Sol-Gel Technologies and Galderma Announce FDA Approval of EPSOLAY®

April 25, 2022

- EPSOLAY (benzoyl peroxide, cream, 5%) utilizes Sol-Gel's proprietary microencapsulation technology for the treatment of inflammatory lesions of rosacea and is patent protected until 2040
- *Galderma set to commercialize EPSOLAY in the U.S. under exclusive license*

NESS ZIONA, Israel and ZUG, Switzerland, April 25, 2022 (GLOBE NEWSWIRE) -- Sol-Gel Technologies, Ltd. (NASDAQ: SLGL), a dermatology company focused on identifying, developing and commercializing branded and generic topical drug products for the treatment of skin diseases, announced today the Food and Drug Administration (FDA) approval of its drug product, EPSOLAY®, a proprietary cream formulation of benzoyl peroxide, 5%, for the treatment of inflammatory lesions of rosacea in adults.

The benzoyl peroxide in EPSOLAY is encapsulated within silica-based patented microcapsules. The silica-based shell is designed to slowly release benzoyl peroxide over time to provide a favorable efficacy and safety profile. The approval of EPSOLAY is supported by data from 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 people with inflammatory lesions of rosacea (N = 733). The coprimary endpoints in both trials were the proportion of subjects with treatment success and the absolute change from baseline in lesion counts at Week 12. EPSOLAY was more effective than vehicle cream on the co-primary efficacy endpoints starting from 4 weeks of treatment in both trials. With EPSOLAY treatment, inflammatory lesions of rosacea were reduced by nearly 70% by the end of both 12-week trials vs. 38-46% with vehicle. Nearly 50% of subjects were 'clear' (IGA=0) or 'almost clear' (IGA=1) at 12 weeks vs. 38-46% with placebo. Post-hoc analysis of lesion count and IGA success at Week 2 confirmed a significantly greater treatment effect for EPSOLAY relative to vehicle as early as Week 2. In the open-label extension, 73% of subjects were 'clear' (IGA=0) or 'almost clear' (IGA=1) at 52 weeks (N = 547).

Sol-Gel has granted to Galderma Holding SA ("Galderma") the exclusive rights to commercialize EPSOLAY in the United States. Founded in 1981, Galderma is the world's largest independent dermatology company.

"Having EPSOLAY approved by the FDA is a watershed moment for the 16 million people in the United States suffering from rosacea," stated Alon Seri-Levy, PhD, Chief Executive Officer of Sol-Gel. "Based on the robust clinical data, we believe that EPSOLAY has the potential to change the treatment landscape. We are proud to have Galderma as our partner to launch this drug since Galderma has an unparalleled track record of introducing innovative drugs in the United States' rosacea market," said Dr. Seri-Levy.

Neal D. Bhatia. M.D., dermatologist at Therapeutics Clinical Research in San Diego, California, commented, "There is poor adherence of my patients to current treatments for inflammatory rosacea and I look forward to being able to prescribe EPSOLAY to them, primarily because EPSOLAY has demonstrated outstanding and rapid efficacy results and also because EPSOLAY has been shown to be well-tolerated, both of which are important factors to ensure patients' satisfaction."

"Galderma is committed to delivering innovation in dermatology so that healthcare professionals and their patients have the products they need," said Baldo Scassellati Sforzolini, M.D., Ph.D., Global Head of Research & Development at Galderma. "People with rosacea experience a significant burden of disease with diminished quality of life and the approval of EPSOLAY represents an important advancement for those who are living with rosacea. We are pleased to be able to launch EPSOLAY and look forward to bringing this new treatment option to the United States."

About EPSOLAY

EPSOLAY is a topical cream containing benzoyl peroxide, 5%, for the treatment of inflammatory lesions of rosacea in adults. EPSOLAY utilizes a proprietary technology to encapsulate benzoyl peroxide within silica-based microcapsules to create a barrier between the medication and the skin. The silica-based shell is designed to slowly release benzoyl peroxide over time to provide a favorable efficacy and safety profile. EPSOLAY is covered by granted patents until 2040.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

EPSOLAY is contraindicated in patients with a history of a serious hypersensitivity reactions to benzoyl peroxide or any component of the formulation in EPSOLAY.

WARNINGS AND PRECAUTIONS

- Hypersensitivity: Severe hypersensitivity reactions, including anaphylaxis and angioedema, have been reported with the use of benzoyl peroxide products. (5.1)
- Skin irritation/contact dermatitis: Erythema, scaling, dryness, stinging/burning, irritation and allergic contact dermatitis may occur with use of EPSOLAY and may necessitate discontinuation.
- Photosensitivity: Avoid or minimize exposure to natural or artificial sunlight and use sun protection measures while using EPSOLAY.

ADVERSE REACTIONS

- The most common adverse reactions were application site reactions: pain (2%), erythema (2%), pruritis (1%) and edema

(1%).

To report SUSPECTED ADVERSE REACTIONS, contact Sol-Gel Technologies Inc. at [1-866-SGT-AERS (748-4377)] or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see the full Prescribing Information here: http://ml.globenewswire.com/Resource/Download/c90c6cab-73f1-4f49-a08a-83bbf291a415

About Inflammatory Lesions of Rosacea

Rosacea is a chronic and recurrent skin condition that can potentially worsen over time. More than 82% of people with rosacea feel that their condition is uncontrolled and rosacea can deeply affect self-esteem and mental health.

Inflammatory lesions of rosacea is a chronic and recurrent skin disorder that affects millions of Americans. The condition is especially common 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 inflammatory lesions often appear. Other symptoms may include burning, stinging, dry skin, plaques and skin thickening.

About Sol-Gel Technologies

Sol-Gel is a dermatology company focused on identifying, developing and commercializing branded and generic topical drug products for the treatment of skin diseases. Sol-Gel leveraged its proprietary microencapsulation technology platform for TWYNEO®, which is approved for the treatment of acne vulgaris in adults and pediatric patients nine years of age and older; and EPSOLAY, which is approved for the treatment of inflammatory lesions of rosacea in adults. Both drugs are exclusively licensed to Galderma for U.S. commercialization.

The Company's pipeline also includes early-stage topical drug candidates SGT-210, SGT-310 and SGT-510 under investigation for the treatment of plaque psoriasis and other dermatologic indications.

For additional information, please visit www.sol-gel.com.

About Galderma

Galderma is the world's largest independent dermatology company, present in approximately 100 countries. Since our inception in 1981, we have been driven by a complete dedication to dermatology. We deliver an innovative, science-based portfolio of sophisticated brands and services across Aesthetics, Consumer Care and Prescription Medicine. Focused on the needs of consumers and patients, we work in partnership with healthcare professionals to ensure superior outcomes. Because we understand that the skin we're in shapes our life stories, we are advancing dermatology for every skin story.

For additional information, please visit www.galderma.com/us.

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 commercial launch of EPSOLAY and statements regarding the benefits we expect to receive under our agreement with Galderma. 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 expectations 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 risk that we will not receive all of the anticipated benefits under our agreement with Galderma, the risk of a delay in the commercial availability of EPSOLAY and/or TWYNEO, the risk that EPSOLAY and TWYNEO will not provide treatment to the number of patients anticipated, risks relating to the effects of COVID-19 (coronavirus) as well as 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, the potential delay in receiving such regulatory approvals 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 April 4, 2022, 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. Except as required by law, we undertake no obligation to update any forward-looking statements in this press release.

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Source: Sol-Gel Technologies Ltd.