Sol-Gel Technologies Provides Program Update for TWIN for the Treatment of Acne Vulgaris

September 4, 2018

Announces Positive End-of-Phase II Meeting with the FDA

Receives Special Protocol Assessment (SPA) Agreement from FDA

Company expects to commence the TWIN Phase III clinical trials in the fourth quarter of 2018 with top-line data expected in 2019

NESS ZIONA, Israel, Sept. 04, 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, announced today that it has completed an End-of-Phase II meeting with the U.S. Food and Drug Administration (FDA) for TWIN in the treatment of acne vulgaris.

As a result, the Company reiterates its prior guidance that it expects to commence the pivotal Phase III clinical trials for TWIN in the fourth quarter of 2018. The Company expects to report top-line data from the Phase III clinical program in 2019. Sol-Gel also announced today that it has reached an agreement with the FDA regarding a Special Protocol Assessment (SPA) for TWIN. The SPA provides agreement that the protocol 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 a New Drug Application (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.
- Each of the two TWIN Phase III clinical trials will consist of approximately 420 subjects aged 9 and above, with a power of 99%.
- 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 is comparable to our reference-listed drug (RLD).

"The combination of the positive End-of-Phase II meeting coupled with the SPA helps to clearly define the regulatory path for TWIN," commented Dr. Alon Seri-Levy, Sol-Gel Technologies' Chief Executive Officer. "TWIN is designed to be a highly effective benzoyl peroxide and tretinoin combination product which we are committed to bringing to the market as a treatment alternative for acne patients not satisfied with currently available therapies. Management believes that if our Phase III results show efficacy similar to that shown in our 726 patient Phase II study, then TWIN, if approved, has the potential to have the highest placebo-adjusted efficacy for the treatment of acne patients."

An updated Corporate Presentation may be viewed at: http://ir.sol-gel.com/events-and-presentations.

About Special Protocol Assessment (SPA)

SPA is a process in which sponsors may ask to meet with FDA to reach agreement on the design and size of a clinical trial to determine if they adequately address scientific and regulatory requirements for a study that could support marketing approval. An SPA agreement indicates concurrence by FDA with the adequacy and acceptability of specific critical elements of overall protocol design (e.g., entry criteria, dose selection, endpoints, and planned analyses) for a study intended to support a future marketing application. These elements are critical to ensuring that the trial conducted under the protocol can be considered an adequate and well-controlled study that can support marketing approval. For further information regarding the SPA process, please visit the FDA website at www.fda.gov.

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, including statements regarding the commencement of our planned clinical trials for TWIN, the commencement of our planned bioequivalence study for a generic product candidate and our expected date to report top-line data from our pivotal Phase III clinical program for Epsolay® and TWIN. 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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