Q32 Bio Announces FDA Fast Track Designation Granted to Bempikibart (ADX-914) for the Treatment of Alopecia Areata

April 30, 2025

WALTHAM, Mass., April 30, 2025 /PRNewswire/ -- Q32 Bio Inc. (Nasdaq: QTTB) ("Q32 Bio"), a clinical stage biotechnology company focused on developing innovative therapies for alopecia areata (AA) and other autoimmune and inflammatory diseases, today announced that the United States Food and Drug Administration ("FDA") has granted Fast Track designation (FTD) to Q32 Bio's bempikibart (ADX-914) for the treatment of AA. Bempikibart is a fully human anti-IL-7Rα antibody that re-regulates adaptive immune function by blocking IL-7 and TSLP signaling that is in development for the treatment of AA and currently being evaluated in a Phase 2 program.

"The Fast Track designation granted by the FDA recognizes the seriousness of AA and the significant current unmet medical need while underscoring bempikibart's potential as a novel, differentiated therapy for patients needing new options," said Jodie Morrison, Chief Executive Officer of Q32 Bio. "This Fast Track designation follows the encouraging clinical activity observed in Part A of our SIGNAL-AA clinical trial and the recent initiation of dosing in the Part A open-label extension and Part B portions of the SIGNAL-AA trial. We look forward to continued collaboration with the FDA as we work to deliver this potentially paradigm-shifting treatment to patients."

Fast Track is a process designed to facilitate the development and expedite the review of new drugs to treat serious diseases and fill an unmet medical need with the purpose of getting important new drugs to patients earlier. Filling an unmet medical need is defined as providing a therapy where either none exists or providing a therapy which may be potentially better than available therapies. A drug that receives FTD may be eligible for more frequent meetings and communications with the FDA to discuss development plans and ensure the collection of appropriate data needed to support approval and for a rolling review of an application for marketing approval. Drugs receiving FTD may also be eligible for Accelerated Approval and Priority Review if relevant criteria are met. More information on the FDA's Fast Track process is available here.

About Q32 Bio

Q32 Bio is a clinical stage biotechnology company whose science targets potent regulators of the adaptive immune system to re-balance immunity and is focused on developing innovative therapies for alopecia areata and other autoimmune and inflammatory diseases. About 700,000 people in the United States live with alopecia areata[1], a disease which has a life-altering impact on patients and limited current treatment options. Q32 Bio is advancing bempikibart (ADX-914), a fully human anti-IL-7Rα antibody that re-regulates adaptive immune function, for the treatment of alopecia areata in an ongoing Phase 2 program. The IL-7 and TSLP pathways have been genetically and biologically implicated in driving several T cell-mediated pathological processes in numerous autoimmune diseases.

For more information, visit www.Q32Bio.com.

[1]National Alopecia Areata Foundation

Availability of Other Information About Q32 Bio

Investors and others should note that Q32 Bio communicates with its investors and the public using its website www.Q32Bio.com, including, but not limited to, Q32 Bio's disclosures, investor presentations and FAQs, Securities and Exchange Commission (the "SEC") filings, press releases, public conference call transcripts and webcast transcripts, as well as on X (formerly Twitter) and LinkedIn. The information that Q32 Bio posts on its website or on X or LinkedIn could be deemed to be material information. As a result, Q32 Bio encourages investors, the media and others interested to review the information that it posts there on a regular basis. The contents of Q32 Bio's 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, and other federal securities laws. Any statements contained herein which do not describe historical facts, including, among others, Q32 Bio's beliefs, observations, expectations and assumptions regarding the data reported to date from Part A of the SIGNAL-AA Phase 2a clinical trial, the plan, purpose and timing of Part B of the SIGNAL-AA Phase 2a clinical trial and the anticipated timing of its data, the safety, tolerability, clinical activity, potential efficacy and potential benefits of bempikibart, and the potential benefits conferred by Fast Track designation for bempikibart; which involve risks and uncertainties that could cause actual results to differ materially from those discussed in such forward-looking statements.

Forward-looking statements are based on management's current beliefs and assumptions, which are subject to risks and uncertainties and are not guarantees of future performance. Such risks and uncertainties include, among others, the risk that additional data, or the results of ongoing data analyses, may not support Q32 Bio's current beliefs and expectations for bempikibart, including with respect to the durability of clinical responses, safety profile, and the risk that ongoing and future clinical studies, including Part B of the SIGNAL-AA Phase 2a clinical trial may not be enrolled as quickly as expected or at all or might be more costly than expected or might not yield anticipated results, and that Fast Track designation by the FDA may not actually lead to a faster development or regulatory review or approval process and such other risks and uncertainties identified in Q32 Bio's periodic, current and other filings with the SEC, including its Annual Report on Form 10-K for the year ended December 31, 2024 and any subsequent filings with the SEC, which are available at the SEC's website at www.sec.gov. Any such risks and uncertainties could materially and adversely affect Q32 Bio's results of operations and its cash flows, which would, in turn, have a significant and adverse impact on Q32 Bio's stock price. Q32 Bio cautions you not to place undue reliance on any forward-looking statements, which speak only as of the date they are made. Q32 Bio disclaims any obligation to publicly update or revise any such statements to reflect any change in expectations or in events, conditions or circumstances on which any such statements may be based, or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements.

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