Sol-Gel Announces Initiation of SGT-210 Phase 1 Proof of Concept Study in Palmoplantar Keratoderma (PPK)

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NESS ZIONA, Israel, Jan. 02, 2020 (GLOBE NEWSWIRE) -- Sol-Gel Technologies, Ltd. (NASDAQ: SLGL) today announced the initiation of a Phase 1 proof of concept clinical study of SGT-210, its novel, topical, epidermal growth factor receptor inhibitor in patients with punctate palmoplantar keratoderma type -1 (PPPK type 1), a genetic form of PPK. Top-line data is expected in the first half of 2021.

"Patients with PPK suffer from the physical manifestations of the disease and the thickened skin can interfere with daily activities," said Dr. Eli Sprecher MD, Ph.D., Chairman of the Division of Dermatology at the Tel Aviv Sourasky Medical Center. "I am delighted that The Tel Aviv Medical Center is running a clinical trial aimed at assessing the clinical efficacy of Sol-Gel's novel product."

The Phase 1 proof of concept study SGT-84-01 is a single-center, single-blinded, vehicle-controlled study designed to evaluate the bioavailability, safety and tolerability of SGT-210 as well as inform on potential efficacy. The study is targeting enrollment of approximately 15 patients to undergo a three month treatment period, followed by a three month follow-up period.

"Initiation of this study is another important step forward with our SGT-210 development program into PPK and to expand our proprietary pipeline," commented Dr. Alon Seri-Levy, Chief Executive Officer of Sol-Gel. "Existing approaches, often result in disappointing efficacy and poor tolerability, SGT-210 may represent a significant advancement for patients suffering with PPK disorders. We look forward to the upcoming top-line results from this trial, which are expected the first half of 2021."

About Palmoplantar Keratoderma
Palmoplantar keratoderma (PPK) is a group of skin conditions characterized by the thickening of the skin on the palms and soles of the feet. PPK may lead to impairment of quality of life through pain, decreased acral functionality and cosmetic concerns. Traditional therapeutic approaches for PPK are mainly based on decreasing scale, controlling hyperkeratosis and blunting inflammation when present. Existing remedies may further impair the epidermal barrier and lead to compensatory exaggerated epidermal proliferation. Therefore, safe and effective management of PPK represents an important unmet medical need.

About SGT-210
SGT-210 is a topically administered, epidermal growth factor receptor (EGFR) inhibitor. EGFR is a growth factor receptor that induces cell differentiation and proliferation upon activation through the binding of one of its ligands. It is believed that SGT-210 will work to inhibit this action and thus address the excessive skin growth and thickening which results in the significant impairment associated with PPK disorders. Prevalence estimates of PPK suggest approximately 90,000 people in the US alone may have some variant of the disease. Should SGT-210 succeed, it may represent a US market potential of approximately $500 million with additional potential outside the US.

About Sol-Gel Technologies
Sol-Gel is a clinical-stage dermatology company focused on identifying, developing and commercializing branded and generic topical drug products for the treatment of skin diseases. Sol-Gel leverages its proprietary microencapsulation technology platform for both branded and generic product development. SolGel's current late-stage branded pipeline includes Twyneo®, for the treatment of acne vulgaris, Epsolay®, for the treatment of papulopustular rosacea, and SGT-210, an early-stage topical epidermal growth factor receptor inhibitor for the treatment of punctate palmoplantar keratoderma type I. 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. 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 expectation, 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, including risks related to the timing of top-line data for the Phase 1 proof of concept clinical study of SGT-210. Important factors that could cause such differences include, but are not limited to: (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 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 March 21, 2019 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. Any such forward-looking statements represent management's estimates as of the date of this press release. Except as required by law, we undertake no obligation to update publicly any forward-looking statements after the date of this press release to conform these statements to changes in our expectations.

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