Sol-Gel Technologies Announces 50% Enrollment in Pivotal Phase III Epsolay® Program for the Treatment of Papulopustular Rosacea

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

Top-line results expected in 2019

NESS ZIONA, Israel, Sept. 25, 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 enrollment of half of the patients in its pivotal Phase III clinical trials of Epsolay (formerly VERED) in subjects with papulopustular rosacea (also known as subtype II rosacea), a chronic, inflammatory skin condition that most often affects the face. Epsolay is a once-daily topical cream containing encapsulated benzoyl peroxide, 5%, using Sol-Gel's proprietary microencapsulation technology.

The pivotal Phase III clinical program is being conducted in accordance with Special Protocol Assessment (SPA) agreements with the U.S. Food and Drug Administration (FDA) and consists of two randomized, multi-center, double-blind, vehicle-controlled clinical trials at 50 sites in the United States. Each pivotal trial is planned to enroll 350 subjects in a 2:1 ratio of Epsolay in comparison to its vehicle, with a power of greater than 99%. The primary efficacy endpoints for both trials are success in Investigator Global Assessment (IGA), defined as a two-grade reduction in IGA on a scale of 0 to 4 with "clear" (0) or "almost clear" (1) at week 12, and a reduction in mean inflammatory lesion count at week 12.

"The progress we have made with patient enrollment in these trials and the high interest expressed by both the patients and physicians highlights the unmet medical need for a new safe and efficacious rosacea treatment," said Dr. Alon Seri-Levy, Chief Executive Officer of Sol-Gel. "Our goal is to advance Epsolay as a potential treatment option for papulopustular rosacia patients as quickly as possible and we look forward to reporting the top-line results in 2019."

About Epsolay®

Epsolay® is an innovative topical cream containing encapsulated benzoyl peroxide, 5%, that Sol-Gel is developing for the treatment of inflammatory papules and pustules of 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 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 (Subtype II) Rosacea

Rosacea is a chronic and recurrent inflammatory dermatological disorder of unknown etiology. The disease is common, especially in fair-skinned people of Celtic and northern European heritage. The onset of the disorder is usually after age 30. Rosacea typically starts 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, patients experience inflammatory lesions (papules and pustules). According to market research conducted on behalf of the company, approximately 4.8 million people in the United States experience inflammatory papules and pustules of rosacea. Papulopustular rosacea is characterized by persistent central facial erythema with transient papules and pustules in a central facial distribution. It resembles acne, except that comedones are absent, and patients may report associated burning and stinging sensations.

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 expected date to report top-line data from our pivotal Phase III clinical program for Epsolay. 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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