Sol-Gel Technologies Announces 50% Enrollment in Pivotal Phase III TWIN Program for the Treatment of Acne Vulgaris

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Patient enrollment of the pivotal Phase III TWIN clinical trials is on schedule

Top-line results expected in the fourth quarter of 2019

NESS ZIONA, Israel, April 15, 2019 (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 enrollment of half of the patients in its pivotal Phase III clinical trials of TWIN in subjects with acne vulgaris. TWIN is a once daily topical cream containing a fixed-dose combination of encapsulated benzoyl peroxide and encapsulated tretinoin using Sol-Gel's proprietary microencapsulation platform.

"We have reached another important milestone for the company as patient enrollment for the TWIN Phase III program has progressed well, reinforcing the need for a new treatment option for acne vulgaris containing a safe and efficacious combination of encapsulated benzoyl peroxide and encapsulated tretinoin," commented Dr. Alon Seri-Levy, Chief Executive Officer of Sol-Gel. "Based on the current rate of enrollment, we plan to report top-line results in the fourth quarter of 2019."

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 benzoyl peroxide and encapsulated tretinoin, compared to a 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 reflects FDA's agreement that the protocol design, primary endpoints and statistical analysis approach for Sol-Gel's Phase III program evaluating TWIN for the treatment of patients with acne vulgaris are acceptable to support a future New Drug Application (NDA) filing for marketing approval.

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 encapsulated benzoyl peroxide and encapsulated 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 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. 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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