Sol-Gel Announces Positive Top-Line Phase 3 Trial Results of Twyneo® for the Treatment of Acne Vulgaris

December 30, 2019

- *All co-primary endpoints achieved in both Phase 3 clinical trials*
- *Twyneo was well-tolerated and the majority of local skin reactions, when reported, were mild and improved over time*
- *Additional data to be shared during the January 8th investor conference call and webcast*

NESS ZIONA, Israel, Dec. 30, 2019 (GLOBE NEWSWIRE) -- Sol-Gel Technologies, Ltd. (NASDAQ: SLGL) today announced top-line results from two pivotal Phase 3 clinical trials for Twyneo®, an investigational, combination of microencapsulated tretinoin 0.1% and microencapsulated benzoyl peroxide 3% cream, which demonstrated statistically significant improvement on all co-primary endpoints in the treatment of patients with acne vulgaris. Twyneo was also found to be well-tolerated.

The primary endpoints for both trials included: the proportion of patients who succeeded in achieving at least a two grade reduction from baseline and Clear (grade 0) or Almost Clear (grade 1) at Week 12 on a 5-point Investigator Global Assessment (IGA) scale; an absolute change from baseline in inflammatory lesion count at Week 12; and an absolute change from baseline in non-inflammatory lesion count at Week 12.

“We are excited to share these robust results which further demonstrate the potential of our microencapsulation technology to deliver first-of-its kind efficacy in a topical acne treatment,” said Dr. Alon Seri-Levy, Chief Executive Officer of Sol-Gel. “We thank the patients and investigators involved in the Twyneo trials. We look forward to submitting our NDA in the second half of 2020 and to working with the FDA through their review of our application, with a view to making Twyneo available to physicians and patients in the second half of 2021.”

If approved, Twyneo has the potential to be the first acne vulgaris treatment to bring together benzoyl peroxide and a potent retinoid, tretinoin, in a once-daily cream – enabled using the Company’s proprietary microencapsulation technology.

“Twyneo combines, for the first time, two of the safest and most effective topical agents available for the treatment of acne into a single application. Due to stability issues these products don’t play well together and we were never able to recommend even consecutive co-application of the two agents; Sol-Gel’s technology has solved that,” said Hilary Baldwin, M.D., Clinical Associate Professor of Dermatology, Rutgers Robert Wood Johnson School of Medicine, Medical Director, The Acne Treatment and Research Center, Past President the American Acne and Rosacea Society. “The data presented today show that this unique formulation offers superior efficacy without compromising tolerability in a very convenient treatment. I believe physicians will look forward to adding Twyneo to their acne treatments toolbox.”

SGT-65-04 and SGT-65-05 Trials Design
To assess the efficacy and safety of Twyneo, 858 subjects, aged nine and older, with moderate-to-severe acne were enrolled in two multicenter, randomized, double-blind, parallel-group, vehicle-controlled trials (SGT-65-04 and SGT-65-05) at 63 sites across the U.S. Subjects were randomized at a 2:1 ratio to be treated once-daily with either Twyneo (n=571) or vehicle cream (n=287) for 12 weeks. The co-primary endpoints for both trials included: the proportion of patients who succeeded in achieving at least a two grade reduction from baseline and Clear (grade 0) or Almost Clear (grade 1) at Week 12 on a 5-point Investigator Global Assessment (IGA) scale; an absolute change from baseline in inflammatory lesion count at Week 12; and an absolute change from baseline in non-inflammatory lesion count at Week 12.

Co-Primary Endpoint Results (Intention-to-Treat Population)
In trial SGT-65-04, 38.5% of patients treated with Twyneo achieved success in IGA versus 11.5% in the vehicle treated group (P<0.001). In trial SGT-65-05, 25.4% of patients treated with Twyneo achieved success in IGA versus 14.7% in the vehicle group (P=0.017).

In trial SGT-65-04, the absolute change from baseline of inflammatory lesion count for Twyneo was -21.6 versus -14.8 for the vehicle group (P<0.001). In trial SGT-65-05, the absolute change from baseline of inflammatory lesion count for Twyneo was -16.2 versus -14.1 for the vehicle group (P=0.021).

In trial SGT-65-04, the absolute change from baseline of non-inflammatory lesion count for Twyneo was -29.7 versus -19.8 for the vehicle group (P<0.001). In trial SGT-65-05, the absolute change from baseline of non-inflammatory lesion count for Twyneo was -24.2 versus -17.4 for the vehicle group (P<0.001).

Safety and Tolerability
In both trials, Twyneo was found to be well-tolerated and the majority of local skin reactions, when reported, were mild and improved over time. There were no treatment-related serious adverse events and 4 unrelated serious adverse events (1 Twyneo, 3 vehicle) were reported across both trials.

Conference Call with Live Webcast (with slides) Jan 8th at 8:00 AM Eastern Time
The Company will share additional trials results on January 8, 2020 during an investor conference call and webcast.

U.S. toll free: (877) 282-0504
International: 1809457877
Conference ID: 5779723

Webcast: https://edge.media-server.com/mmc/p/3yyp8or8

The webcast can be accessed live on the Events & Presentations section of the Company’s website at http://ir.sol-gel.com. It will be archived for 30 days following the call.

About Twyneo
Twyneo is an investigational, antibiotic-free, fixed-dose combination of microencapsulated tretinoin 0.1% and microencapsulated benzoyl peroxide 3% cream. Benzoyl peroxide and tretinoin are widely prescribed and considered to be highly effective in the treatment for acne vulgaris; however, benzoyl

peroxide causes degradation of the tretinoin, thereby reducing its effectiveness. Twyneo overcomes this degradation through the use of Sol-Gel's microencapsulation technology platform, thereby allowing for a stable drug combination, extending drug delivery time of the active ingredients, and reducing potential irritation caused by direct application of the drug to the 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 approximately 80% 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. In addition to Twyneo, Sol-Gel's current branded product candidate pipeline consists of Epsolay®, a late-stage branded product candidate for the treatment of papulopustular rosacea that also leverages - the proprietary microencapsulation technology platform, and SGT-210, a 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. Important risks and uncertainties that could cause such differences include, but are not limited to, risks and uncertainties relating to the timing of the submission of an NDA for Twyneo and the timing of availability of Twyneo to patients, as well as the following risks and uncertainties: (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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