Surrozen Announces Safety, Pharmacodynamic and Liver Function Data for SZN-043

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-Phase 1a trial demonstrated acceptable safety and tolerability with no reported serious adverse events
-Phase 1a data demonstrated target engagement, a pharmacodynamic effect and effects on liver function
-Initiating Phase 1b proof-of-concept trial in severe alcohol-associated hepatitis
- Expect to Present Safety, PD and PK Data for SZN-043 at Upcoming Medical Meeting in 2024

SOUTH SAN FRANCISCO, Calif., April 01, 2024 (GLOBE NEWSWIRE) -- Surrozen, Inc. ("Surrozen" or the "Company") (Nasdaq: SRZN), a company pioneering targeted therapeutics that selectively activate the Wnt Pathway for tissue repair and regeneration, today provided an update on the Phase 1a clinical trial of SZN-043 in healthy volunteers and patients with cirrhosis. The Phase 1a study was completed in February 2024. SZN-043 demonstrated acceptable safety and tolerability in all subjects, with evidence of target engagement, Wnt signal activation and effects on liver function. The observed safety and pharmacodynamic activity were the basis for the Company's previous announcement that it planned to initiate enrollment in the Phase 1b study in alcohol-associated hepatitis.

The randomized, placebo-controlled Phase 1a trial enrolled a total of 48 subjects, including 40 healthy volunteers and 8 patients with cirrhosis and a history of liver disease. Single or multiple IV doses were administered in doses ranging from 0.5mg/kg to 3 mg/kg. There were no serious adverse events nor infusion reactions observed. In the planned Phase 1b trial dose range (0.5mg/kg to 1.5 mg/kg), adverse events assessed to be drug related were mild to moderate and all resolved during the study. In healthy volunteers a few asymptomatic and transient transaminase elevations (ranging from mild to moderate) were observed which resolved without intervention, and with no clinical sequelae. There were no drug related adverse events reported in patients with cirrhosis at any dose. The pharmacokinetics of SZN-043 were consistent with our expectations and supportive of the planned doses, schedule and route of administration for alcohol-associated hepatitis.

In cirrhotic patients with a history of liver disease, the Phase 1a study also demonstrated dose dependent pharmacodynamic (PD) activity through activation of Wnt signaling as assessed by the methacetin breath test. This test measures activation of the Wnt pathway via the metabolism of a Wnt target gene (CYP1A2) substrate. Target engagement was confirmed via transient increases in alkaline phosphatase (ALP). Increases in ALP are indicative of SZN-043 binding to its targeting receptor ASGR1 and reduction in its capacity to clear ALP, consistent with observations in other ASGR1 binding agents. Cirrhotic patients also showed evidence of liver function effects after treatment with SZN-043 as measured by HepQuant which is a test that measures cholate clearance, a liver specific function that quantifies liver function.

"We are excited to have observed activation of Wnt signaling, target engagement and improvement in markers of liver function during the Phase 1a studies and are pleased to advance SZN-043 into the Phase 1b clinical trial in severe alcohol-associated hepatitis. We look forward to presenting the encouraging Phase 1a data at an upcoming medical conference - the first clinical data for this innovative antibody-based approach to modulating the Wnt pathway," said Craig Parker, President and Chief Executive Office of Surrozen. "Progress with our platform technologies supports our belief that modulation of the Wnt pathway has the potential to provide important new therapeutic options through targeted tissue regeneration."

The Company is in the process of initiating the multi-center Phase 1b clinical trial in multiple countries and expects that proof-of-concept data from this trial may be available in the first half of 2025. The study will enroll patients with severe alcohol-associated hepatitis in an open-label trial. The Company plans to evaluate safety, pharmacokinetics, immunogenicity and a number of efficacy endpoints including MELD score, Lille score and survival. The MELD and Lille scores have been shown to correlate with clinical improvement and 90-day survival.

About SZN-043 for Severe Alcohol-Associated Hepatitis
SZN-043 is the first development candidate using Surrozen's SWEETS™ technology. Surrozen is developing SZN-043 for severe liver diseases, initially focusing on alcohol-associated hepatitis. The Company has completed a Phase 1a clinical trial in patients with chronic liver disease and healthy volunteers. SZN-043 demonstrated acceptable safety and tolerability in all subjects, with evidence of target engagement, Wnt signal activation and effects on liver function. The Company is initiating the Phase 1b clinical trial in patients with severe alcohol-associated hepatitis and expects that proof-of-concept data from this trial may be available in the first half of 2025.

