



Q32 Bio Presents Results from Part B of the SIGNAL-AA Clinical Trial of Bempikibart in Alopecia Areata in a Late-Breaker at the European Academy of Dermatology and Venereology Congress 2026

September 30, 2026

-- Clinically meaningful efficacy data observed on primary and key secondary endpoints at Week 36 --

-- Robust durability, including maintenance and deepening of response, observed following the 16-week off-drug period supporting potential for less frequent, chronic maintenance dosing --

-- Mechanism of action supported by biomarker results and biopsy findings --

-- Generally well-tolerated safety profile, consistent with prior studies, with no new safety signals --

-- Data supports further development of bempikibart as a chronic treatment in alopecia areata; Q32 Bio intends to advance a registration-directed program in the first half of 2027 --

WALTHAM, Mass., Sept. 30, 2026 /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 additional 36-week results and initial findings from the 16-week off-drug period from Part B of the SIGNAL-AA Phase 2a clinical trial evaluating bempikibart in patients with severe or very severe AA. These results were presented across a late-breaking oral and poster presentation at the European Academy of Dermatology and Venereology ("EADV") Congress 2026. Q32 Bio [previously announced](#) topline results from this trial in July 2026. Bempikibart is a fully human anti-IL-7R α antibody designed to re-regulate adaptive immune function by blocking IL-7 and TSLP signaling.

"We're proud to share our compelling SIGNAL-AA Part B results with the scientific community in late-breaking oral and poster presentations at EADV. We are committed to developing bempikibart as a highly differentiated, targeted treatment option for patients with alopecia areata and believe our Part B results demonstrate meaningful progress on that commitment," said Jodie Morrison, Chief Executive Officer of Q32 Bio. "Bempikibart's robust efficacy data and durability observed across the 36-week treatment period and 16-week off-drug period in both JAK inhibitor-experienced and JAK inhibitor-naïve patients, changes on biomarkers supportive of its bifunctional mechanism, and its favorable safety and tolerability profile support its continued development in a registration-directed program in patients with severe or very severe alopecia areata as well as in expanded alopecia areata populations and other autoimmune and inflammatory indications."

"Patients and physicians currently lack a treatment option for this complex, immune driven disease that combines robust efficacy, a favorable safety profile that excludes black box warnings and other frequent monitoring requirements, and delivers durable control supporting less frequent, chronic maintenance dosing," said Arash Mostaghimi, M.D., M.P.A., M.P.H., Associate Professor of Dermatology and Vice Chair of Clinical Trials and Innovation, Brigham and Women's Hospital, Harvard Medical School. "The SIGNAL-AA Part B results support the potential of bempikibart to address this unmet need and become a standard of care, first-line option for patients with alopecia areata, and I look forward to results from future clinical trials."

Results from Part B of the SIGNAL-AA Program:

The Part B portion of the SIGNAL-AA program is an open-label clinical trial building upon the previously completed Part A, which established proof-of-concept of bempikibart in AA. In Part B, bempikibart is being evaluated in 33 patients with severe or very severe AA (baseline Severity of Alopecia Tool ("SALT") scores of 50-100) with a maximum duration of current episode of four years. Enrollment amongst patients with prior exposure to JAK inhibitor ("JAKi") therapy was allowed; amongst the 33 enrolled patients, 36.4% had previously been treated with oral JAKis.

Total enrollment exceeded the initial target due to patient demand. In Part B, patients are treated with bempikibart for 36 weeks, with 16-week off-drug follow-up through Week 52 before optional enrollment in the open-label extension ("OLE"). Dosing includes an initial loading regimen of 200mg of bempikibart dosed weekly for four doses, followed by continued dosing of 200mg every-other-week over a 32-week period, for a total dosing period of 36 weeks. Across both regimens, bempikibart was administered subcutaneously ("SC").

