



Surrozen Initiates Dosing in Phase 1 Clinical Trial of SZN-1326 for Moderate to Severe Ulcerative Colitis

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- SZN-1326 is a Fzd5-targeted Wnt-mimetic (SWAP) bi-specific antibody
- First part of three-part Phase 1/1b trial starts in healthy volunteers

SOUTH SAN FRANCISCO, Calif., May 18, 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 three-part Phase 1 clinical trial to evaluate SZN-1326 for the potential treatment of moderate to severe ulcerative colitis. The trial initiation is approximately one quarter earlier than previously expected. Surrozen also recently announced the publication of an article by Surrozen scientists in the journal [Cellular and Molecular Gastroenterology and Hepatology](#). The results highlight the potential for this novel approach to treating inflammatory bowel disease.

The Phase 1, randomized, placebo-controlled, single- and multiple-ascending-dose study will evaluate the safety, pharmacokinetics, and activity of SZN-1326. The first part of the trial will evaluate single doses of SZN-1326 via intravenous injection or infusion, or subcutaneous injection in healthy volunteers, progressing from 25 mg through 1500 mg. The second part will evaluate multiple ascending doses of SZN-1326 for a period of four weeks in healthy volunteers, with each subject assigned to one of three dose level cohorts increasing from 75 mg IV up to 750 mg IV. The primary endpoint of Parts 1 and 2 of the trial are safety and tolerability of SZN-1326 and secondary outcomes include pharmacokinetics as well as prevalence of Anti-Drug Antibodies (ADA).

"The dosing of the first participant in our clinical study of SZN-1326 marks a significant milestone for Surrozen as we officially transition to a clinical-stage organization," said Craig Parker, President and Chief Executive Officer of Surrozen. "In addition, the trial marks a milestone in the advancement of Wnt signaling research, which plays an essential role in regulating many biological processes. I am proud of our team's advances in creating uniquely engineered antibodies that selectively modulate the Wnt pathway and their strong and timely execution in completing our preclinical package and initiating our clinical development program months earlier than planned. We look forward to continuing to build a broad discovery and clinical pipeline of Wnt antibodies to repair a broad range of tissues and organs damaged by serious disease."

Trudy Vanhove, M.D., Ph.D., Chief Medical Officer of Surrozen, added: "This trial is a significant step toward bringing a new approach to patients with ulcerative colitis, who still have a significant need for treatments that have a rapid onset of action, attain mucosal healing and are non-immunosuppressive. We believe SZN-1326 holds significant promise in this field based on the strong results in preclinical studies, including repair of damaged intestinal epithelium, improvements in disease activity, and anti-inflammatory effects in models of intestinal injury."

SZN-1326 for Moderate to Severe Ulcerative Colitis

SZN-1326 is the first development candidate designed using Surrozen's SWAP™ technology and targets the Wnt-signaling pathway in the intestinal epithelium. In preclinical animal models of acute and chronic colitis, SZN-1326 has been shown to activate Wnt signaling in the diseased intestine, stimulate intestinal epithelial regeneration, reduce inflammation and reduce disease activity with no treatment related adverse effects observed in 13-week toxicology evaluations in rats and non-human primates (NHPs). Surrozen is initially developing SZN-1326 for moderate to severe ulcerative colitis. The Phase 1 clinical study is posted to the Australian New Zealand Clinical Trial Registry. Click [HERE](#) for the SZN-1326 posting.

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," "continue," "plan," "potential," "expect," "advance," "suggest," "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-413, SZN-043, and potential future drug candidates; Surrozen's ability to identify, develop and commercialize drug candidates; Surrozen's ability to advance SZN-1326, SZN-043, SZN-413, or other future product candidates into, and successfully complete, preclinical studies and clinical studies; the effects of the ongoing coronavirus (COVID-19) pandemic or other infectious diseases and natural disasters on Surrozen's business; volatility in global economic, regulatory and market conditions, which may be adversely affected by the conflict between Russia and Ukraine; and those 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.

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