Sol-Gel Technologies Announces Positive Update Related to FDA Review Status of EPSOLAY®

December 21, 2021

- *FDA informs Sol-Gel that it intends to conduct a pre-approval inspection of the production site for EPSOLAY during the week of February 14th, 2022*

NESS ZIONA, Israel, Dec. 21, 2021 (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 that the Food and Drug Administration (FDA) has informed the Company that it intends to conduct a pre-approval inspection of the production site for the Company's drug product, EPSOLAY ®, a proprietary topical formulation of benzoyl peroxide, 5%, during the week of February 14th, 2022. EPSOLAY is under review by the FDA for the treatment of the inflammatory lesions of rosacea in adults.

"We are pleased that the FDA has informed us of the timing of its pre-approval inspection of the production site for EPSOLAY, which, since April 26, 2021, has been delayed due to COVID-19 related travel restrictions," said Alon Seri Levy, Ph.D., Chief Executive Officer of Sol-Gel. "We believe that EPSOLAY has the potential to change the treatment landscape for adult patients suffering from inflammatory lesions of rosacea, a skin disorder that affects millions of people in the U.S. and expect that this development will bring us closer to the anticipated EPSOLAY approval and launch in the U.S. by our partner Galderma."

About EPSOLAY

EPSOLAY is a topical cream containing benzoyl peroxide, 5%, under FDA review 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 protected by granted patents until 2040.

About Inflammatory Lesions of Rosacea

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, under investigation for the treatment of inflammatory lesions of rosacea with an NDA filed with the FDA and a PDUFA goal date that was set for April 26, 2021. Both drugs are exclusively licensed for U.S. commercialization to Galderma.

The Company's pipeline also includes early-stage topical drug candidates SGT-210 (topical erlotinib) under investigation for the treatment of palmoplantar keratoderma, SGT-310 (tapinarof cream) and SGT-510 (topical roflumilast) under investigation for the treatment of plaque psoriasis and other dermatologic 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, but not limited to, statements regarding the timing of the pre-approval inspection of the production site for EPSOLAY and the FDA approval of EPSOLAY. 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 risk of a further delay in the timing of the pre-approval inspection of the production site for EPSOLAY, whether due to COVID-19 travel restrictions or otherwise, a delay in the receipt of approval, if any, of the NDA for EPSOLAY, the risk of a delay in the commercial availability of ESPSOLAY, the risk that EPSOLAY 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 March 4, 2021 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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