The prespecified primary efficacy analysis was evaluated on the basis of mean percentage change from baseline in SALT scores in the modified intent-to-treat ("mITT") population. Additional prespecified efficacy analyses included the proportion of patients achieving various relative and absolute SALT improvements including SALT₂₀ (80% of scalp hair coverage), SALT₃₀ (30% improvement in SALT score from baseline), and SALT₅₀ (50% improvement in SALT score from baseline) responses at Week 36. Patients were then followed through the off-drug period to Week 52.

Highlights from the EADV Congress 2026 late-breaking and poster presentations include:

Results from the 36-Week Treatment Period in Part B of the SIGNAL-AA Program:

Bempikibart demonstrated clinically meaningful efficacy data on primary and key secondary endpoints at Week 36 supporting its advancement into a registration-directed program.

- Mean percent reduction in SALT score from baseline of 35.3% in the mITT analysis.
- 40.0% (10/25) of patients in the mITT analysis and 30.3% (10/33) of patients in the intent-to-treat ("ITT") analysis achieved a SALT₂₀ response.
- In addition to SALT₂₀ response being observed in patients with both severe and very severe disease, it was also observed in both IgE-high and IgE-low patients and in both patients with greater than and less than two-year duration of episode.
- 44.0% (11/25) of patients in the mITT analysis and 33.3% (11/33) of patients in the ITT analysis achieved SALT₃₀ response.

- 44.0% (11/25) of patients in the mITT and 33.3% (11/33) of patients in the ITT analysis achieved SALT₅₀ response.
- In the mITT analysis, 10 patients had received an oral JAKi before enrolling. Of these, four had responded to their most recent JAKi (defined as at least 30% improvement in SALT score) and six had not. Mean percent reduction in SALT score from baseline was 48.3% in prior JAK responders, compared with 4.8% in prior JAK non-responders. Reduction in mean SALT score of JAK-naïve patients was 44.1%.

Results from the 16-Week Off-Drug Follow-Up Period in Part B of the SIGNAL-AA Program:

Bempikibart demonstrated robust durability, with maintenance and deepening of response observed, in the 16-week off-drug follow-up period.

- In total, 18 patients entered the 16-week off-drug period. At the 16-week off-drug time point, 44% of patients achieved a SALT-20 response, 61% achieved SALT₃₀ response, and 50% achieved SALT₅₀ response.
- Of the patients who entered the off-drug follow-up period, 12 patients had demonstrated hair growth by the end of the treatment period at Week 36. Maintenance of response (with maintenance defined as a less than 20-point SALT score worsening from the last on-treatment value) was observed in 100% of these patients and deepening of response was observed in 42% of these patients. Mean SALT score in these patients remained stable through 16-weeks off-drug.
- In the 16-week off-drug follow-up period, one patient who achieved a SALT-10 at Week 36 achieved complete hair growth (SALT = 0) and two additional patients who achieved SALT-20 at Week 36 had a deepening of response and achieved a SALT-10.
- One latent responder during the 36-week treatment period converted to a response, achieving a SALT-20, at the end of the 16-week off-drug period.

"We are excited to show once again that bempikibart was able to induce deep, durable responses in severe and very severe alopecia areata. Responses were maintained and deepened through the 16-week off-drug period, and one latent responder converted to SALT-20 after stopping treatment, similar to what we saw in Part A, demonstrative of the potential for even greater clinical impact with continued dosing," said José Trevejo, M.D., Ph.D., Chief Medical Officer of Q32 Bio. "We believe these data support a less frequent, chronic maintenance dosing regimen once patients respond. We look forward to exploring a potential maintenance regimen in our open-label extensions as we move rapidly into registrational studies in the first half of 2027."

Pharmacokinetic ("PK"), Pharmacodynamic ("PD"), and Anti-Drug Antibody ("ADA") Profile:

Bempikibart demonstrated a favorable PK, PD and ADA profile in Part B.

