Sol-Gel Technologies Screens First Patient for SGT-610 Phase 3 Study

November 30, 2023

- *SGT-610 has "Orphan Drug" designation status in the U.S. and E.U. and "Breakthrough Therapy" designation status in the U.S., as potentially the first and only therapy aimed at preventing new BCCs in Gorlin syndrome*
- *Sol-Gel to host a virtual Key Opinion Leader event to discuss the Gorlin syndrome patient experience and treatment needs, as well as the SGT-610 Phase 3 trial on Wednesday, December 6th at 12 pm ET*

NESS ZIONA, Israel, Nov. 30, 2023 (GLOBE NEWSWIRE) -- Sol-Gel Technologies, Ltd. (Nasdaq: SLGL) ("Sol-Gel"), a dermatology company leveraging innovative approaches to develop pioneering treatments for patients with severe skin conditions, and with two approved large-category dermatology products, TWYNEO® and EPSOLAY®, today announced that it has begun Phase 3 testing of SGT-610 (patidegib gel, 2%) for Gorlin syndrome with the first patient screened. SGT-610 is a new topical hedgehog inhibitor being developed to prevent the new basal cell carcinoma (BCC) lesions in patients with Gorlin syndrome that is expected to have an improved safety profile compared to oral hedgehog inhibitors. Patidegib was acquired by Sol-Gel from PellePharm and is currently the only therapy in development to prevent the development of new BCC lesions in Gorlin syndrome patients.

"We are pleased to initiate patient screening in this Phase 3 trial that has been long awaited by the Gorlin syndrome patient community," said Alon Seri-Levy, Ph.D., Chief Executive Officer of Sol-Gel. "To increase the probability of success of this trial we have refined screening criteria to enroll subjects with more severe disease at baseline in terms of a higher baseline number of facial BCC lesions. This may help to better demonstrate the preventive effect of the medication. Other insights that we are using in our Phase 3 trial design strategy are to pre-screen patients for a specific genetic mutation associated with Gorlin syndrome and to ease patient study compliance by reducing the number of study visits over the 12-months of treatment. We hope that our learnings to optimize this trial's design will help Sol-Gel advance this important drug candidate to Gorlin syndrome patients with no approved therapies."

"We anticipate SGT-610, with Orphan- and Breakthrough designation from FDA, could have a market potential of over $300 million. We look forward to discussing the experience of the Gorlin syndrome patient, the market opportunity for SGT-610, and the Phase 3 trial design during a Key Opinion Leader investor day that we are hosting on December 6th," added Dr. Seri-Levy.

Sol-Gel will conduct the Phase 3 study to investigate SGT-610 in approximately 140 subjects at approximately 40 experienced clinical centers in North America, United Kingdom and Europe. For more information about the trial and study design, visit NCT06050122.

Register for Sol-Gel's KOL event
Sol-Gel will host a virtual KOL event featuring Julie Breneiser (Executive Director, Gorlin Syndrome Alliance) and Ervin Epstein Jr, M.D. (Co-Founder of PellePharm). The event will highlight the patient's experience through the eyes of a Gorlin syndrome patient as well as discuss the therapeutic potential of SGT-610 to prevent new BCCs in Gorlin syndrome patients and Sol-Gel's Phase 3 trial.

Register for the event here.

About Gorlin Syndrome and SGT-610
SGT-610, a topical hedgehog signaling pathway inhibitor, has the potential to be the first ever preventive treatment for Gorlin syndrome, if approved. Gorlin syndrome, an autosomal dominant genetic disorder affecting approximately one 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 basal cell carcinoma (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 for the treatment of 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. Both drugs are exclusively licensed to and commercialized by Galderma in the U.S.

The Company's pipeline includes Orphan- and Breakthrough designated dug candidate, SGT-610, under investigation for the prevention of new basal cell carcinomas in Gorlin syndrome patients, and also includes topical drug candidate SGT-210 under investigation for the treatment of rare skin keratodermas.

For additional information, please visit 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, potential of SGT-610 as the first and only therapy aimed at preventing new BCCs in Gorlin syndrome; improved safety profile of SGT-610, success of the SGT-610 clinical studies, obtaining regulatory approval for our product candidates including SGT-610; and the market potential of SGT-610. 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, a delay in the timing of our clinical trials, 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, 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 10, 2023, as amended, 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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