# Sol-Gel and Mayne Pharma Announce the Purchase of EPSOLAY® and TWYNEO® in the U.S.

April 17, 2025

- Sol-Gel to receive $16 million during 2025
- Cash runway is expected to extend into the first quarter of 2027; Company expects to have sufficient cash to complete its Phase III clinical trial
- SGT-610 Phase III clinical trial top-line results are expected in the fourth quarter of 2026; a significant milestone in the clinical trial of recruiting more than 80% of the patients has been achieved
- Sol-Gel now estimates the U.S. market potential for SGT-610 to be between $400 to $500 million annually
- SGT-210 Phase 1b trial in Darier patients is ongoing; 50% of the patients have already completed the trial

NESS ZIONA, Israel, April 17, 2025 (GLOBE NEWSWIRE) -- Sol-Gel Technologies, Ltd. (NASDAQ: SLGL), a clinical-stage dermatology company, today announced it has entered into a product purchase agreement with a subsidiary of Mayne Pharma Group Limited (ASX: MYX) (Mayne Pharma) for the sale and exclusive license of the U.S. rights to EPSOLAY and TWYNEO. Under the terms of the agreement, Sol-Gel will receive a total of $16 million in two installments: $10 million in the second quarter of 2025 and $6 million in the fourth quarter of 2025, which is expected to extend the Company's cash runway into the first quarter of 2027. This agreement was executed following the mutual termination by Sol-Gel and Galderma of the exclusive five-year license agreement in the U.S. for both products.

EPSOLAY is a topical cream containing encapsulated benzoyl peroxide, 5%, for the treatment of inflammatory lesions of rosacea (papulopustular rosacea) in adults. TWYNEO is a fixed-dose combination of encapsulated benzoyl peroxide, 3%, and encapsulated tretinoin, 0.1%, cream for the treatment of acne vulgaris.

Facilitating the amounts received from this agreement with Mayne Pharma, Sol-Gel will concentrate on the clinical and commercial development of its most advanced innovative product, SGT-610, a hedgehog signaling pathway blocker designed to potentially become the first ever preventative treatment of basal cell carcinomas (BCCs) in Gorlin syndrome patients, if approved.

Based on recent independent market research commissioned by Sol-Gel, in which the optimal price recommendation has been established, and based on prevalence of Gorlin syndrome in the U.S., Sol-Gel now estimates the U.S. market potential for SGT-610 to be between $400 and $500 million annually.

As of December 31, 2024, Sol-Gel had $19.5 million in cash, cash equivalents, and deposits and $4.4 million in marketable securities for a total balance of $23.9 million.

As of March 31, 2025, Sol-Gel had $16.9 million in cash, cash equivalents, and deposits and no marketable securities for a total balance of $16.9 million.

"We are pleased to enter into this agreement with Mayne Pharma," said Mori Arkin, Chairman of the Board and CEO of Sol-Gel. "Having concluded this U.S. transaction, we are in advanced stages of establishing the commercial network of Epsolay and Twyneo outside the U.S. Many partnership agreements have already been signed and others are under negotiation. If the forecasts of our partners, who all made upfront payments for the rights in their territories, are accurate, we believe that the value of the global business could far exceed that of the U.S. business alone.

"This agreement with Mayne Pharma is expected to significantly enhance our cash position and enable us to bolster our SGT-610 program and bring the Phase-III trial to completion. In addition to the potential of SGT-610 in the U.S., we believe that the worldwide potential of SGT-610 is very significant as Gorlin syndrome is prevalent globally.

"Our Phase-III clinical trial is progressing well, with all of our 41 sites open for enrollment and approximately 80% of the planned number of patients enrolled. We confidentially expect to complete recruitment no later than the third quarter of this year and announce top-line results in the fourth quarter of 2026.

"With the funding of the clinical trial accomplished and the timeline established, we would like to share with our investors the reasons as to why we are optimistic about the trial's potential success."

Mr. Arkin further commented, "It is important to note that all the data supporting our optimistic outlook are based on our post-hoc analysis of the results of the Phase-III clinical study of patidegib that was conducted by our predecessor, PellePharm Inc.

"This type of analysis is called a 'post-hoc analysis', which we cannot assure you that its conclusions will be replicated in our study. With that said, I would like to explain the reasons for our optimism.

"The study conducted by PellePharm did not achieve the statistical significance of the primary endpoint. However, with the assistance of three independent statisticians and several clinical experts, all commissioned by Sol-Gel, significant findings were made after studying the data.

"Gorlin syndrome patients who lacked the PTCH-1 mutation responded poorly to patidegib.

"When we included in our analysis only patients with a confirmed hedgehog mutation and excluded an additional subset of patients, the superiority of patidegib became very significant – P <0.01. Our experts believe that this selection is not only warranted statistically but is based on sound scientific considerations."

Mr. Arkin further commented, "I am also pleased to share an update on Sol-Gel's of our vehicle controlled phase 1b clinical trial on SGT-210 (topical

erlotinib) in patients with Darier disease, a significant unmet medical need with an estimated market potential of $200 to $300 million. If the trial will demonstrate the clinical efficacy that we expect, we anticipate filing for a Phase 2 IND in Q2 2025. SGT-210 is currently being used in a compassionate use treatment for a pediatric patient suffering from a rare disease, and the repeated requests for supply from the patient's family indicates to us that the drug was probably helpful for this patient."

**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 Darier Disease and SGT-210**

SGT-210 is a topical erlotinib drug candidate that is formulated for the treatment of Darier Disease and other hyperkeratosis-related indications. Erlotinib is a tyrosine kinase receptor inhibitor that acts on the epidermal growth factor receptor, a protein present on cell surfaces that plays a key role in promoting cell growth and division. Darier Disease is a rare, genetic keratinization disorder which is classically characterized scaly crusted papules in a seborrheic distribution and in skin folds.

**About Sol-Gel Technologies**

Sol-Gel Technologies, Ltd. is a dermatology company focused on identifying, developing and commercializing or partnering drug products for the treatment of 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 includes Orphan Drug candidate, SGT-610 under investigation for the prevention of new basal cell carcinomas in Gorlin syndrome patients, and also includes topical drug candidate SGT-210 under investigation for the treatment of rare skin keratodermas.

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

**About Mayne Pharma**

Mayne Pharma is an ASX-listed specialty pharmaceutical company focused on commercializing novel pharmaceuticals, to offer patients better, safe and more accessible medicines. Mayne Pharma is a leader in dermatology and women's health in the United States and also provides contract development and manufacturing services to clients worldwide. Mayne Pharma has a 40- year track record of innovation and success in developing new oral drug delivery systems. These technologies have been successfully commercialized in numerous products that continue to be marketed around the world. To learn more about Mayne Pharma, please visit Maynepharma.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 to be received under our current and future licensing agreements, our expected cash runway, the potential of Sol-Gel's assets including Twyneo, Epsolay, SGT-610, and SGT-210, the timeline for advancing SGT-610, and SGT-210, and the size of SGT-610's market. 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, delays in regulatory milestones, such as a delay in top-line results for our SGT-610 clinical trial, our ability to enter into further collaborations, lower than anticipated annual revenue income from new collaborations and a delay in the timing of our clinical trials, 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 March 13, 2024, 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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