Q32 Bio Announces Completion of Enrollment in Part B of SIGNAL-AA Phase 2a Clinical Trial of Bempikibart for Alopecia Areata

October 21, 2025

-- SIGNAL-AA Part B exceeded target enrollment based on demand from patients; trial size increased to 33 patients --

WALTHAM, Mass., Oct. 21, 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 it has completed enrollment in Part B of its SIGNAL-AA Phase 2a clinical trial evaluating bempikibart in patients with severe or very severe AA. Bempikibart is a fully human anti-IL-7Rα antibody designed to re-regulate adaptive immune function by blocking IL-7 and TSLP signaling.

"We are pleased to complete enrollment and exceed our initial enrollment target in Part B of the SIGNAL-AA trial, which reflects our team's capabilities to execute our clinical development plan and the strong interest from patients and their healthcare providers in bempikibart's IL-7Rα antagonist approach in AA," said Jodie Morrison, Chief Executive Officer of Q32 Bio. "In SIGNAL-AA Part A, bempikibart demonstrated encouraging clinical activity, a well-tolerated safety and tolerability profile, and expected on-mechanism changes in T-cells, indicative of potent IL-7 inhibition. Part B, which includes a loading regimen and dosing through 36 weeks, is intended to build upon these findings as we advance bempikibart in AA."

Ms. Morrison added, "Patients with AA are in need of new, safer, and more durable treatment alternatives to currently approved agents, and this milestone underscores our commitment to advancing bempikibart as a potentially differentiated therapeutic option. We look forward to sharing topline data from Part B of the SIGNAL-AA trial next year, which, pending the results, could support advancement into pivotal trials upon completion."

The Part B portion of SIGNAL-AA is an open-label clinical trial dosing severe or very severe AA patients with a maximum duration of current episode of four years. Patients will be treated with bempikibart for 36 weeks, with follow-up out to 52 weeks. Dosing includes an initial loading regimen of 200mg of bempikibart dosed weekly for four doses, 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 Severity of Alopecia Tool (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.

Emerging signs of clinical activity are being observed amongst the early-enrolling patients in Part B of the trial. In addition, based on preliminary pharmacokinetic data available to date in the Part B portion of SIGNAL-AA, steady state concentration of drug in patients is achieved at least nine weeks earlier as compared to Part A of the clinical trial due to the inclusion of the loading regimen, which may have the potential to induce earlier responsiveness.

Total enrollment of 33 patients exceeded the initial target of approximately 20 patients due to demand from patients and their healthcare providers. As a result of the over-enrollment, Q32 Bio expects to report topline data from SIGNAL-AA Part B in mid-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 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 are forward-looking statements, including, among others, Q32 Bio's beliefs, observations, expectations and assumptions regarding 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, durability, potential efficacy and potential benefits of bempikibart, and Q32 Bio's beliefs, expectations and assumptions regarding the future of its business, future plans and strategies, 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 including emerging signs of clinical activity and pharmacokinetic data available to-date from early-enrolling patients in Part B of the SIGNAL-AA Phase 2a clinical trial, may not support Q32 Bio'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 mid-2026 or at all, might be more costly than expected or might not yield anticipated results, that Q32 Bio may use its capital resources sooner than currently anticipated and such other risks and uncertainties identified in Q32 Bio's periodic, current and other filings with the SEC, including its Quarterly Report on Form 10-Q for the quarter ended June 30, 2025 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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