Surrozen Initiates Dosing in Phase 1 Clinical Trial of SZN-043 for Severe Alcoholic Hepatitis

June 13, 2022

- *SZN-043 is a novel hepatocyte-specific R-spondin mimetic bispecific fusion protein targeting ASGR1*
- *First part of two-part Phase 1 trial starts in healthy volunteers*

SOUTH SAN FRANCISCO, Calif., June 13, 2022 (GLOBE NEWSWIRE) -- Surrozen, Inc. ("Surrozen" or the "Company") (Nasdaq: SRZN), a clinical-stage company pioneering targeted therapeutics that selectively activate the Wnt pathway for tissue repair and regeneration, today announced that the first subject has been dosed in its two-part Phase 1 clinical trial for SZN-043 which is in development for the potential treatment of severe alcoholic hepatitis.

The Phase 1, randomized, single and multiple ascending dose study will evaluate the safety, pharmacokinetics and activity of SZN-043. The first part of the trial will evaluate single doses of SZN-043 administered via intravenous injection or infusion in healthy volunteers, progressing from 3 mg through 30 mg. The second part will evaluate multiple ascending doses of SZN-043 for a period of four weeks in patients with a documented history of liver cirrhosis and a Child-Pugh score between 5 and 7 at the 2 highest dose levels tolerated in part 1. The primary endpoint of the trial is safety and tolerability of SZN-043 and secondary outcomes include pharmacokinetics, pharmacodynamic markers as well as prevalence of Anti-Drug Antibodies (ADA).

"We are gaining momentum as a clinical organization with two studies now enrolling subjects, and both reaching the clinic ahead of schedule," said Craig Parker, President and Chief Executive Officer of Surrozen. "Our team has remained diligently focused on applying our Wnt research and platforms while rapidly advancing these uniquely engineered antibodies. We look forward to continuing to build on this momentum with SZN-043 and SZN-1326, as well as our research- and discovery-stage programs."

Trudy Vanhove, M.D., Ph.D., Chief Medical Officer of Surrozen, added: "Severe alcoholic hepatitis has a 30% mortality at 90 days and there remains a significant need for new acute treatment options for these patients. As a first step towards testing SZN-043 in severe AH patients, we are evaluating safety and pharmacokinetics of SZN-043 in healthy volunteers and patients with cirrhosis, a common feature in patients with severe AH. We will also be evaluating pharmacodynamic markers of Wnt activation, hepatocyte function and hepatocyte proliferation."

SZN-043 for Severe Alcoholic Hepatis
SZN-043 is the first development candidate using Surrozen's SWEETS™ technology which is designed to mimic the regenerative properties of the protein R-Spondin by enhancing Wnt signaling in a cell-targeted manner. In multiple preclinical animal models of liver injury and fibrosis, SZN-043 has been shown to selectively activate Wnt signaling in the liver, stimulate transient hepatocyte proliferation, improve liver function and reduce fibrosis with no treatment-related adverse effects observed in 4-week GLP toxicology evaluations in mice and NHPs. Surrozen is developing SZN-043 for severe liver diseases, initially focusing on severe alcoholic hepatitis. The first subject in the Phase 1 clinical study of SZN-043 was dosed in June, and the trial is posted to the Australian New Zealand Clinical Trial Registry here.

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 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 potential application across multiple disease areas, including inflammatory bowel disease, hepatitis, eye diseases, hearing loss, lung and airway diseases, and certain neurological disorders. For more information, please visit 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," "potential," "expect," "advance," "outcome," "endpoint," "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-1326, SZN-043, and SZN-413, including anticipated clinical development timelines, and the potential for such product candidates to be used to treat human disease. 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-1326, SZN-043, SZN-413, and potential future drug candidates; Surrozen's ability to identify, develop and commercialize drug candidates; Surrozen's ability to successfully complete preclinical and clinical studies for SZN-1326, SZN-043, SZN-413, or other future product candidates; the effects that arise from volatility in global economic, political, regulatory and market conditions, which may be adversely affected by the conflict between Russia and Ukraine; the ongoing coronavirus (COVID-19) pandemic; and all other factors discussed in our Annual

Report on Form 10-K for the year ended December 31, 2021 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 subsequent to the date of this press release. Accordingly, undue reliance should not be placed upon the forward-looking statements.

Media Contacts:
CanaleComm
Ian Stone, Managing Director
Tel.: (619) 518-3518
Email: ian.stone@evokegroup.com

Ingrid Mezo, Account Director
Tel.: (301) 473-2881
Email: ingrid.mezo@evokegroup.com

Investor Contact:
Email: Investorinfo@surrozen.com