Sol-Gel Technologies Announces the Commercial Availability of TWYNEO®

April 14, 2022

- *TWYNEO is the first-ever tretinoin and benzoyl peroxide combination to treat facial acne*
- *Sol-Gel's U.S. commercialization partner, Galderma, launched TWYNEO® in the U.S. at the Annual Meeting of the American Academy of Dermatology, March 25-29, 2022 in Boston, MA.*
- *TWYNEO is now available for purchase with a physician's prescription*

NESS ZIONA, Israel, April 14, 2022 (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, today announced that TWYNEO® , a topical cream containing a fixed-dose combination of tretinoin, 0.1%, and benzoyl peroxide (BPO), 3% for the treatment of acne vulgaris in adults and pediatric patients nine years of age and older, is now available for purchase by consumers who obtain a prescription from their physician. TWYNEO Cream was approved by the U.S. Food and Drug Administration on July 27, 2021 and is being commercialized in the U.S. by Galderma. It is the first and only tretinoin and benzoyl peroxide (BPO) 2-in-1 combination ever approved by FDA and has been proven to rapidly treat even moderate to severe facial acne.[1]

"We are very excited that our partners at Galderma are now able to bring this first-ever tretinoin-BPO combination as a treatment option for the tens of millions of Americans afflicted with acne," stated Alon Seri-Levy, PhD, Chief Executive Officer of Sol-Gel. "TWYNEO uses Sol-Gel's patented microencapsulation technology which allows these two ingredients to be combined and enables their controlled release."

TWYNEO's launch was covered in print, video and audio interview by major beauty, personal care and industry publications and media outlets including Allure magazine, Practical Dermatology, The Dermatologist, Healio.com, Personal Care Insights, and Monthly Prescribing Reference (MPR).

TWYNEO Cream is now available at all major pharmacy chains throughout the U.S. by prescription. TWYNEO Cream is a once-daily application that can be used any time of day and even for severe cases of acne, as indicated by a physician's prescription.

About Acne Vulgaris

Acne is a widespread skin condition affecting 85% of Americans ages 12 to 24 that can trigger feelings of depression, poor body image and low self-esteem.[4,5] Despite acne being common during this age, as many as 50% of teens have reported they experience unfair treatment at school because of their acne.[6] Teens often fail multiple over-the-counter (OTC) acne treatment options before consulting a dermatology provider, despite 70% of parents wishing they sought specialist help sooner for their teen's acne. [2,3]

About TWYNEO®

TWYNEO (tretinoin and benzoyl peroxide) Cream, 0.1%/3% is indicated for the topical treatment of inflammatory and noninflammatory lesions of acne vulgaris.[1] The patented microencapsulation technology in TWYNEO Cream segregates and envelopes the active ingredients in silica core shells (microcapsules) so that tretinoin is protected from the oxidizing effects of BPO, allowing the combination of both drugs into one product and gradual release onto the skin.

Sol-Gel Technologies (Nasdaq: SLGL) received FDA approval for TWYNEO Cream on July 27, 2021, and has granted exclusive rights to Galderma to commercialize the treatment in the U.S.

For additional information, including prescribing and safety information, please visit www.twyneo.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 additional information, please visit www.galderma.com/us.

About TWYNEO

TWYNEO is a topical cream containing a fixed-dose combination of tretinoin, 0.1%, and benzoyl peroxide, 3%, for the treatment of acne vulgaris in adults and pediatric patients nine 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 microencapsulate tretinoin crystals and benzoyl peroxide crystals enabling inclusion of the two active ingredients in the same cream.

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 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, which is under review for the treatment of inflammatory lesions of rosacea in adults. Both drugs are exclusively licensed to Galderma for U.S. commercialization.

The Company's pipeline also includes early-stage drug candidates SGT-210, SGT-310 and SGT-510 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 commercial launch of TWYNEO, the regulatory approval of EPSOLAY, our expected cash runway, and the benefits we expect to receive under our agreement with Galderma. 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 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 we will not receive all of the anticipated benefits under our agreement with Galderma, the risk of a delay in the commercial availability of TWYNEO and/or EPSOLAY, the risk that 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 April 4, 2022 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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References:

1. TWYNEO (tretinoin and benzoyl peroxide) cream. Prescribing Information.
2. Galderma Laboratories, L.P. Clinical Study Report SGT-65-04. 2020, May 28.
3. Galderma Laboratories LP. Clinical Study Report SGT-65-05. 2020, June 5.
4. Bhate K, Williams HC. Epidemiology of acne vulgaris. The British Journal of Dermatology 2013;168:474-85.
5. American Academy of Dermatology Association. Acne can affect more than your skin. Accessed 03/10/2022. https://www.aad.org/public/diseases/acne/acne-emotional-effects.
6. Galderma Laboratories LP. Burden Summary Report: Combined Facial & Truncal Acne. 2021, March.
7. Practical Dermatology. Survey: Parents Extremely Worried About the Physical and Emotional Toll that Severe Acne Takes on Teens. Accessed 03/10/2022. https://practicaldermatology.com/news/survey-parents-extremely-worried-about-the-physical-and-emotional-toll-that-severe-acne-takes-on-teens?c4src=news-landing:feed

Source: Sol-Gel Technologies Ltd.