Sol-Gel Announces Positive Top-Line Results from Epsolay® Phase 3 Program in Papulopustular Rosacea

July 8, 2019

- *All primary and secondary endpoints achieved in both Phase 3 clinical trials*
- *Rapid efficacy demonstrated, with statistical significance reached as early as Week 2 compared with vehicle*
- *Favorable safety and tolerability profile, similar to vehicle*
- *Conference call and webcast today at 8:30 AM ET*

NESS ZIONA, Israel, July 08, 2019 (GLOBE NEWSWIRE) -- Sol-Gel Technologies, Ltd. (NASDAQ: SLGL) ("Sol-Gel" or the "Company"), today announced positive results from its Phase 3 program evaluating Epsolay® microencapsulated benzoyl peroxide cream, 5%, made with the Company's proprietary microencapsulation technology, for the treatment of papulopustular rosacea. In two 12-week clinical studies, SGT 54-01 and SGT 54-02, Epsolay demonstrated statistically significant improvement in both co-primary endpoints of (1) the number of patients achieving "clear" or "almost clear" in the Investigator Global Assessment (IGA) and (2) absolute mean reduction from baseline in inflammatory lesion count. In an additional analysis, Epsolay demonstrated rapid efficacy achieving statistically significant improvements on both co-primary endpoints compared with vehicle as early as Week 2. Epsolay demonstrated a favorable safety and tolerability profile similar to vehicle.

James J. Leyden, M.D., dermatologist and Emeritus Professor CE of Dermatology at the University of Pennsylvania commented on the results, "It's exciting that Epsolay delivered outstanding and rapid efficacy with a microencapsulated benzoyl peroxide without irritating the sensitive skin of rosacea patients. These findings are extremely positive and, if Epsolay is approved, it has the potential to represent a significant advance in the treatment of papulopustular rosacea."

Epsolay is the first in a pipeline of dermatologic product candidates in development using Sol-Gel's proprietary microencapsulation technology. This platform was designed to enable drug substances to be entrapped in porous silica microcapsules in order to address the limitations of topical drug delivery by stabilizing active drug ingredients, extending drug delivery time and reducing potential irritation caused by direct application to the skin. In the fourth quarter of 2019, top-line Phase 3 results are expected for TWIN, the Company's investigational fixed-dose combination of microencapsulated benzoyl peroxide and microencapsulated tretinoin being studied for acne vulgaris.

"While we expected to see strong efficacy and tolerability with Epsolay, the rapid efficacy was a standout in our Phase 3 studies," said Dr. Alon Seri-Levy, Chief Executive Officer of Sol-Gel. "It's very difficult for patients of any dermatological disease, let alone rosacea, to wait months for a positive clinical result. That a quarter of Epsolay patients in both trials reached their treatment goals within a month, when the efficacy of existing topical products can be quite slow, is clinically meaningful and illustrates a clear unmet need within a rapidly growing marketplace."

SGT 54-01 and SGT 54-02 Trial Design

To assess the efficacy and safety of Epsolay in moderate-to-severe papulopustular rosacea, 733 patients aged 18 and older were enrolled in two identical, double-blind, vehicle-controlled Phase 3 clinical trials at 54 sites across the U.S. Patients were randomized at a 2:1 ratio to be treated once-daily with either Epsolay (n=493) or vehicle cream (n=240) for 12 weeks. After the initiation of treatment, clinical and safety evaluations were performed at Weeks 2, 4, 6, 8 and 12. The primary efficacy endpoints for both trials were success in IGA score at Week 12, defined as "clear" (0) or almost clear" (1) on a scale of 0 to 4, and a reduction in absolute mean inflammatory lesion count at week 12.

Baseline Papulopustular Rosacea Severity

In study SGT 54-01, patients in the Epsolay and vehicle treatment groups had a baseline mean inflammatory lesion count of 25.7 and 26.3, respectively. The proportion of patients with "moderate" (3) or "severe" (4) IGA in the Epsolay treatment group was 86.4% and 13.6%, respectively, and 88.1% and 11.9%, respectively, in the vehicle treatment group.

In study SGT 54-02, patients in Epsolay and vehicle treatment groups had a baseline mean inflammatory lesion count of 29.8 and 27.5, respectively. The proportion of patients with "moderate" (3) or "severe" (4) IGA in the Epsolay treatment group was 90.8% and 9.2%, respectively, and 91.8% and 8.2%, respectively, in the vehicle treatment group.

