ACELYRIN

ACELYRIN, INC. Announces Positive Phase 3 Data for Izokibep in Hidradenitis Suppurativa; Focuses Strategy on Lonigutamab and Reports Second Quarter 2024 Financial Results

August 13, 2024

Phase 3 trial of izokibep in hidradenitis suppurativa met primary endpoint of HiSCR75 at 12 weeks

Company to prioritize development of lonigutamab; dose confirmation ongoing in Phase 2 trial with plans to initiate Phase 3 program in Q1 2025

Cash, cash equivalents, and short-term marketable securities at June 30, 2024 of $635.2 million; projected to extend cash runway to mid-2027

Company to hold webcast and conference call at 5:00pm ET today

LOS ANGELES, Aug. 13, 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 the Phase 3 trial of izokibep in Hidradenitis Suppurativa (HS) achieved its primary endpoint of HiSCR75 at 12 weeks, as well as a refocused pipeline strategy that prioritizes lonigutamab in thyroid eye disease (TED) and is projected to extend cash runway.

“While today’s positive HS data and previously announced psoriatic arthritis (PsA) data support a path to approval for izokibep, we have determined that a program of this breadth and size is best brought to market by a larger organization with the resources and existing footprint in these indications,” said Mina Kim, Chief Executive Officer of ACELYRIN. “We remain excited by the opportunity for lonigutamab to address unmet needs of patients with TED. Consistent with our commitment to disciplined capital allocation, we have decided to focus our efforts toward rapidly advancing lonigutamab through late-stage development with our existing cash resources. Combined with a reduction in force, this strategic shift allows us to extend our cash runway to mid-2027 and fully fund both Phase 3 trials for lonigutamab.”

Izokibep

In the global Phase 3 trial in HS, izokibep demonstrated statistically significant responses across multiple efficacy endpoints at 12 weeks, including 33% of patients receiving izokibep 160mg weekly (QW) achieving HiSCR75, compared to 21% receiving placebo (p-value=0.0294). In higher order endpoints, 25% of patients achieved HiSCR90, compared to 9% on placebo (p-value=0.0009), and 22% of patients achieved HiSCR100, compared to 8% on placebo (p-value=0.001).

While the primary endpoint was measured at 12 weeks, ACELYRIN has continued dosing patients in a placebo-controlled manner through week 16. The Company has data from two-thirds of patients at week 16 and the preliminary data demonstrate continued deepening of HiSCR responses over time.

No new safety signals for izokibep were observed. The most common adverse events were mild-to-moderate injection site reactions, headache, nasopharyngitis, fatigue and diarrhea. Notably, there were no cases of candida infection, liver toxicity or suicidal ideation/behavior in the izokibep treatment arm.

ACELYRIN will complete the on-going PsA and HS trials, but will suspend new investment in these indications. The ongoing Phase 2b/3 trial of izokibep in uveitis will continue through its primary endpoint, with top line data expected in the fourth quarter of 2024.

Lonigutamab

ACELYRIN has completed the Phase 1 proof-of-concept portion of the ongoing lonigutamab trial and the dose-ranging Phase 2 portion in TED patients is continuing. This Phase 2 trial is testing different doses and dose regimens with a goal of establishing a minimum effective dose and enabling selection of the optimal dose and dose regimen for the Phase 3 program. Dose administration every three or four weeks is now being tested.

With this dose ranging experience in hand, ACELYRIN plans to forgo the originally planned Phase 2b/3 trial design and move directly into a Phase 3 program, potentially with concurrent trials, which is anticipated to be initiated in the first quarter of 2025. The Company will hold an EOP2 meeting with the FDA later this year and thereafter host an investor presentation to provide additional Phase 2 data and details for the planned Phase 3 program.

“ACELYRIN has taken a patient-centered approach to developing lonigutamab, being the first company to conduct dose exploration work with a subcutaneous anti-IGF-1R treatment in patients with Thyroid Eye Disease,” said Shoaib Ugradar, MD, Department of Orbital and Oculoplastic Surgery, private practice, Beverly Hills, California. “I am encouraged by this approach and look forward to participating in the pivotal trials.”

SLRN-517

ACELYRIN has completed a single ascending dose study of SLRN-517, the Company’s early anti-C-KIT program, in healthy volunteers and has stopped further development of this program.

Corporate Reorganization

Aligned with the Company’s prioritization of lonigutamab and associated strategic shifts for izokibep and SLRN-517, ACELYRIN is completing an approximately 33% reduction in its workforce.

“I want to thank our colleagues who will be departing from ACELYRIN as part of the restructuring and acknowledge their many contributions to the development of izokibep, and to the evolution of our company. We wish them the very best in the future,” added Ms. Kim.

The Company expects these combined efforts will extend cash runway to mid-2027, guidance which includes both the financial impact of the corporate reorganization and clinical program reprioritization. Specifically, the Company’s existing cash resources are expected to fund the ongoing Phase 2 trial and two planned registrational Phase 3 trials for lonigutamab in TED, the on-going izokibep Phase 3 trial in uveitis, and the completion of the ongoing

izokibep HS and PsA trials.

