



Q32 Bio Doses First Patients in Both Part A Open-Label Extension and Part B of SIGNAL-AA Phase 2a Trial Evaluating Bempikibart in Alopecia Areata

April 16, 2025

-- SIGNAL-AA Part B topline data readout on-track for 1H'26 --

WALTHAM, Mass., April 16, 2025 /PRNewswire/ -- Q32 Bio Inc. (Nasdaq: QTTB) ("Q32 Bio" or the "Company"), a clinical stage biotechnology company focused on developing innovative therapies for alopecia areata and other autoimmune and inflammatory diseases, today announced that the Company has dosed the first patients in both the Part A open-label extension (OLE) and Part B of the SIGNAL-AA Phase 2a clinical trial evaluating bempikibart in patients with alopecia areata (AA).

"Dosing the first patients in both the Part A OLE and Part B of our SIGNAL-AA trial highlights our ongoing momentum in the clinical development of bempikibart as a potential treatment for AA," said Jodie Morrison, Chief Executive Officer of Q32 Bio. "Based upon the encouraging clinical activity observed to date, including patients with continued responses in long-term follow-up months after completing treatment, robust pharmacologic data and a well-tolerated safety profile, we believe bempikibart has the potential to transform the AA treatment paradigm as a new and differentiated therapy for patients, if approved."

Q32 previously announced results from Part A of the SIGNAL-AA Phase 2a clinical trial, a randomized, double-blind, placebo-controlled, multi-center clinical trial evaluating bempikibart in adult patients with severe and very severe AA (baseline Severity of Alopecia Tool (SALT) scores of 50-100) treated over 24 weeks, with follow-up through 36 weeks. Results reported to date have demonstrated encouraging clinical activity, including improvement from baseline on SALT score and meaningful achievement of SALT-20 (SALT score less than or equal to 20) response through week 36. Part A of the SIGNAL-AA clinical trial has been completed. Through additional post-clinical trial data collection after 36 weeks, continued responses were observed in multiple patients through week 55, approximately seven months post last dose, along with continued SALT reductions in some patients, despite dosing through only 24 weeks. The Company believes these findings may be suggestive of a remittive effect, durability of response, and a key differentiation from currently approved therapies. Based on re-consent rates and strong patient demand for continued dosing, Q32 Bio initiated the OLE for eligible patients that completed Part A to enable longer-term follow-up of patients.

Part B of the SIGNAL-AA Phase 2a clinical trial is an open-label clinical trial, dosing approximately 20 evaluable severe or very severe AA patients with bempikibart for 36 weeks, with follow-up out to 52 weeks. Dosing will include an initial loading regimen of 200mg of bempikibart dosed weekly over four weeks, followed by a maintenance dose of 200mg every-other-week over a 32-week period for a total dosing period of 36 weeks. Efficacy will be evaluated on the basis of mean percentage change from baseline in SALT scores as well as the proportion of subjects achieving various relative and absolute SALT improvements at week 36, with follow-up through week 52. The trial is intended to support advancement into pivotal trials upon completion, pending review of the results. Q32 Bio expects to report topline data from SIGNAL-AA Part B in the first half of 2026.

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 areata¹, a disease which has a life-altering impact on patients and limited current treatment options. The Company is advancing bempikibart (ADX-914), a fully human anti-IL-7R α 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, the Company'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 the Company'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, and the safety, tolerability, clinical activity, potential efficacy and potential benefits of 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 the Company's current beliefs and expectations for bempikibart, including with respect to the durability of clinical responses, the risk that ongoing and future clinical studies, including Part B of the SIGNAL-AA Phase 2a clinical trial, may not be completed by the first half of 2026 or at all, might be more costly than expected or might not yield anticipated results, and such other risks and uncertainties identified in the Company'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 the Company's results of operations and its cash flows, which would, in turn, have a significant and adverse impact on the Company's

stock price. The Company cautions you not to place undue reliance on any forward-looking statements, which speak only as of the date they are made. The Company 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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