Sol-Gel Technologies and Galderma Announce Exclusive Licenses for the Commercialization of EPSOLAY® and TWYNEO® in the United States

June 28, 2021

- Upfront and approval payments of up to $15 million
- Tiered royalties ranging from mid- to high-teen percentage of net sales
- Sol-Gel option to regain commercialization rights 5 years following first commercialization

NESS ZIONA, Israel & LAUSANNE, Switzerland--(BUSINESS WIRE)--Jun. 28, 2021-- Sol-Gel Technologies, Ltd. (NASDAQ: SLGL), a clinical-stage dermatology company, and Galderma, the world's largest independent dermatology company, today announced they have signed two exclusive 5-year license agreements for the commercialization of EPSOLAY® and TWYNEO® in the United States.

Under these agreements, Galderma has an exclusive license to commercialize Sol-Gel's most advanced investigational drug products using Sol-Gel's proprietary micro-encapsulation technology, in each case provided the product is approved by the FDA:

- EPSOLAY (benzoyl peroxide, 5%, cream) is under investigation for the treatment of inflammatory lesions of rosacea in adults, with a Prescription Drug User Fee Act (PDUFA) goal date originally set for April 26, 2021. 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 due to COVID-19 travel restrictions.
- TWYNEO (benzoyl peroxide, 3%, and tretinoin, 0.1%, cream) is under investigation for the treatment of acne vulgaris with a PDUFA goal date set for August 1, 2021.

Sol-Gel is entitled to up to $15 million in upfront payments and regulatory approval milestone payments assuming 2021 approval of both products. Sol-Gel is also eligible to receive tiered double-digit royalties ranging from mid-teen to high-teen percentage of net sales as well as up to $9 million in sales milestone payments.

"Galderma already owns the current market leading brands for rosacea and acne, and I am therefore delighted that Galderma views EPSOLAY and TWYNEO as innovative and with the potential to become key market brands," stated Dr. Alon Seri-Levy, Chief Executive Officer of Sol-Gel. "Our partnerships with Galderma represent an important development for rosacea and acne patients while also strengthening our balance sheet by providing non-dilutive capital without compromising our desire to establish Sol-Gel as a leading dermatology company. We intend to remain focused on developing our promising pipeline and we are appreciative of the flexibility that these agreements provide through Sol-Gel retaining commercial rights after the initial five-year term," commented Dr. Seri-Levy.

"Innovation is at the heart of our commitment to advancing dermatology," said Baldo Scassellati Sforzolini, Global Head of Research & Development at Galderma. "The potential to deliver two innovative products featuring Sol-Gel's proprietary micro-encapsulation technology represents an important milestone for acne and rosacea patients and underscores Galderma's position as the partner of choice in dermatology."

About EPSOLAY
EPSOLAY is an investigational topical cream containing encapsulated benzoyl peroxide, 5%, for the treatment of inflammatory lesions of rosacea, also known as papulopustular rosacea, in adults. EPSOLAY utilizes a patented technology process 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 release benzoyl peroxide slowly over time to provide a favorable efficacy and safety profile. If approved, EPSOLAY has the potential to be the first FDA-approved single-active benzoyl peroxide prescription drug product. EPSOLAY is not approved by the FDA and the safety and efficacy have not been established.

About Papulopustular Rosacea
Papulopustular rosacea is a chronic and recurrent inflammatory skin disorder that affects nearly 5 million Americans. Rosacea condition is common, especially 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 (papules and pustules) often appear. Other symptoms may include burning, stinging, dry skin, plaques and skin thickening.

About TWYNEO
TWYNEO is an investigational, fixed-dose combination of encapsulated benzoyl peroxide, 3%, and encapsulated tretinoin, 0.1%, cream for the treatment of acne vulgaris. If approved, TWYNEO will be the first acne treatment that contains a fixed-dose combination of benzoyl peroxide and tretinoin, which are separately encapsulated in silica using Sol-Gel's proprietary micro-encapsulation technology. Tretinoin and benzoyl peroxide are widely prescribed separately as a combination treatment for acne; 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. The silica-based microcapsule is designed to protect tretinoin from oxidative decomposition by benzoyl peroxide, thereby enhancing the stability of the active drug ingredients. The silica-based shell is also designed to release the ingredients slowly over time to provide a favorable efficacy and safety profile. TWYNEO is not approved by the FDA and the safety and efficacy have not been established.

About Acne Vulgaris
Acne vulgaris is a common multifactorial skin disease that according to the American Academy of Dermatology affects approximately 40 to 50 million people in the United States. The disease occurs most frequently during childhood and adolescence (affecting 80% to 85% of all adolescents) but it may also appear in adults. Acne patients suffer from the appearance of lesions on areas of the body with a large concentration of oil glands, such as the face, chest, neck and back. These lesions can be inflamed (papules, pustules, nodules) or non-inflamed (comedones). Acne can have a profound effect on the quality of life of those suffering from the disease. In addition to carrying a substantial risk of permanent facial scarring, the appearance of lesions may cause psychological strain, social withdrawal and lowered self-esteem.

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 micro-encapsulation technology platform for the development of TWYNEO, under investigation for the treatment of acne vulgaris, and EPSOLAY, under investigation for the treatment of papulopustular rosacea. 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.

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 more information: www.galderma.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 FDA approval of EPSOLAY AND TWYNEO and statements regarding the timing and potential commercialization of EPSOLAY and TWYNEO. 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 financial benefits of the agreements with Galderma, the benefits of EPSOLAY and TWYNEO to patients, and the timing of the commercial availability of EPSOLAY and TWYNEO. 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 that Sol-Gel will not receive all the financial benefits under the agreements with Galderma, the risk of a delay in the commercial availability of ESPSOLAY 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 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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