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ACELYRIN, INC. Announces Long-term 32-Week Data from the Phase 2b Trial of Izokibep in Hidradenitis Suppurativa Demonstrating Sustained Responses and Deepening Clinical Benefit - Improving Quality of Life for Patients

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Dose ordered and robust HiSCRs were rapidly demonstrated with about a third of patients achieving HiSCR100, or resolution of abscesses and nodules, by week 16 and through week 32

Deep and consistent HiSCR responses were observed for placebo patients switching to active treatment

Marked reductions in draining tunnels and skin pain also contributed to clinically meaningful improvements in quality of life

Potential for differentiation was demonstrated with both high clinical responses as well as a favorable safety profile consistent with the IL-17A class and previous izokibep experience

LOS ANGELES, March 11, 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 long-term data from a Phase 2b clinical trial of izokibep in hidradenitis suppurativa (HS). These data demonstrated no evidence of increased safety liability with longer-term treatment and increased duration of therapy was associated with further clinical improvements over time.

Patients who switched from placebo to izokibep at week 16 achieved a similar speed and magnitude of response as those who began treatment with izokibep at baseline for HiSCRs, draining tunnels, skin pain and Dermatology Life Quality Index (DLQI). High orders of HiSCR were achieved with the majority of patients achieving HiSCR75 and about a third achieving HiSCR100 by week 16 and through 32 weeks.

These results are from an open label extension with all subjects through week 32. Additional information can be found at ACELYRIN.com. Further data from this trial will be presented at future scientific meetings.

“The magnitude and depth of responses for signs and symptoms of Hidradenitis Suppurativa in this long-term study are consistent with izokibep’s mechanism of action. These results are corroborated by the appreciable clinical responses observed in the placebo cross-over cohort, which demonstrate rapid, HiSCR response,” said Kim Papp, MD, PhD, President and Director of Research, Probity Medical Research, Inc. “We believe that these consistent and robust results in HS point to the future potential for izokibep to deliver differentiated clinical benefits for patients.”

“It’s heartening to see the exciting results from this longer term follow up across all of the important manifestations of this debilitating disease, despite the initial primary endpoint of this study not meeting statistical significance,” said Shao-Lee Lin, MD, PhD, Founder and CEO of ACELYRIN. “Across indications, we have observed clinically meaningful and potentially differentiated benefit from izokibep. We have consistently seen responses in high order efficacy measures such as HiSCR100 in HS and ACR70 and PASI100 in PsA, that move patients toward disease resolution. This reinforces our enthusiasm for developing izokibep as an important potential new medicine for patients.”

Izokibep was well-tolerated with a favorable safety profile consistent with previous experience and the IL-17A class. Potential for differentiation was demonstrated with higher clinical responses achieved earlier than reported by other IL-17A agents and the IL-17A&F agents without evidence to date for increased risk of infection, especially fungal or suicidal ideation and behavior, in a patient population predisposed to infection and clinical depression.

“The pain and discomfort that people living with HS experience on a daily basis is extremely debilitating,” said Falk Bechara, MD, Clinical Professor in the Department of Dermatology at the Ruhr-University Bochum. “These data are impressive, showing izokibep dose ordered, fast speed of onset across endpoints. The consistency and magnitude of responses in resolution of abscesses and nodules, reduction in draining tunnels, and improvement in pain, impact overall quality of life and suggest that izokibep could be a significant therapeutic for HS, with a positive benefit risk in addressing an unmet need.”

Topline data from an ongoing phase 3 trial in HS is expected by the end of 2024. A confirmatory phase 3 trial of approximately 400 patients is planned to address guidance on size of safety database given the FDA no longer considers moderate-to-severe HS an orphan disease.

About the Phase 2b Hidradenitis Suppurativa clinical trial
The Phase 2b clinical trial (NCT05355805) is a global, multi center, randomized double-blind, placebo-controlled, trial evaluating the safety and efficacy of izokibep dosed 160 mg every week (QW) or every two weeks (Q2W) versus placebo. At week 16, patients who received placebo were randomized to either the weekly or every two week active treatment arm and all patients were assessed through week 32. The objective of the study was to determine the effect of izokibep versus placebo on various measures of clinical impact and determine the appropriate dose(s) for further clinical development in hidradenitis suppurativa.

For more information about the Phase 2b HS clinical trial, please visit www.clinicaltrials.gov.

About Hidradenitis Suppurativa
Hidradenitis Suppurativa (HS) is a chronic Inflammatory skin disease causing scarring, abscesses, malodor and pain. HS typically occurs in areas with high concentrations of sweat glands and is typically accompanied by pain, malodor, drainage, and disfigurement that contribute to disability and a devastating impact on quality of life. Patients with HS miss a greater number of days of work and have increased disability compared to the average population. In 2019, there were an estimated 317,000 HS patients in the U.S., of which 50-60% were moderate-to-severe HS patients.

About Izokibep
Izokibep is a small protein therapeutic designed to inhibit IL-17A with high potency through tight binding affinity, the potential for robust tissue penetration due to its small molecular size, about one-tenth the size of a monoclonal antibody, and an albumin binding domain that extends half-life.

Clinical trial data supports the hypothesis that these unique characteristics of izokibep may provide clinically meaningful and differentiated benefits for patients, including resolution of key manifestations of disease. Izokibep is being evaluated in multiple late-stage trials in moderate-to-severe hidradenitis suppurativa (HS), psoriatic arthritis (PsA), and uveitis, with plans to initiate an additional Phase 3 program in axial spondyloarthritis (AxSpA).

About ACELYRIN, INC.
ACELYRIN, INC. (Nasdaq: SLRN) is a Los Angeles area-based late-stage clinical biopharma company – with additional operations in the San Francisco Bay area – focused on providing patients life-changing new treatment options by identifying, acquiring, and accelerating the development and commercialization of transformative medicines.

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 the overall advancement of ACELYRIN's programs and ability to accelerate the development and delivery of transformative medicines; anticipated development activities including the planned initiation of a clinical program in AxSpA; the therapeutic potential of ACELYRIN's product candidates including its ability to offer clinically meaningful, differentiated benefits for patients that may include resolution of key manifestations of disease and limit safety liability; 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 ACELYRIN's product candidates 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, 2023. 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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