Surrozen Presents Preliminary Results from Phase 1a Study of SZN-043 in Healthy Volunteers and Patients with a History of Liver Cirrhosis at the 2024 European Association for the Study of the Liver (EASL) in Milan

June 10, 2024

SZN-043 is a novel biotherapeutic shown to potentiate Wnt signaling and induce proliferation of hepatocytes in preclinical models

Treatment with SZN-043 in the Phase 1a trial was safe and well tolerated in healthy volunteers and patients with a history of liver cirrhosis

Phase 1a trial of SZN-043 demonstrated evidence of target engagement and Wnt-pathway mediated pharmacodynamic effects in the liver

Enrollment is ongoing in Phase 1b study in severe alcohol-associated hepatitis

SOUTH SAN FRANCISCO, Calif., June 10, 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, presented a poster on the preliminary results of a Phase 1a study of SZN-043, a novel R-Spondin mimetic, in healthy volunteers and subjects with liver cirrhosis on June 8, 2024 at the 2024 European Association for the Study of the Liver (EASL) in Milan (LINK: HERE).

Study Overview

- Safe and well-tolerated doses of SZN-043 were established in the randomized, placebo-controlled, first-in-human, Phase 1a trial in 40 healthy volunteers (HVs) and 8 patients with a history of liver cirrhosis.
- Single or multiple intravenous infusion doses were administered in a range from 0.5 mg/kg to 3 mg/kg.
- In some treated subjects, there were mild-to-moderate, transient, and dose-related serum transaminase elevations that resolved without intervention. These serum transaminase elevations were not associated with other changes in clinical pathology that are indicative of liver disease or bile duct damage.

Pharmacodynamic Biomarkers
The study provided evidence of Wnt-mediated pharmacodynamic activity in the liver after treatment with SZN-043.

1. Target engagement was confirmed via transient increases in alkaline phosphatase (ALP). Increases in ALP are indicative of SZN-043 binding to, and elimination of, its targeting receptor asialoglycoprotein (ASGPR) from the surface of the hepatocytes and this reduction in its capacity to clear ALP is consistent with observations in other ASGPR binding agents.
2. Wnt signal activation was demonstrated by the results of the methacetin breath test. This test showed increased methacetin clearance following SZN-043 administration which is indicative of activation of the Wnt target gene, CYP1A2, in hepatocytes.
3. HepQuant measurements demonstrated increases in the portal hepatic filtration rate (HFR). The HepQuant test is a quantitative liver function test that measures cholate clearance to assess liver function. The increase in portal HFR is thought to be related to Wnt-mediated induction of cholate clearance by SZN-043.

”We were pleased to present the first clinical data from this innovative bispecific antibody-based approach to modulating the Wnt pathway. The Phase 1a study demonstrated activation of Wnt signaling, target engagement in the liver, the initial effects observed on liver function and that the drug was safe and well tolerated,” said Craig Parker, President and Chief Executive Office of Surrozen. “We are making significant progress with our platform technologies as we focus on optimizing our abilities to modulate the Wnt pathway and provide important new therapeutic options through targeted cell and tissue regeneration. Wnt modulation in hepatocytes is a promising new mechanism for supporting regeneration in injured livers.”

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 severe alcohol-associated hepatitis. The Company has completed a Phase 1a clinical trial in patients with a history of liver cirrhosis and healthy volunteers. SZN-043 was safe and well tolerated in single or multiple IV doses and demonstrated evidence of target engagement, Wnt signal activation and effects on liver function.

The Phase 1b clinical trial in patients with severe alcohol-associated hepatitis began enrollment in the second quarter of 2024 and the Company expects that proof-of-concept data from this trial may be available in the first half of 2025. The study will enroll up to 30 patients with severe alcohol-associated hepatitis in an open-label trial. The study will 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-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, 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 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, 2023 and Surrozen's Quarterly Report on Form 10-Q for the quarter ended March 31, 2024 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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