed Phase 2 Dose Selection
Presenter: Dr. Bernd Jilma, M.D., Professor, Department of Clinical Pharmacology, Medical University of Vienna, Austria

Date & Time: Saturday, October 26, 2024, from 10:00 a.m. to 12:00 p.m. PT
Session Type: Poster
Session Title: C3G, TMA, MGRS, Amyloidosis, and More
Abstract ID: 4123429

Summary:

- ADX-097, a C3d mAb – fH fusion protein, was designed to inhibit complement in the diseased kidney while avoiding systemic blockade, providing the potential for an enhanced activity and safety profile. In a Phase 1 ascending dose clinical study of ADX-097 in healthy volunteers, ADX-097 demonstrated a favorable safety profile and desired PK/PD properties, supporting a Phase 2 dose that is predicted to provide tissue inhibition of complement in glomerular diseases while sparing systemic complement activity.

About ADX-097

ADX-097, the lead product candidate from Q32 Bio's tissue-targeted complement inhibitor platform, is a humanized anti-C3d mAb fusion protein. ADX-097 is designed to restore complement regulation—an integral part of the innate immune system—through a novel, tissue-targeted mechanism. Q32 Bio is currently evaluating ADX-097 in an open-label Phase 2 renal basket clinical trial and is planning to evaluate ADX-097 in a Phase 2 clinical trial in ANCA-Associated Vasculitis (AAV).

About Q32 Bio

Q32 Bio is a clinical stage biotechnology company developing biologic therapeutics targeting potent 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.

Q32 Bio's program for adaptive immunity, bempikibart (ADX-914), is a fully human anti-IL-7Rα antibody that re-regulates adaptive immune function for the treatment of autoimmune diseases. It is being evaluated in two Phase 2 trials for the treatment of atopic dermatitis and alopecia areata. 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 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 has completed a first-in-human, Phase 1 ascending dose clinical study of ADX-097 in healthy volunteers.

For more information, visit www.Q32Bio.com.

Availability of Other Information About Q32 Bio

Investors and others should note that we communicate with our investors and the public using our company website www.Q32Bio.com, including, but not limited to, company disclosures, investor presentations and FAQs, Securities and Exchange Commission filings, press releases, public conference call transcripts and webcast transcripts, as well as on X (formerly Twitter) and LinkedIn. The information that we post on our website or on X or LinkedIn could be deemed to be material information. As a result, we encourage investors, the media and others interested to review the information that we post there on a regular basis. The contents of our website or social media shall not be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended.

Forward-Looking Statements

This communication contains forward-looking statements within the meaning of the U.S. Private Securities Litigation Reform Act of 1995, as amended, relating to our business, operations and financial condition, including but not limited to current beliefs, expectations and assumptions regarding the future of our business, future plans and strategies, our clinical results and related timing, including statements regarding expectations surrounding the potential, safety, efficacy, and regulatory and clinical progress of Q32 Bio's product candidates, including ADX-097, and anticipated milestones and timing, among others.

Forward-looking statements generally include statements that are predictive in nature and depend upon or refer to future events or conditions, and include words such as "may," "will," "should," "would," "expect," "anticipate," "plan," "likely," "believe," "estimate," "project," "intend," and other similar expressions among others. Statements that are not historical facts are forward-looking statements. Forward-looking statements are based on current beliefs and assumptions that are subject to risks and uncertainties and are not guarantees of future performance. Actual results could differ materially from those contained in any forward-looking statement as a result of various factors, including, without limitation: interim, topline and preliminary data may change as more patient data become available, and are subject to audit and verification procedures that could result in material changes in the final data; data generated from our preclinical and clinical studies such as our Phase 2 clinical trials of ADX-097, may not meet our expectations; our product candidates may not provide the intended therapeutic benefits; our product candidates may cause serious adverse side effects; the ability to integrate our business with our merger partner successfully and to achieve anticipated synergies; the possibility that other anticipated benefits of the merger will not be realized, including without limitation, anticipated revenues, expenses, earnings and other financial results, and growth and expansion of our operations, and the anticipated tax treatment of the merger; our ability to retain, attract and hire key personnel; potential adverse reactions or changes to relationships with employees, suppliers or other parties resulting from the completion of the merger; potential business uncertainty, including changes to existing business relationships that could affect our financial performance; the need for additional funding, which may not be available; failure to identify additional product candidates and develop or commercialize marketable products; the early stage of our development efforts; potential unforeseen events during clinical trials could cause delays or other adverse consequences; risks relating to the regulatory approval process; the inability to maintain our collaborations, or the failure of these collaborations; our reliance on third parties, including for the manufacture of materials for our research programs, preclinical and clinical studies; failure to obtain U.S. or international marketing approval; ongoing regulatory obligations; effects of significant competition; unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives; product liability lawsuits; securities class action litigation; the impact of global pandemics and general economic conditions on our business and operations, including the our preclinical studies and clinical trials; the possibility of system failures or security breaches; risks relating to intellectual property; significant costs incurred as a result of operating as a public company; and such other factors as are set forth in Q32 Bio's periodic public filings with the SEC, including but not limited to those described under the heading "Risk Factors" in our Form 10-Q filed with the Securities and Exchange Commission on August 8, 2024 and any subsequent filings made with the Securities and Exchange Commission. Except as required by applicable law, we undertake no obligation to revise or update any forward-looking statement, or to make any other forward-looking statements, whether as a result of new information, future events or otherwise.

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