Sol-Gel Announces Positive Topline Results from Open-Label, Long-Term Safety Study of Epsolay® for Treatment up to 52 Weeks

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Successful topline results, strengthens Epsolay's long-term safety and tolerability profile in the treatment of papulopustular rosacea

Results pave the way for NDA submission in the second quarter of 2020

NESS ZIONNA, Israel, Feb. 13, 2020 (GLOBE NEWSWIRE) -- Sol-Gel Technologies (NASDAQ: SLGL), ("Sol-Gel"), today announced positive topline data for its open-label, long-term safety study, evaluating Epsolay®, microencapsulated benzoyl peroxide cream, 5%, in papulopustular rosacea for a treatment duration up to 52 weeks.

The study enrolled 547 subjects, all of whom had completed 12 weeks of treatment with Epsolay or vehicle in the preceding double-blind Phase 3 studies. Patients continued onto open-label treatment with Epsolay once-daily for up to an additional 40 weeks. The safety population of 535 subjects received Epsolay therapy for an overall period of at least 28 weeks. Of these 535 subjects, 209 subjects completed 52 weeks of treatment with Epsolay, exceeding the sample size requirements previously defined by the FDA for the one-year safety evaluation.

Non-cutaneous adverse events were similar in frequency and type to those observed in the preceding Phase 3 trials. The most common adverse event reported was nasopharyngitis (5.4%). Less than 3% of patients experienced application site adverse events that were considered to be drug-related, and no serious drug-related adverse events were reported.

At every study visit, the investigator conducted Local Tolerability and Cutaneous Safety Assessments. At the end of 52 weeks more than 90% of subjects had "none" or "mild" signs or symptoms (burning or stinging, itching, dryness and scaling) and no "severe" tolerability scores were recorded.

Although the study was designed to evaluate long-term safety, subjects also continued to undergo evaluation according to the Investigator Global Assessment (IGA) 5-point scale. Of the 209 patients treated with Epsolay for 52 weeks, 73.2% reported a score of 0 ("clear") or 1 ("almost clear") at 52 weeks.

"We are very pleased that these long-term use results further support and strengthen the positive safety and tolerability data we previously observed in our Phase 3 program for Epsolay," said Alon Seri-Levy, Sol-Gel's Chief Executive Officer. "It is our hope that this data can provide patients, seeking long term control of their chronic condition, the confidence in a treatment that has demonstrated a favorable safety and tolerability profile. We believe these results will complete the data required to finalize our NDA submission, which is planned for the second quarter of this year."

About Epsolay
Epsolay is an innovative topical cream containing encapsulated benzoyl peroxide, 5%, that Sol-Gel is developing for the treatment of inflammatory lesion of rosacea (Papulopustular Rosacea). Epsolay, if approved, is intended to be applied to the face once a day. Sol-Gel uses a patented process to encapsulate benzoyl peroxide in silica-based microcapsules. The silica shell is aimed to serve as a barrier between the benzoyl peroxide and the epidermis, reducing the ability of the benzoyl peroxide to induce strong oxidation processes that may result in cutaneous adverse events such as erythema, burning and stinging. The slow migration of benzoyl peroxide from the microcapsules is aimed to deliver effective doses of benzoyl peroxide onto the skin, while the barrier improves the tolerability of benzoyl peroxide. Silica is chemically inert, photochemically and physically stable, and safe for topical use. If approved, Epsolay has the potential to be the first FDA-approved single-active benzoyl peroxide prescription drug product.

About Papulopustular Rosacea
Papulopustular rosacea also known as inflammatory lesion of rosacea, is a chronic and recurrent inflammatory skin disorder that affects nearly 5 million Americans. The condition is common, especially in fair-skinned people of Celtic and northern European heritage. Onset is usually after age 30 and typically begins as flushing and subtle redness on the cheeks, nose, chin or forehead. If left untreated, rosacea can slowly worsen over time. As the condition progresses the redness becomes more persistent, blood vessels become visible and pimples often appear. Other symptoms may include burning, stinging, dry skin, plaques and skin thickening.

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 Twyneo, for the treatment of acne vulgaris, and Epsolay, for the treatment of papulopustular rosacea. The Company's pipeline also includes SGT-210, an early-stage topical epidermal growth factor receptor inhibitor, erlotinib, for the treatment of punctate palmoplantar keratoderma, and preclinical assets tapinarof and roflumilast. 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, but not limited to, statements regarding the clinical progress of our product candidates and the plans and timing of submitting an NDA for Epsolay with the FDA. 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, the following factors: (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.

For further information, please contact:
Sol-Gel Contact:
Gilad Mamlok
Chief Financial Officer
+972-8-9313433

Investor Contact:
Chiara Russo
Solebury Trout
+1-617-221-9197
crusso@soleburytrout.com

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