Sol-Gel Announces Pipeline Update and Future Development Plans

June 28, 2021

- *Sol-Gel investigational* SGT-510 *was found to be more effective than roflumilast cream, 0.3%, in a human xenograft psoriasis animal model*
- *Sol-Gel is developing tapinarof cream, 1%, aiming to offer* product formulation innovations and increased affordability for patients compared to the brand expected to be launched
- *Our proof-of-concept study for SGT-210 (erlotinib gel) in palmoplantar keratoderma patients has been completed and indicated a possible modest improvement*
- *Sol-Gel to host Conference Call today at 8:00 am U.S. EDT to discuss the data and provide a corporate update*

NESS ZIONA, Israel, June 28, 2021 (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 positive pre-clinical data for SGT-510, its investigational topical roflumilast drug candidate and provided a corporate update.

The study was conducted at the Skin Research Laboratory, Rappaport Faculty of Medicine, Technion Institute of Technology, Haifa, Israel, under the supervision of Professor Amos Gilhar, M.D. Professor Gilhar has pioneered a human psoriasis xenograft mouse model, consisting of immunodeficient mice transplanted with healthy human skin, and used it to validate a number of approved topical and systemic dermatology products, including those sold by large pharmaceutical companies. For the study, the human xenograft animal model was induced with psoriasis by injection of activated allogeneic IL2-enriched peripheral blood mononuclear cells isolated from psoriatic patients. The mice were then treated with several topical agents and assessed for recovery after each intervention.

"Our model has been proven to predict efficacy for novel approaches in the treatment of psoriasis, providing very valuable information to the companies leveraging this assay," commented Professor Gilhar.

All tested articles were applied for 14 days either once or twice daily:

- Nine (9) out of 10 animals fully recovered following a twice-daily application of dexamethasone (the positive control);
- None (0) out of 10 recovered following a once-daily application of vehicle cream (the negative control);
- Three (3) out of 10 animals recovered following a once-daily application of roflumilast cream, 0.3% that was formulated by Sol-Gel according to conventional methods of cream formulation;
- Six (6) out of 10 animals fully recovered following once-daily application of SGT-510.

Based on these results, Sol-Gel filed a provisional patent application for its novel and non-obvious formulation of SGT-510. By the end of 2022, the Company expects to have head-to-head data against a formulation of roflumilast cream, 0.3% and expects to initiate Phase 2 work thereafter.

Mr. Mori Arkin, Executive Chairman of the Board of Sol-Gel, commented, "While this small study does not represent a formal statistical analysis, we are very pleased that these early-stage results, demonstrating 60% recovery after a once-daily application of SGT-510 in the human psoriasis xenograft mouse model, supported our predefined hypothesis and confirmed our expectations about formulation superiority using our approach. Given our expertise in formulation science and topical drug delivery, we believe that we have an advantage due to the patentability of SGT-510. It is our belief that if these results are corroborated by clinical studies, a patent, if granted, will provide us not only freedom to operate, but more importantly, intellectual property protection against generic entrants until expiry of our patent in 2040."

Mr. Arkin continued, "Due to the safety-limiting features of steroids, the prospect of an effective alternative to steroid medicine for the treatment of psoriasis, such as SGT-510, is significant and would fill a critical unmet need for these patients. Sol-Gel intends to develop SGT-510 in accordance with the 505(b)(2) regulatory pathway by only referencing the oral roflumilast brand DALIRESP®. The rationale for this carefully planned regulatory strategy is to create a clear path to market, with no litigation requirement. We expect that all Orange Book-listed DALIRESP® patents will have expired by the time of its New Drug Application (NDA) submission, and that no Paragraph IV certification with a consequent 30-month stay would be required. As we plan to develop more than one roflumilast product, including potential combination products, we may also utilize alternative regulatory strategies. Our deep involvement in topical generics along with the supportive view of independent intellectual property experts guides us to believe that there is a significant risk that present patents and patent applications for roflumilast 0.3% cream may be unable to prevent early genericization of the roflumilast products currently under development. Should this be the case, our innovative formulations of roflumilast, if approved by the FDA, would give us the opportunity to become a leading player in the multi-billion-dollar psoriasis and atopic dermatitis markets in the second half of the decade."

Mr. Arkin added, "Separately, we have made progress towards the development of our proprietary formulation of tapinarof cream, 1%, SGT-310. We plan to pursue a de-novo NDA via the 505(b)(1) regulatory pathway, with the goal of creating a second alternative to an investigational tapinarof cream, 1%, for which an NDA was already submitted to the FDA. According to this strategy, we plan to launch our tapinarof drug product worldwide no later than five years following the U.S. approval of the first tapinarof cream, aiming to increase affordability for patients compared to the brand expected to be launched. In addition, we intend to differentiate ourselves by offering tapinarof product formulation innovations for new indications. We have already been refining our strategy in line with best regulatory practices, and our drug product will be developed via our active pharmaceutical ingredient (API) manufacturing collaboration with Wavelength Pharmaceuticals, previously known as Perrigo API, a company with an impressive track

record of FDA GMP compliance."

