



## Sol-Gel Technologies Announces FDA Acceptance for Filing of New Drug Application for Epsolay® for the Treatment of Inflammatory Lesions of Rosacea

September 10, 2020

- PDUFA Goal Date Set for April 26, 2021

- Potential to be first FDA-approved single-agent benzoyl peroxide prescription drug product

NESS ZIONA, Israel, Sept. 10, 2020 (GLOBE NEWSWIRE) -- Sol-Gel Technologies, Ltd. (NASDAQ: SLGL), a clinical-stage dermatology company focused on identifying, developing and commercializing branded and generic topical drug products for the treatment of skin diseases, today announced that its New Drug Application (NDA) for Epsolay® (benzoyl peroxide), an investigational proprietary topical cream for the treatment of inflammatory lesions of rosacea, containing 5% encapsulated benzoyl peroxide, has been accepted for filing by the U.S. Food and Drug Administration (FDA). The Prescription Drug User Fee Act (PDUFA) goal date assigned by the FDA for Epsolay is April 26, 2021.

The NDA filing is based on two positive, identical Phase 3 randomized, double-blind, multicenter, 12-week, clinical trials that evaluated the safety and efficacy of Epsolay compared to vehicle in patients with papulopustular rosacea (N = 733). In both trials, Epsolay demonstrated a statistically significant improvement in both co-primary endpoints of (i) the number of patients achieving "Clear" or "Almost Clear" in the Investigator Global Assessment (IGA) scale and (ii) absolute mean reduction from baseline in inflammatory lesion count starting as early as Week 2, and continued through Week 12. Epsolay also demonstrated a favorable safety and tolerability profile similar to vehicle. The most common adverse reactions occurring in >1% of subjects treated with Epsolay and more frequently than in subjects treated with vehicle was application site erythema (2.3% vs. 0.9%), application site pain (2.3% vs. 0.9%), and application site pruritis (1.2% vs. 0.4%). Most subjects experienced adverse reactions that were mild or moderate in severity.

"Papulopustular rosacea is a chronic and recurrent inflammatory skin disorder that affects nearly 5 million Americans. Regretfully, rosacea patients are dissatisfied with the efficacy of current therapies," stated Dr. Alon Seri-Levy, Chief Executive Officer of Sol-Gel. "The results from our Phase 3 studies showed statistically significant higher success in IGA compared with the vehicle, at every visit, and as early as at Week 2, as well as statistically significant higher reduction in absolute inflammatory lesion counts compared with the vehicle, at every visit, and as early as Week 2. In addition, a quarter of Epsolay patients in both trials reached their treatment goals within a month, which is very encouraging."

### 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 the development of Twyneo® (encapsulated benzoyl peroxide and encapsulated tretinoin) Cream, under investigation for the treatment of acne vulgaris, and Epsolay, under investigation for the treatment of papulopustular rosacea. The Company's pipeline also includes SGT-210, an early-stage topical epidermal growth factor receptor inhibitor, erlotinib, under investigation for the treatment of palmoplantar keratoderma, and preclinical assets tapinarof and roflumilast. For additional information, please visit [www.sol-gel.com](http://www.sol-gel.com).

### About Epsolay®

Epsolay is an investigational topical cream containing encapsulated benzoyl peroxide, 5%, for the treatment of inflammatory lesions of rosacea. Epsolay utilizes a patented technology process to encapsulate benzoyl peroxide within silica-based microcapsules to create a barrier between the medication and the skin. The slow migration of medication from the microcapsules is designed to deliver an effective dose of benzoyl peroxide to the skin, while reducing the ability of benzoyl peroxide to induce skin irritation, such as erythema, burning and stinging. If approved, Epsolay has the potential to be the first FDA-approved single-active benzoyl peroxide prescription drug product. Epsolay is not approved by the FDA and the safety and efficacy has not been established.

### About Papulopustular Rosacea

Papulopustular 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.

### 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 timing of the PDUFA action date for Epsolay and the potential to be the first FDA-approved single-agent benzoyl peroxide prescription drug product. 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 24, 2020 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.*

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