



Sol-Gel Provides Update Following Unblinding of Phase 1b Study of SGT-210 in Darier Disease

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NESS ZIONA, Israel, Dec. 17, 2025 (GLOBE NEWSWIRE) -- **Sol-Gel Technologies, Ltd.** (NASDAQ: SLGL), a dermatology company, pioneering treatments for patients with rare and severe skin conditions, today provided an update following the unblinding of clinical data from its vehicle-controlled proof-of-concept Phase 1b study of SGT-210 on Darier disease.

Following unblinding, the data from the vehicle-controlled Phase 1b proof-of-concept study did not show differentiation between SGT-210 and vehicle on the study's efficacy assessments.

Mr. Mori Arkin, Executive Chairman of Sol-Gel, stated: "After unblinding the clinical data from our trial, the study did not demonstrate a signal of superiority of active treatment versus vehicle, and we have therefore decided not to advance to the next stage of development in this indication. We intend to pursue very small, low-cost feasibility studies in other areas of unmet medical need where the mechanistic rationale for SGT-210 is strong. We continue to prioritize the successful completion of our Phase 3 program of SGT-610 in Gorlin syndrome and preparatory activities supporting a potential Phase 3 program in high-frequency BCC, subject to successful completion of the Gorlin Phase 3 trial."

About Gorlin Syndrome and SGT-610

SGT-610, a hedgehog signaling pathway blocker, has the potential to be the first ever treatment for prevention of BCCs in Gorlin syndrome patients, if approved. Gorlin syndrome, an autosomal dominant genetic disorder affecting approximately 1 in 27,000-31,000 people in the U.S., is mostly caused by inheritance of one defective copy of the tumor suppressor patched homolog 1 (PTCH1) gene. Normally, the PTCH1 gene blocks the smoothened, frizzle class receptor (SMO) gene, turning off the hedgehog signaling pathway when it is not needed. Mutations in the PTCH1 gene may cause a loss of PTCH1 function, release of SMO, and may allow BCC tumor cells to divide uncontrollably. Patidegib, the active substance in SGT-610, is designed to block the SMO signal, thus, allowing cells to function normally and reducing the production of new tumors.

About Sol-Gel Technologies

Sol-Gel Technologies Ltd. is a dermatology company focused on identifying, developing and commercializing or partnering drug products to treat skin diseases. Sol-Gel developed TWYNEO which is approved by the FDA for the treatment of acne vulgaris in adults and pediatric patients nine years of age and older; and EPSOLAY, which is approved by the FDA for the treatment of inflammatory lesions of rosacea in adults.

The Company's pipeline also includes Phase 3 clinical trial of Orphan and breakthrough drug candidate SGT-610, which is a new topical hedgehog inhibitor being developed to prevent the new basal cell carcinoma lesions in patients with Gorlin syndrome that is expected to have an improved safety profile compared to oral hedgehog inhibitors as well as topical drug candidate SGT-210 under investigation for the treatment of rare hyper keratinization disorders.

For additional information, please visit our new website: www.sol-gel.com

Forward Looking Statements

This press release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. All statements contained in this press release that do not relate to matters of historical fact should be considered forward-looking statements, including, but not limited to statements regarding the successful completion of Phase 3 program of SGT-610 in Gorlin syndrome and a potential Phase 3 program in high-frequency BCC. In some cases, you can identify forward-looking statements by terminology such as "believe," "may," "estimate," "continue," "anticipate," "intend," "should," "plan," "expect," "predict," "potential," or the negative of these terms or other similar expressions. Forward-looking statements are based on information we have when those statements are made or our management's current expectations and are subject to risks and uncertainties that could cause actual performance or results to differ materially from those expressed in or suggested by the forward-looking statements. Important factors that could cause such differences include, but are not limited to, the risk that we will not successfully complete the Gorlin Phase 3 trial or that it will be delayed, that we will not commence a potential Phase 3 program in high-frequency BCC, and if we do that it will not be successful, the risk that the market for SGT-610 and SGT-210 will not be as anticipated, including with respect to High-Frequency BCC for SGT-610, our ability to enter into further collaborations, a delay in the timing of our clinical trials, top-line results and regulatory filings, the success of our clinical trials, and an increase in our anticipated costs and expenses, as well as the following factors: (i) the adequacy of our financial and other resources, particularly in light of our history of recurring losses and the uncertainty regarding the adequacy of our liquidity to pursue our complete business objectives; (ii) our ability to complete the development of our product candidates; (iii) our ability to find suitable co-development partners; (iv) our ability to obtain and maintain regulatory approvals for our product candidates in our target markets, the potential delay in receiving such regulatory approvals and the possibility of adverse regulatory or legal actions relating to our product candidates even if regulatory approval is obtained; (v) our collaborators' ability to commercialize our pharmaceutical product candidates; (vi) our ability to obtain and maintain adequate protection of our intellectual property; (vii) our collaborators' ability to manufacture our product candidates in commercial quantities, at an adequate quality or at an acceptable cost; (viii) our collaborators' ability to establish adequate sales, marketing and distribution channels; (ix) acceptance of our product candidates by healthcare professionals and patients; (x) the possibility that we may face third-party claims of intellectual property infringement; (xi) the timing and results of clinical trials that we may conduct or that our competitors and others may conduct relating to our or their products; (xii) intense competition in our industry, with competitors having substantially greater financial, technological, research and development, regulatory and clinical, manufacturing, marketing and sales, distribution and personnel resources than we do; (xiii) potential product liability claims; (xiv) potential adverse federal, state and local government regulation in the United States, China, Europe or Israel; and (xv) loss or retirement of key executives and research scientists; (xvi) general market, political and economic conditions in the countries in which the Company operates; and, (xvii) the current war between Israel and Hamas and any deterioration of the war in Israel into a broader regional conflict involving Israel with other parties. These factors and other important factors discussed in the Company's Annual Report on Form 20-F filed with the Securities and Exchange Commission ("SEC") on March 13, 2024, and our other reports filed with the SEC, could cause actual results to differ materially from those indicated by the forward-looking statements made in this press release. Except as required by law, we undertake no obligation to update any forward-looking statements in this press release.

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