ACELYRIN, INC. Announces Topline Results From Phase 2b/3 Study of Izokibep for the Treatment of Uveitis

December 10, 2024

Phase 2b/3 trial of izokibep did not meet primary endpoint; secondary endpoints also did not achieve statistical significance

Company continues focus on development of subcutaneous lonigutamab in thyroid eye disease, with initiation of Phase 3 program on schedule for Q1 2025

$562.4 million in cash, cash equivalents, and short-term marketable securities on September 30, 2024 projected to provide runway to mid-2027, including completion of planned Phase 3 trials and BLA-enabling activities for lonigutamab as well as selective pipeline expansion

LOS ANGELES, Dec. 10, 2024 (GLOBE NEWSWIRE) -- ACELYRIN, INC. (Nasdaq: SLRN), a late-stage clinical biopharma company focused on accelerating the development and delivery of transformative medicines in immunology, today announced that its Phase 2b/3 trial of izokibep in non-infectious, non-anterior uveitis did not meet the primary endpoint of a statistically significant improvement in time to treatment failure versus placebo as measured by treatment failure rates at 24 weeks. Based on these data, and previously announced guidance regarding other indications, ACELYRIN will not make any additional internal investment in developing izokibep. ACELYRIN will continue to focus on executing its late-stage development program for lonigutamab in thyroid eye disease (TED).

“We are very grateful to all the patients, families and clinical investigators for their time and effort put into this trial, and, like them, we are disappointed that it did not meet its primary endpoint,” said Mina Kim, Chief Executive Officer of ACELYRIN. “Consistent with our previously announced pipeline prioritization strategy, we will continue to focus on advancing subcutaneous lonigutamab for patients with thyroid eye disease. We look forward to hosting a lonigutamab investor event in early 2025 and remain on track to initiate the Phase 3 program in the first quarter of 2025. Given our strong balance sheet, we will also continue evaluating selective and opportunistic pipeline expansion opportunities.”

About the Phase 2b/3 Uveitis Clinical Trial and Topline Results:
The Phase 2b/3 clinical trial (NCT05683496) evaluated izokibep versus placebo in non-infectious, non-anterior uveitis. Patients in the study were randomized 1:1 to receive weekly subcutaneous injections of izokibep 160 mg or placebo. The primary endpoint of the study was improvement in time to treatment failure versus placebo as measured by treatment failure rates at 24 weeks. Key secondary endpoints included measurement of the change in best corrected visual acuity (BCVA), change in visual function as measured by the National Eye Institute’s Visual Function Questionnaire (VFQ25), % change in central retinal thickness (CRT) as measured by Spectral-Domain Optical Coherence Tomography and achievement of Quiescence.

In the trial, the treatment failure rate at 24 weeks was 45.0% (p-value: 0.4914) for izokibep and 50.7% for placebo. Statistical significance was not reached for any secondary endpoint and no clinical benefit was observed. Izokibep was well-tolerated in the trial, with a safety profile consistent with previous data and the IL-17A class.

ACELYRIN’s revised operating plan in connection with the announcement of the pipeline prioritization and corporate restructuring on August 13, 2024 included the funding of two Phase 3 trials and BLA-enabling activities for lonigutamab, selective pipeline expansion and the completion of the izokibep uveitis trial. Consistent with that plan, there will be no organizational or operational plan changes related to today’s announcement. The Company continues to project that its existing cash resources will provide runway to mid-2027.

About ACELYRIN, INC.
ACELYRIN, INC. (Nasdaq: SLRN) is focused on providing patients life-changing new treatment options by identifying, acquiring, and accelerating the development and commercialization of transformative medicines. ACELYRIN’s lead program, lonigutamab, is a subcutaneously delivered monoclonal antibody targeting IGF-1R being investigated for the treatment of thyroid eye disease.

For more information about ACELYRIN, visit us at www.acelyrin.com or follow us on LinkedIn and X.

Forward Looking Statements
This press release contains forward-looking statements including, but not limited to, statements related to ACELYRIN’s expectations regarding its cash runway and ability to fund several milestones; ACELYRIN’s ability to accelerate the development and delivery of transformative medicines in immunology; ACELYRIN’s plan to not make any additional internal investment in developing izokibep and to focus on executing its late-stage development program for lonigutamab in TED; anticipated development activities including the planned initiation of the lonigutamab Phase 3 program and the timing thereof; the therapeutic potential of lonigutamab; the potential expansion of ACELYRIN’s pipeline; and other statements that are not historical fact. These forward-looking statements are based on ACELYRIN’s current plans, objectives and projections, and are inherently subject to risks and uncertainties that may cause ACELYRIN’s actual results to materially differ from those anticipated in such forward-looking statements. Such risks and uncertainties include, without limitation, those associated with the successful completion of development and regulatory activities with respect to lonigutamab; maintaining and defending intellectual property protection; delays or failures to secure adequate supply of lonigutamab; ACELYRIN’s failure to realize the expected benefits of its potential acquisition of additional programs; legal proceedings, government investigations or other actions; macroeconomic conditions; market volatility; and other risks and uncertainties affecting ACELYRIN including those described from time to time under the caption “Risk Factors” and elsewhere in ACELYRIN’s current and future reports filed with the Securities and Exchange Commission, including its Quarterly Report on Form 10-Q for the quarter ended September 30, 2024. Forward-looking statements contained in this press release are made as of this date, and ACELYRIN undertakes no duty to update such information except as required under applicable law.

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