Primary Endpoint Results (intention-to-treat population)

	SGT 54-01			SGT 54-02		
	Epsolay N=243	Vehicle N=118	p-value	Epsolay N=250	Vehicle N=122	p-value
Proportion of patients achieving "clear" or "almost clear" at Week 12	43.5 %	16.1%	<0.001	50.1 %	25.9	<0.001
Absolute mean change in inflammatory lesion count from baseline at week 12	-17.4	-9.5	<0.001	-20.3	-13.3	<0.001

Secondary Endpoint Results (intention-to-treat population)

	SGT 54-01			SGT 54-02		
	Epsolay	Vehicle	p-value	Epsolay	Vehicle	p-value
Proportion of patients achieving "clear" or "almost clear" at Week 4	25.4%	6.5%	<0.001	26.1%	14.1%	0.009

Absolute mean change in inflammatory lesion count from baseline at Week 4	-14.6	-8.7	<0.001	-16.7	-10.5	<0.001
Proportion of patients achieving “clear” or “almost clear” at Week 8	39.6%	15.8%	<0.001	44.0%	26.0%	0.006
Absolute mean change in inflammatory lesion count from baseline at Week 8	-16.8	-10.6	<0.001	-20.0	-12.4	<0.001

Exploratory Endpoint Results (intention-to-treat population)

	SGT 54-01			SGT 54-02		
	Epsolay	Vehicle	p-value	Epsolay	Vehicle	p-value
Proportion of patients achieving “clear” or “almost clear” at Week 2	9.5%	3.1%	0.009	13.2%	5.5%	0.017
Absolute mean change in inflammatory lesion count from baseline at Week 2	-10.5	-5.5	<0.001	-13.0	-8.0	<0.001

Safety and Tolerability

Epsolay appeared to be generally safe and well-tolerated with a low rate of cutaneous side effects (e.g., dryness, scaling, itching and burning/stinging) comparable to vehicle. Adverse events were primarily mild to moderate in severity with the most frequently reported adverse events across both studies being application site erythema and application site pain reported by less than 3.4% of subjects. There was no treatment-related serious adverse events, with a combined total of 2 unrelated serious adverse events (1 Epsolay, 1 vehicle) reported across both trials. A combined total of 11 subjects (9 Epsolay, 2 vehicle) discontinued treatment due to an adverse event across both trials.

Preliminary Financial Results for the Second Quarter Ended June 30, 2019

The Company estimates its revenue for the second quarter of 2019 attributable to sales of its partnered generic product, acyclovir cream, 5%, with Perrigo to be approximately $7.0 million. To date, this is the only generic acyclovir cream available on the U.S. market. As of June 30, 2019, the Company’s cash, cash equivalents, deposits and marketable securities is expected to be approximately $49.8 million, excluding the approximate $7.0 million in revenue from acyclovir cream, 5%, in the second quarter of 2019. Based on current assumptions, the Company expects its existing cash resources will enable funding of operational and capital expenditure requirements through the third quarter of 2020.

The estimates above represent the most current information available to the Company’s management and do not present all necessary information for an understanding of the Company’s financial condition as of and the results of operations for the quarter ended June 30, 2019. The Company is currently preparing its financial results for the three months ended June 30, 2019. The Company’s actual results may differ materially from these estimates. The company plans to release final second quarter financial results on August 8, 2019.

Conference Call and Live Webcast (with slides) @ 8:30 AM Eastern Time

U.S. toll free: 877-282-0504

International: 270-215-9895

Passcode: 2570059

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

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 Epsolay

Benzoyl peroxide has not been approved by the FDA for the treatment of rosacea and may cause significant skin irritation in rosacea patients. Epsolay is an innovative topical cream containing microencapsulated benzoyl peroxide, 5%, in development for the treatment of papulopustular rosacea. Epsolay utilizes a patented technology process to encapsulate benzoyl peroxide within silica microcapsules to create a barrier between the medication and the skin. The slow migration of medication from the microcapsules delivers treatment doses onto the skin, while the barrier reduces the ability of benzoyl peroxide to induce the strong oxidation process that can result in significant skin irritation, such as erythema, burning and stinging. Silica is chemically inert, photochemically and physically stable, and is safely used in topical products. If approved, Epsolay has the potential to be the first FDA-approved single-active benzoyl peroxide prescription drug product.

About Papulopustular Rosacea

Papulopustular rosacea is a chronic and recurrent inflammatory skin disorder that affects nearly 5 million Americans.[1] 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’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.

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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Source: Sol-Gel Technologies Ltd.

[1] Data on file, Sol-Gel

Source: Sol-Gel Technologies Ltd.