



Sol-Gel Acquires Patidegib, a Phase 3, FDA-Breakthrough-Designated Orphan Product Candidate to Pursue Potential Market of Over \$300 Million

January 27, 2023

- *Patidegib, an Orphan Drug candidate, broadens Sol-Gel's pipeline with the potential to be the first therapy for preventing new basal cell carcinomas in Gorlin syndrome, if approved by the FDA*
- *Phase 3 study expected to initiate in the second half of 2023, with results expected by the end of 2025*
- *Conference call to be held this morning at 8:30 a.m. U.S. ET*

NESS ZIONA, Israel, Jan. 27, 2023 (GLOBE NEWSWIRE) -- Sol-Gel Technologies, Ltd. (NASDAQ: SLGL), a dermatology company with FDA approvals for EPSOLAY® and TWYNEO®, two innovative dermatology products that were launched in the U.S. by partner Galderma during 2022, announced today the acquisition of topically-applied patidegib, a hedgehog signaling pathway blocker, for the treatment of Gorlin syndrome from PellePharm, Inc. Gorlin syndrome is a rare disease with no currently approved therapies by the U.S. Food and Drug Administration (FDA) or European Medical Association (EMA). Sol-Gel broadens its pipeline with this new chemical entity, designated as investigational compound SGT-610, which has the potential to be the first-ever drug for treatment of Gorlin syndrome. Sol-Gel expects the transaction to close on or about January 30, 2023, subject to the satisfaction of customary closing conditions.

Patidegib has been granted Orphan Drug Designation by the FDA and the EMA as well as Breakthrough Therapy Designation by the FDA. Both FDA and EMA have stated that approval may be supported by a single pivotal Phase 3 study.

Alon Seri-Levy, Ph.D., Chief Executive Officer of Sol-Gel, stated, "Rare diseases represent a high margin therapeutic category, and we estimate that SGT-610, if approved by the FDA, has the potential to generate, at peak, annual net sales in excess of \$300 million. We believe that the risk/reward of this deal is extremely favorable to Sol-Gel and its shareholders. We conducted extensive due diligence on patidegib's earlier development programs and consulted with expert clinicians to design a rigorous new Phase 3 trial that we believe can overcome the deficiencies of the earlier Phase 3 study to generate the safety and efficacy data necessary to support an FDA approval. We have a strong track record of conducting clinical studies of topical dermatologic drugs and we expect to leverage our experience to advance SGT-610 toward FDA approval, with the objective of providing Gorlin syndrome patients with the first drug that could prevent new basal cell carcinomas (BCCs)."

Gorlin syndrome affects approximately 1 in 31,000 people in the U.S. and is an autosomal dominant genetic disorder, mostly caused by inheritance of one defective copy of the tumor suppressor gene PTCH1. Gorlin syndrome is also called nevoid BCC syndrome because approximately 90% of individuals with this syndrome develop multiple BCCs by age 35, ranging from a few to many thousands of lesions during a patient's lifetime. Painful surgical excision is the treatment of choice for BCCs. However, as multiple BCCs continue to evolve, repeated surgical intervention becomes impractical, and therefore, an important consideration in the treatment of Gorlin syndrome is preventing the development of new BCCs. SGT-610 is intended to prevent new BCC formation in adults with Gorlin syndrome without the accompanying systemic adverse events observed with oral BCC therapies.

Julie Breneiser, Executive Director of the Gorlin Syndrome Alliance, commented, "BCCs are the most burdensome manifestation reported by Gorlin syndrome patients. The volume of BCCs in Gorlin syndrome and associated need for repeated treatments leads to significant permanent scarring, anxiety, and loss of time from work, school and other daily life activities."

The planned Phase 3 study of SGT-610 will include well-defined modifications to an earlier Phase 3 study in which the patidegib arm was found to be as tolerable as the vehicle and the significant adverse events associated with oral hedgehog inhibitors were not observed. These modifications will include selecting patients positive for the PTCH1 mutation (in contrast to the previous study which included symptomatic patients without testing them for the mutation), as well as a requirement for a higher minimum number of BCCs at baseline. Sol-Gel's Phase 3 study is expected to begin in the second half of 2023 with results expected by the end of 2025.

Subject to the satisfaction of customary closing conditions, Sol-Gel will pay PellePharm an upfront payment of \$4.7 million and total development and NDA acceptance milestones of up to \$6.0 million, and up to \$64.0 million in commercial milestones as well as single digit royalties.

Dr. Seri-Levy continued, "SGT-610 is a late-stage Orphan Drug candidate and we are therefore prioritizing the development of SGT-610, along with SGT-210 in development for the treatment of rare skin keratodermas and other hyperproliferative skin disorders, which represent high-margin dermatology market opportunities, and suspend the development of SGT-310 and SGT-510 in psoriasis, a market that has turned more crowded and competitive. For these latter projects we will seek to out-license their development instead."

Mori Arkin, Executive Chairman of the Board of Sol-Gel, commented, "Given the team's strong expertise in drug development and partnering, as well as the conviction gained from interacting with the scientific and patient communities, patidegib represents an ideal next asset for the Sol-Gel pipeline to maximize shareholder value."

Conference Call Information

Sol-Gel will host an investor conference call and webcast today at 8:30 a.m. U.S. ET to discuss today's announcement.

To participate in the call, dial either the domestic or international number fifteen minutes before the conference call begins:

Domestic: 1-877-704-4453

International: 1-201-389-0920

Passcode: 13736097

The live conference call and replay can also be accessed by audio webcast [here](#) and also on the Investor Relations section of the Company's website, located at <https://ir.sol-gel.com/investor-relations>. Slides for the accompanying corporate presentation can also be viewed at this link.

About Gorlin Syndrome and SGT-610

SGT-610, a hedgehog signaling pathway blocker, has the potential to be the first ever treatment for Gorlin syndrome, 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 gene PTCH1. Normally, the PTCH1 gene blocks the SMO gene, turning off the hedgehog signaling pathway when it is not needed; mutations in PTCH1 may cause 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 is a dermatology company focused on identifying, developing and commercializing or partnering topical 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 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, statements regarding the benefits we expect to receive under our agreement with Galderma; expected net sales and royalty income in line with volume growth of EPSOLAY and/or TWYNEO; the timing and consummation of our acquisition of SGT-610; the benefits of and projections of our future financial performance as a result of our acquisition of SGT-610; the timing and success of any clinical studies for our product candidates, including SGT-610; and our expected cash runway. These forward-looking statements include information about possible or assumed future results of our business, financial condition, results of operations, liquidity, plans and objectives. 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 the initiation or results of the Phase 3 study for SGT-610 will be delayed or not occur, the risk that our annual net sales from SGT-610, if approved, will be lower than expected, risks that our cash runway will be shorter than expected, risks relating to the effects of COVID-19 (coronavirus) 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 ability to commercialize our pharmaceutical product candidates; (vi) our ability to obtain and maintain adequate protection of our intellectual property; (vii) our ability to manufacture our product candidates in commercial quantities, at an adequate quality or at an acceptable cost; (viii) our 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. These and other important factors discussed in the Company's Annual Report on Form 20-F filed with the Securities and Exchange Commission ("SEC") on April 4, 2022, 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.

For further information, please contact:

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