Sol-Gel Technologies Initiates Pivotal Phase III Clinical Program of TWIN for the Treatment of Acne Vulgaris

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First subject dosed in pivotal Phase III program evaluating TWIN in subjects with moderate-to-severe acne vulgaris

Two Phase III trials expected to enroll a total of approximately 840 subjects

Top-line data anticipated by the end of 2019

NESS ZIONA, Israel, Dec. 17, 2018 (GLOBE NEWSWIRE) -- Sol-Gel Technologies Ltd. (NASDAQ: SLGL) ("Sol-Gel" or the "Company"), a clinical-stage dermatology company focused on identifying, developing and commercializing branded and generic topical drug products for the treatment of skin diseases, today announced dosing of the first subject in the pivotal Phase III clinical program evaluating the safety and efficacy of TWIN in subjects with acne vulgaris. TWIN is a cream containing a fixed-dose combination of encapsulated tretinoin and encapsulated benzoyl peroxide using Sol-Gel's proprietary microencapsulation platform.

"Initiating the Phase III program for TWIN is a transformational milestone for Sol-Gel as we now have two product candidates in Phase III development," commented Dr. Alon Seri-Levy, Sol-Gel Technologies' Chief Executive Officer. "We have a clearly defined regulatory path for TWIN and we are committed to our goal of providing acne patients not satisfied with currently available therapies, a safe and highly efficacious treatment alternative. We anticipate top-line results from this clinical program by the end of 2019 and, if the results from our program are positive, are planning to submit a New Drug Application (NDA) for marketing approval in 2020."

The program consists of two randomized, double-blind, vehicle-controlled Phase III clinical trials. Each pivotal trial is planned to enroll approximately 420 subjects aged 9 and above at a 2:1 ratio, with a power of 99%. The objective of the study is to evaluate the efficacy and safety of TWIN, a topical cream containing encapsulated tretinoin and encapsulated benzoyl peroxide, compared to vehicle when applied once daily for 12 weeks in patients with moderate-to-severe acne vulgaris.

The pivotal TWIN clinical program is being executed under a Special Protocol Assessment (SPA) agreement with the U.S. Food and Drug Administration (FDA). The SPA provides agreement that the study design, clinical endpoints and statistical analysis approach for Sol-Gel's Phase III program evaluating TWIN for the treatment of patients with acne vulgaris will be deemed adequate to support an NDA filing for marketing approval.

Based on the FDA's feedback provided in the minutes of the End-of-Phase II meeting and the associated SPA agreement, key elements of the Phase III program are:

- Only the TWIN and vehicle cream (placebo) arms are required for the Phase III clinical trials, as the requirements of the combination rule act were satisfied in our Phase II trial.
- No pediatric clinical studies are required to support our future marketing application.
- No long-term safety study will be required to support our marketing application, as long as we demonstrate that the systemic exposure of our product candidate is comparable to the reference-listed drug.

About TWIN

TWIN is a novel non-antibiotic topical cream for the treatment of acne vulgaris that is designed to be tolerable and highly effective. TWIN is the first acne treatment that contains a fixed-dose combination of benzoyl peroxide and tretinoin, which are separately encapsulated in silica using our proprietary technology. Tretinoin and benzoyl peroxide are widely believed to be effective as a combination treatment for acne. The silica microcapsule protects tretinoin from oxidative decomposition by benzoyl peroxide, thereby enhancing the stability and shelf-life of the product. The silica shell also creates a barrier between the drug substances and the skin and as a result is expected to reduce irritation typically associated with topical application of benzoyl peroxide and tretinoin, thereby increasing the tolerability of TWIN on acne-affected skin.

About Acne Vulgaris

Acne vulgaris is a common multifactorial skin disease that according to the American Academy of Dermatology affects approximately 40 to 50 million people in the United States. The disease occurs most frequently during childhood and adolescence (affecting 80% to 85% of all adolescents) but it may also appear in adults. Acne patients suffer from the appearance of lesions on areas of the body with a large concentration of oil glands, such as the face, chest, neck and back. These lesions can be inflamed (papules, pustules, nodules) or non-inflamed (comedones). Acne can have a profound effect on the quality of life of those suffering from the disease. In addition to carrying a substantial risk of permanent facial scarring, the appearance of lesions may cause psychological strain, social withdrawal and lowered self-esteem.

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's current product candidate pipeline consists of late-stage branded product candidates that leverage our proprietary, silica-based microencapsulation technology platform, and several generic product candidates across multiple indications. 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 statements are neither promises nor guarantees, but involve known and unknown risks, uncertainties and other important factors that may cause our actual results,

performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statement, including but not limited to, the following: the fact that we have and expect to continue to incur significant losses; our need for additional funding, which may not be available; our ability to complete the development of our product candidates; 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; our ability to rely on data from our Phase II TWIN trial to advance the development of SIRS-T; our ability to commercialize our product candidates; our ability to obtain and maintain adequate protection of our intellectual property; our ability to manufacture our product candidates in commercial quantities, at an adequate quality or at an acceptable cost; our ability to establish adequate sales, marketing and distribution channels; acceptance of our product candidates by healthcare professionals and patients; the possibility that we may face third-party claims of intellectual property infringement; 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; 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; potential product liability claims; potential adverse federal, state and local government regulation in the United States, Europe or Israel; and 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 26, 2018 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. While we may elect to update such forward-looking statements at some point in the future, we disclaim any obligation to do so, even if subsequent events cause our views to change.

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