Sol-Gel Announces Health Canada Approval of EPSOLAY®

September 4, 2025

NESS ZIONA, Israel, Sept. 04, 2025 (GLOBE NEWSWIRE) -- **Sol-Gel Technologies, Ltd.** (NASDAQ: SLGL), a dermatology company, pioneering treatments for patients with severe skin conditions, conducting a Phase-3 clinical trial of SGT-610 (patidegib gel, 2%) for Gorlin syndrome, a Phase-1b, double blinded clinical trial of SGT-210 (erlotinib ointment, 5%) on Darier disease patients and with two approved large-category dermatology products, TWYNEO and EPSOLAY, announced today that on August 27, 2025 Health Canada issued a Notice of Compliance (NOC) for EPSOLAY for the treatment of inflammatory lesions of rosacea in adults.

This approval comes as a result of Sol-Gel's partnership with Searchlight Pharma, Sol-Gel's exclusive licensee for commercializing EPSOLAY in the Canadian market. Under the exclusive license agreement signed in 2023, Searchlight was responsible for obtaining Canadian regulatory approval for EPSOLAY, and with this milestone achieved, Searchlight is preparing to launch EPSOLAY for rosacea patients in Canada. As part of the agreement, Sol-Gel is eligible to receive up to $11 million in combined potential upfront, regulatory and sales milestone payments for TWYNEO and EPSOLAY in Canada, in addition to tiered royalties on net sales. This non-dilutive revenue, alongside other partnerships, strengthens Sol-Gel's balance sheet and supports the Company's growth strategy.

Mr. Mori Arkin, Executive Chairman of Sol-Gel, stated: "We are delighted that Health Canada has approved EPSOLAY, enabling us to bring this innovative treatment to rosacea patients in Canada. The recently announced U.S. transaction with Mayne Pharma and agreements executed during the past year, underscore our ability to unlock value from our assets while strengthening our financial position. We look forward to supporting Searchlight Pharma in the Canadian launch of EPSOLAY and to advancing our pipeline of novel dermatological therapies."

Mr. Arkin further commented: "Health Canada's approval of EPSOLAY brings the company a step closer towards achieving its strategy to commercialize EPSOLAY and TWYNEO throughout the world, across ex-U.S. territories, including Europe, Asia, Africa, Latin America, and Australia, where most partnership agreements are already in place. Based on current plans, launches in many of these territories are expected to begin in 2027 and 2028, and partners forecasts indicate that ex-U.S. contribution to the EBITDA of the company are expected to gradually increase and potentially reach approximately $10 million annually by 2031. These figures do not include milestone payments which, if materialized, would provide additional important non-dilutive income to support the implementation of our strategy of becoming a leader in dermatological rare diseases."

Lastly, Mr. Arkin added: "As acne and rosacea are no longer a core business for the company, we expect that at the right time when the commercial potential of our ex-U.S. TWYNEO and EPSOLAY will become more visible, we will look to seek strategic alternatives for this business."

About TWYNEO and EPSOLAY

TWYNEO is a topical cream containing a fixed-dose combination of tretinoin, 0.1%, and benzoyl peroxide, 3%, cream for the treatment of acne vulgaris in adults and pediatric patients 9 years of age and older. TWYNEO is the first acne treatment that contains a fixed-dose combination of benzoyl peroxide and tretinoin. Tretinoin and benzoyl peroxide are widely prescribed separately for acne vulgaris; however, benzoyl peroxide causes degradation of the tretinoin molecule, thereby potentially reducing its effectiveness if used at the same time or combined in the same formulation. TWYNEO uses silica (silicon dioxide) core shell structures to separately micro-encapsulate tretinoin crystals and benzoyl peroxide crystals enabling inclusion of the two active ingredients in the cream.

EPSOLAY is a topical cream containing benzoyl peroxide (BPO), 5%, for the treatment of bumps and blemishes (inflammatory lesions) of rosacea in adults. EPSOLAY utilizes a proprietary, patented technology to encapsulate BPO within silica-based microcapsules to create a barrier between the medication and the skin. The silica-based shell is designed to slowly release BPO over time to provide a tolerable and effective treatment.

About Gorlin Syndrome and SGT-610

SGT-610, a hedgehog signaling pathway blocker, has the potential to be the first ever treatment for prevention of BCCs in Gorlin syndrome patients, if approved. Gorlin syndrome, an autosomal dominant genetic disorder affecting approximately 1 in 27,000-31,000 people in the U.S., is mostly caused by inheritance of one defective copy of the tumor suppressor patched homolog 1 (PTCH1) gene. Normally, the PTCH1 gene blocks the smoothened, frizzle class receptor (SMO) gene, turning off the hedgehog signaling pathway when it is not needed. Mutations in the PTCH1 gene may cause a loss of PTCH1 function, release of SMO, and may allow BCC tumor cells to divide uncontrollably. Patidegib, the active substance in SGT-610, is designed to block the SMO signal, thus, allowing cells to function normally and reducing the production of new tumors.

About Sol-Gel Technologies

Sol-Gel Technologies, Ltd. is a dermatology company focused on identifying, developing and commercializing or partnering drug products to treat skin diseases. Sol-Gel developed TWYNEO which is approved by the FDA for the treatment of acne vulgaris in adults and pediatric patients nine years of age and older; and EPSOLAY, which is approved by the FDA for the treatment of inflammatory lesions of rosacea in adults.

The Company's pipeline also includes Phase 3 clinical trial of Orphan and breakthrough drug candidate SGT-610, which is a new topical hedgehog inhibitor being developed to prevent the new basal cell carcinoma lesions in patients with Gorlin syndrome that is expected to have an improved safety profile compared to oral hedgehog inhibitors as well as topical drug candidate SGT-210 under investigation for the treatment of rare hyperkeratinization disorders.

For additional information, please visit our new website: 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 the amounts expected to be received under our current and future licensing agreements and other collaborations, the timing of the launch of TWYNEO and EPSOLAY in various countries and future strategic alternatives for the company's businesses. 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 the amounts received from our current and future licensing agreements and other collaborations will not be as anticipated, the risk of delay of the launch of TWYNEO and EPSOLAY in various countries, the risk of any change in the Company’s strategic view of the acne and rosacea business, our ability to enter into further collaborations a delay in the timing of our clinical trials, top-line results and regulatory filings, a delay in receipt of payments from Mayne Pharma and others, the success of our clinical trials, and an increase in our anticipated costs and expenses, 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 collaborators’ ability to commercialize our pharmaceutical product candidates; (vi) our ability to obtain and maintain adequate protection of our intellectual property; (vii) our collaborators’ ability to manufacture our product candidates in commercial quantities, at an adequate quality or at an acceptable cost; (viii) our collaborators’ 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, China, Europe or Israel; and (xv) loss or retirement of key executives and research scientists; (xvi) general market, political and economic conditions in the countries in which the Company operates; and, (xvii) the current war between Israel and Hamas and any deterioration of the war in Israel into a broader regional conflict involving Israel with other parties. These factors 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 29, 2025, 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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