Q2 2024 Financial Highlights

Cash Position: Cash, cash equivalents and short-term marketable securities totaled $635.2 million at June 30, 2024. The Company expects these to fund operations to mid-2027.

R&D Expenses: Research and development expenses were $76.4 million for the second quarter as compared to $30.0 million for the same period in 2023. The increases were primarily a result of additional clinical development activity across the pipeline and a $14.3 million expense related to the termination of a supply agreement.

G&A Expenses: General and administrative expenses were $16.6 million for the second quarter as compared to $12.7 million for the same period in 2023. The expenses include stock-based compensation expense of $5.3 million, which decreased from $7.2 million for the same quarter in 2023.

Net Loss: Net loss for the quarter ended June 30, 2024 was $85.7 million, compared to $26.0 million for the same period in 2023.

Webcast and Conference Call Information

ACELYRIN will host a conference call and webcast today, August 13, 2024, at 5:00pm ET to discuss these announcements. A live webcast of the conference call can be accessed in the "Events & Presentations" section of ACELYRIN's website at www.acelyrin.com. A recording of the webcast will be available and archived on the Company's website for approximately 30 days.

Upcoming Investor Presentations

ACELYRIN management will participate in webcasted presentations and 1x1 meetings at several upcoming investor conferences including the 2024 Wells Fargo Healthcare Conference, the 22nd Annual Morgan Stanley Global Healthcare Conference and the H.C. Wainwright 26th Annual Global Investment Conference.

About Lonigutamab
Lonigutamab is a humanized IgG1 monoclonal antibody targeting the IGF-1 receptor and is delivered subcutaneously. Relative to standard of care, lonigutamab binds to a distinct epitope, which results in internalization of the receptor within minutes, and in preclinical binding and functional laboratory assays, it has been shown to be 75-fold more potent. The characteristics of lonigutamab that enable subcutaneous delivery also enable the potential for longer-term, convenient dosing, which can potentially improve depth and durability of clinical response.

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. The late-stage izokibep PsA and HS data have demonstrated levels of clinical response comparable with next generation approaches to IL-17 inhibition. These data also demonstrate that targeting IL-17A alone with greater potency can achieve the same or better clinical responses than agents targeting IL-17 subunits more broadly than IL-17A, without their associated safety liabilities. Izokibep is currently being evaluated in multiple late-stage trials in moderate-to-severe hidradenitis suppurativa (HS), moderate-to-severe psoriatic arthritis (PsA), and noninfectious uveitis.

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 the overall advancement of ACELYRIN's programs and ability to accelerate the development and delivery of transformative medicines; the therapeutic potential of ACELYRIN's product candidates; ACELYRIN's ability to address unmet needs of patients with thyroid eye disease (TED) anticipated development activities including the planned initiation of Phase 3 trials in TED and the ability for such trials to serve as registrational studies, anticipated cash runway guidance to mid-FY2027, and the ability for such funds to support development of lonigutamab through both Phase 3 trials, plans to continue the ongoing izokibep Phase 2b/3 trial in psoriatic arthritis and the ongoing izokibep Phase 3 trial in hidradenitis suppurativa; the anticipated timing and availability of clinical data from the ongoing izokibep Phase 2b/3 trial in uveitis; 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, the risk that future results could differ materially and adversely from early clinical data, the risk that preliminary week 16 data of the Phase 3 trial in HS is not indicative of any future, final week 16 data in such trial, 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. 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.

ACELYRIN, Inc.
Condensed Consolidated Statement of Operations and Comprehensive Loss
(in thousands, except share and per share data)
(unaudited)

	Six months ended June 30,	**Six months ended June 30,**

	2024	2023	2024	2023
Operating expenses				
Research and development	$ 76,382	$ 30,030	$ 134,414	$ 197,950
General and administrative	$ 16,643	$ 12,666	$ 41,385	$ 24,579
Total operating expenses	93,025	42,696	175,799	222,529
Loss from operations	(93,025)	(42,696)	(175,799)	(222,529)
Change in fair value of derivative liability	-	10,144	-	10,291
Interest income	8,447	6,685	17,597	9,984
Other income (expense), net	(1,094)	(172)	37,557	(235)
Net loss	(85,672)	(26,039)	(120,645)	(202,489)
Other comprehensive gain/(loss)				
Unrealized gain (loss) on short-term marketable securities, net	(62)	44	(329)	130
Total other comprehensive gain (loss)	(62)	44	(329)	130
Net loss and other comprehensive loss	$ (85,734)	$ (25,995)	$ (120,974)	$ (202,359)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.86)	$ (0.40)	$ (1.22)	$ (4.71)
Weighted-average common shares outstanding, basic and diluted	99,161,710	65,210,117	98,537,685	42,974,640

ACELYRIN, INC.
Selected Consolidated Balance Sheet Data
(unaudited)
(in thousands)

	June 30, 2024	December 31, 2023
Cash and cash equivalents	$ 128,211	$ 218,097
Short-term marketable securities	507,029	503,229
Total assets	651,739	742,690
Total liabilities	83,521	86,353
Accumulated deficit	(609,364)	(488,719)

ACELYRIN Contact:
Tyler Marciniak
Vice President of Investor Relations and Corporate Affairs
investors@acelyrin.com
media@acelyrin.com