About SZN-413 for Retinal Diseases
SZN-413 is a bi-specific antibody targeting Fzd4-mediated Wnt signaling designed using Surrozen's SWAP™ technology. It is currently being developed for the treatment of retinal vascular-associated diseases. Data generated by Surrozen with SZN-413 in preclinical models of retinopathy demonstrated that SZN-413 could potently stimulate Wnt signaling in the eye, induce normal retinal vessel regrowth, suppress pathological vessel growth and reduce vascular leakage. This novel approach could thus potentially allow for regeneration of healthy eye tissue, not only halting retinopathy, but possibly allowing for a full reversal of the patient's disease.

In the fourth quarter of 2022, Surrozen entered into a strategic partnership with Boehringer Ingelheim for the research and development of SZN-413 for the treatment of retinal diseases. Under the terms of the agreement, Boehringer Ingelheim received an exclusive, worldwide license to develop SZN-413 and other Fzd4-specific Wnt-modulating molecules for all purposes, including as a treatment for retinal diseases, in exchange for an upfront payment to Surrozen of $12.5 million. Surrozen will also be eligible to receive up to $587.0 million in success-based development, regulatory, and commercial milestone payments, in addition to mid-single digit to low-double digit royalties on sales. After an initial period of joint research, Boehringer Ingelheim will assume all development and commercial responsibilities.

About Wnt Signaling
Wnt signaling plays key roles in the control of development, homeostasis, and regeneration of many essential organs and tissues, including liver, intestine, lung, kidney, retina, central nervous system, cochlea, bone, and others. Modulation of Wnt signaling pathways has potential for treatment of

degenerative diseases and tissue injuries. Surrozen's platform and proprietary technologies have the potential to overcome the limitations in pursuing the Wnt pathway as a therapeutic strategy.

About Surrozen
Surrozen is a clinical stage biotechnology company discovering and developing drug candidates to selectively modulate the Wnt pathway. Surrozen is developing tissue-specific antibodies designed to engage the body's existing biological repair mechanisms with a current focus on severe liver and eye diseases. For more information, please visit www.surrozen.com.

Forward Looking Statements
This press release contains certain forward-looking statements within the meaning of the federal securities laws. Forward-looking statements generally are accompanied by words such as "will," "plan," "intend," "potential," "expect," "could," or the negative of these words and similar expressions that predict or indicate future events or trends or that are not statements of historical matters. These forward-looking statements include, but are not limited to, statements regarding Surrozen's discovery, research and development activities, in particular its development plans for its product candidates SZN-043, and SZN-413 (including anticipated clinical development plans and timelines, and the availability of data, the potential for such product candidates to be used to treat human disease, as well as the potential benefits of such product candidates), and the Company's partnership with Boehringer Ingelheim, including the potential for future success-based development, regulatory, and commercial milestone payments, in addition to mid-single digit to low-double digit royalties on sales . These statements are based on various assumptions, whether or not identified in this press release, and on the current expectations of the management of Surrozen and are not predictions of actual performance. These forward-looking statements are provided for illustrative purposes only and are not intended to serve as, and must not be relied on as a guarantee, an assurance, a prediction, or a definitive statement of fact or probability. Actual events and circumstances are difficult or impossible to predict and will differ from assumptions. Many actual events and circumstances are beyond the control of Surrozen. These forward-looking statements are subject to a number of risks and uncertainties, including the initiation, cost, timing, progress and results of research and development activities, preclinical or and clinical trials with respect to SZN-043, SZN-413 and potential future drug candidates; the Company's ability to fund its preclinical and clinical trials and development efforts, whether with existing funds or through additional fundraising; Surrozen's ability to identify, develop and commercialize drug candidates; Surrozen's ability to successfully complete preclinical and clinical studies for SZN-043, SZN-413, or other future product candidates; the effects that arise from volatility in global economic, political, regulatory and market conditions; and all other factors discussed in Surrozen's Annual Report on Form 10-K for the year ended December 31, 2022 and Surrozen's Quarterly Report on Form 10-Q for the quarter ended September 30, 2023 under the heading "Risk Factors," and other documents Surrozen has filed, or will file, with the Securities and Exchange Commission. If any of these risks materialize or our assumptions prove incorrect, actual results could differ materially from the results implied by these forward-looking statements. There may be additional risks that Surrozen presently does not know, or that Surrozen currently believes are immaterial, that could also cause actual results to differ from those contained in the forward-looking statements. In addition, forward-looking statements reflect Surrozen's expectations, plans, or forecasts of future events and views as of the date of this press release. Surrozen anticipates that subsequent events and developments will cause its assessments to change. However, while Surrozen may elect to update these forward-looking statements at some point in the future, Surrozen specifically disclaims any obligation to do so, except as required by law. These forward-looking statements should not be relied upon as representing Surrozen's assessments of any date after the date of this press release. Accordingly, undue reliance should not be placed upon the forward-looking statements.

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