Mr. Arkin further added: "Our proof-of-concept (POC) study for SGT-210 (erlotinib gel) in six (6) palmoplantar keratoderma (PPK) patients has been completed and indicated modest improvement and a favorable safety profile. In this study, we used a very low concentration of erlotinib. We are now planning to test erlotinib at much higher concentrations in an animal model in the second half of 2021 and if successful, will conduct a second POC study on PPK patients in 2022. We remain optimistic about this program."

Management to Host Conference Call Today

Sol-Gel will host an investor conference call today at 8 AM U.S. EDT to discuss today's announcement, herein, and the strategy of the company following today's partnership news, announced separately.

To participate in the call, dial either the domestic or international number fifteen minutes before the conference call begins:

Domestic: **1-877-407-0784**
International: 1-201-689-8560
Passcode: 13720829

The live conference call and replay can also be accessed by audio webcast **here** and also on the Investor Relations section of the Company's website, located at https://ir.sol-gel.com/investor-relations.

About Roflumilast

Roflumilast is a selective, long-acting inhibitor of Phosphodiesterase-4 (PDE4). It is the active ingredient in the Food and Drug Administration (FDA) approved medication, DALIRESP®, which is as an oral treatment indicated in the U.S. as a therapy to reduce the risk of COPD exacerbations in patients with severe COPD associated with chronic bronchitis and a history of exacerbations.

A roflumilast cream 0.3% formulation is under investigation as a once-daily treatment of plaque psoriasis and positive Phase 3 results were recently reported.

About Tapinarof

Tapinarof is a novel, first-in-class, small-molecule topical therapeutic aryl hydrocarbon receptor (AhR)–modulating agent. It is in clinical development for the treatment of psoriasis and atopic dermatitis. The efficacy of tapinarof in psoriasis is attributed to its specific binding and activation of AhR, a ligand-dependent transcription factor, leading to the downregulation of proinflammatory cytokines, including interleukin 17, and regulation of skin barrier protein expression to promote skin barrier normalization.

About Erlotinib

Erlotinib is a tyrosine kinase receptor inhibitor which acts on the Epidermal Growth Factor Receptor (EGFR). It is the active pharmaceutical ingredient (API) in Tarceva® which is used to orally treat non-small cell lung cancer, pancreatic cancer and several other types of cancer. Currently, there are no topical products of erlotinib, and erlotinib is not approved for plaque psoriasis.

About Wavelength Pharmaceuticals

Wavelength is a customer-focused backward-integrated world-class developer and manufacturer of Active Pharmaceutical Ingredients (APIs). It is the independent company of choice for pharmaceutical industry leaders that require advanced API solutions and reliable supply to gain sustainable competitive advantage. The company is on the same wavelength as its customers – a partner in tune with the results required to best support their needs. Founded in Israel in 1987, with more than 280 customers in 50 countries, Wavelength produces more than 630 metric tons of commercial products every year, across a wide range of technologies including injectables, inhalables, highly potent, cytotoxic and controlled substances. Its cGMP-compliant facility is a first-class operation recognized for excellence in safety and environmental stewardship. Wavelength has achieved an exceptional track record for more than 30 years with all leading global regulatory authorities, including USFDA, EU-EMA, PMDA, TGA, KFDA, ANVISA and COFEPRIS. The company includes experts in complex chemistry, process development and scale-up, enzymatic reactions, crystalline forms and particle design, spray drying and other bioavailability-enhancing solutions. Wavelength offers end-to-end customized solutions to meet individual customer requirements, including full-spectrum API CDMO services from pre-clinical grams to multi-ton commercial scale – always with uncompromising consistent quality, regulatory compliance and exceptional customer service.

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® under investigation for the treatment of acne vulgaris with an NDA filed with the FDA and a PDUFA goal date set for August 1, 2021; and EPSOLAY®, under investigation for the treatment of inflammatory lesions of rosacea with an NDA filed with the FDA and a PDUFA goal date set for April 26, 2021. Both product candidates are exclusively licensed for U.S. commercialization with Galderma Holding SA. Action on the NDA for EPSOLAY has not yet been taken due to the inability of the FDA to conduct a pre-approval inspection of the production site of EPSOLAY as a result of COVID-19 travel restrictions. 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.

Forward-Looking Statements

This press release contains "forward-looking statements" within the meaning Securities of the Private 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, including statements regarding the timing for the initiation of a Phase I study for SGT-510, the intellectual property protection that would be provided by a patent for SGT-210, the anticipated status of patents at the time of an NDA submission for SGT-210, the timing of the launch of our tapinarof drug product and the timing of a test of erlotinib with a much higher concentrations in an animal model and a second POC study on PPK patients. 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 delay in receipt of approval, if any, of the NDA for TWNYEO, the risk of a further delay in receipt of approval, if any, of the NDA for EPSOLAY, the risk of a delay in the initiation of a Phase I study for SGT-510, the risk

that a patent for SGT-210 will not provide the anticipated intellectual property protection, the risk that all Orange Book-listed DALIRESP® patents will not have expired by the time of our NDA application for SGT-21 and that a consequent 30-month stay will required, the risk of a delay in the launch of our tapinarof drug product, the risk of a delay the timing of a test of erlotinib with a much higher concentrations in an animal model and the risk of a delay in a second POC study on PPK patients, 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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