Surrozen Initiates Dosing of First Patient in Phase 1b Clinical Trial of SZN-043 for Severe Alcohol-Associated Hepatitis

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- *SZN-043 is a novel hepatocyte-specific R-spondin mimetic bispecific fusion protein targeting ASGR1*
- *Anticipate potential proof-of-concept data available in the first half of 2025*

SOUTH SAN FRANSCISO, Calif., June 04, 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 announced that the first patient has been dosed in its Phase 1b clinical trial for SZN-043 in patients with severe alcohol-associated hepatitis.

The Phase 1b is an open-label, multi-center clinical trial that will enroll approximately 30 patients with severe alcohol-associated hepatitis. The Company plans to evaluate safety, pharmacokinetics, immunogenicity and a number of efficacy endpoints including changes in MELD score, changes in Lille score and overall survival. The MELD and Lille scores have been shown to correlate with clinical improvement and 90-day survival.

"We are excited to begin enrollment in our Phase 1b clinical trial with our lead product candidate, SZN-043. The R&D organization has worked diligently to finalize regulatory approvals in multiple countries, initiate study sites and begin dosing of the first patient on schedule," said Craig Parker, President and Chief Executive Officer of Surrozen. "We are gaining momentum in our SZN-043 clinical trial program in severe alcohol-associated hepatitis and anticipate that proof-of-concept data may be available in the first half of 2025."

"The Phase 1a clinical data for SZN-043 demonstrated encouraging safety and tolerability and provided early evidence of Wnt signal activation and effects on liver function in patients with a history of liver cirrhosis," said Edward Gane MBCHB, MD, FRACP, MNZM, Professor of Medicine at the University of Auckland, New Zealand, Hepatologist and Deputy Director of the New Zealand Liver Unit at the Auckland City Hospital. "Severe alcohol-associated hepatitis remains an unmet medical need with a very high mortality and no improvement in survival for more than 50 years. I am very excited about the potential for SZN-043 to offer a meaningful clinical benefit to these patients."

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 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 initiated enrollment in the Phase 1b clinical trial in patients with severe alcohol-associated hepatitis in the second quarter of 2024 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, 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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