- PK data from Part B support the loading dose regimen had its intended effect, achieving steady state concentrations approximately 10 weeks earlier than in Part A.
- Expected reductions in CD3+ T-cells were observed, with on-mechanism reductions in four T-effector cytokines assessed at baseline and Weeks 24 and 36. Patients in the upper-tier at baseline showed meaningful reductions in IFN γ , IL-17, and IL-6. CXCL10, a downstream marker of IFN γ activity, decreased meaningfully in responders versus non-responders.
- Substantial reductions in biomarkers of Th2, including TARC, IgE and eosinophils.
- Post-treatment biopsies showed reduced CD3+/CD8+ infiltrates around hair follicles and increased presence of anagen follicles supportive of active hair growth.
- Negligible ADA was observed with no impact on PK.

"Reductions in Th1 and Th2 biomarkers observed across Part B further demonstrate the potential of bempikibart's unique IL-7 and TSLP inhibitory mechanism to translate into clinical benefit for patients, while biopsy results provide strong evidence of bempikibart's potential to inhibit local inflammation and restore immune homeostasis in the hair follicle," said Shelia Violette, Ph.D., Co-Founder and Chief Scientific Officer of Q32 Bio. "These results strengthen our conviction in the potential to deliver a meaningful treatment option to patients with alopecia areata and provide strong rationale for advancing bempikibart development in other autoimmune and inflammatory conditions where IL-7 and TSLP play a role."

Safety and Tolerability Results:

Bempikibart was observed to have a generally well-tolerated safety profile in SIGNAL-AA Part B, consistent with prior studies. No new safety signals were observed. There were no serious adverse events or Grade 3 or higher adverse events related to treatment. The most common treatment-emergent adverse event was injection site reaction ("ISR") (36.3%) which were primarily singular events, with ISR incidence of 4% across all Part B dose administrations. All ISRs reported were mild and resolved with no intervention, with the majority resolving within a day. On-target reduction in absolute lymphocyte count flattened at Weeks 24 to 28 with no correlation to infection events.

The presentations will be available in the "[Presentations and Publications](#)" section of the Q32 Bio website following the formal EADV presentation.

Bempikibart Development Program in AA:

Following completion of the Part B 36-week treatment period and 16-week off-drug follow-up period, eligible patients can enroll in an OLE. Enrollment and dosing remain ongoing in the OLE. Analysis from the Part B 16-week off-drug follow-up period and OLE will inform the bempikibart long-term chronic maintenance regimen, which could include monthly, bi-monthly or quarterly dosing, which will be evaluated in future studies. Q32 Bio anticipates data from the Part B OLE in the second half of 2027.

Q32 Bio plans to advance bempikibart into a registration-directed program for patients with severe or very severe AA in the first half of 2027 subject to planned regulatory discussions in the second half of 2026. Additionally, based on results observed, Q32 Bio is evaluating opportunities for bempikibart in expanded AA populations as well as in other autoimmune and inflammatory indications.

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. Q32 Bio 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.

¹National 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 results from the Part B of the SIGNAL-AA Phase 2a clinical trial, the safety, tolerability, clinical activity including biomarker data, potential efficacy and potential benefits of bempikibart, plans and expectations for Part B of the SIGNAL-AA Phase 2a clinical trial, the anticipated timing of data results, safety, tolerability and findings from the potential Part B OLE, the potential of advancing bempikibart in other autoimmune and inflammatory conditions, the expectations surrounding the potential, safety, efficacy, and regulatory and clinical progress of Q32 Bio's product candidates, including bempikibart, and anticipated milestones, timing of anticipated registrational trials, data readouts and timing, and the United States AA market size and potential commercial opportunities, and Q32 Bio's beliefs, expectations and assumptions regarding the future of its business, future plans and strategies, among others, are forward-looking statements; which involve risks and uncertainties that could cause actual results to differ materially from those discussed in such forward-looking statements.

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 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, the risk that ongoing and future clinical studies might be more costly than expected or might not yield anticipated results, that Q32 Bio may use its capital resources sooner than currently anticipated, the sufficiency of Q32 Bio's cash and cash equivalents to provide financial runway and that we may need additional funding to complete clinical studies, which may not be available on favorable terms or at all 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, 2026 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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