Sol-Gel Technologies Announces FDA Approval of TWYNEO®

July 27, 2021

- *TWYNEO®, a once-daily cream treatment for acne vulgaris, is the first FDA-approved fixed-dose combination of tretinoin and benzoyl peroxide*
- *TWYNEO utilizes Sol-Gel's proprietary microencapsulation technology and is patent protected until 2038*
- *Under a previously announced license, Sol-Gel to receive regulatory milestone payment from U.S. commercialization partner, Galderma, in conjunction with this approval and retains the option to regain commercialization rights five years following first commercialization in the U.S.*

NESS ZIONA, Israel, July 27, 2021 (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 the Food and Drug Administration (FDA) has approved its first proprietary drug product, TWYNEO (tretinoin/benzoyl peroxide) cream, 0.1%/3%, indicated for the treatment of acne vulgaris in adults and pediatric patients nine years of age and older. TWYNEO uses Sol-Gel's patented technology to entrap tretinoin, a retinoid, and benzoyl peroxide within silica-based microcapsules to stabilize tretinoin from being degraded by benzoyl peroxide and to slowly release each of the active drug ingredients over time to provide a favorable efficacy and safety profile. TWYNEO is patent protected until 2038. Sol-Gel has partnered with Galderma to commercialize TWYNEO in the U.S. Sol-Gel expects to receive a regulatory milestone payment in conjunction with this approval and retains the option to regain U.S. commercialization rights five years following first commercialization in the U.S.

"The FDA approval of TWYNEO underscores our ability to deliver innovative, proprietary drugs to the market," stated Dr. Alon Seri-Levy, Co-Founder and Chief Executive Officer of Sol-Gel. "Based on the clinical data observed, we believe that TWYNEO has the potential to change the treatment landscape for the tens of millions of patients suffering from acne vulgaris. With market leader, Galderma, handling the product launch of TWYNEO, we are excited that TWYNEO will soon be available to patients in the U.S.," continued Dr. Seri-Levy. "We remain focused on obtaining FDA approval of EPSOLAY® (benzoyl peroxide), our other Galderma-partnered product – the approval of which has been delayed due to FDA's COVID-19-related restrictions. We are also making progress on our innovative earlier stage programs for erlotinib, roflumilast and tapinarof with the intent of advancing them into the clinic," he concluded.

"Galderma was founded forty years ago around a commitment to serve the dermatological needs of healthcare professionals and their patients," said Baldo Scassellati Sforzolini, Global Head of Research & Development at Galderma. "Our heritage in acne dates back to our founding and we are excited to partner with Sol-Gel to bring yet another acne innovation to market for a condition that impacts up to 50 million Americans annually.[1]"

"TWYNEO combines, for the first time, two of the most commonly used topical agents available for the treatment of acne into a single application. Due to stability issues, these products don't play well together, and we were never able to recommend even consecutive co-application of the two agents. Sol-Gel's technology has solved this problem," said Hilary Baldwin, M.D., Clinical Associate Professor of Dermatology, Rutgers Robert Wood Johnson School of Medicine, Medical Director, The Acne Treatment and Research Center and Past President of the American Acne and Rosacea Society. "The approval of TWYNEO offers patients efficacy with these two products in a single convenient application. I believe physicians will look forward to adding TWYNEO to their acne treatments toolbox."

The New Drug Application (NDA) for TWYNEO was approved by the FDA on July 26, 2021. The NDA was supported by positive results from two Phase 3, randomized, double-blind, vehicle-controlled, multi-center studies (NCT03761784, and NCT03761810), in which TWYNEO demonstrated efficacy and a favorable tolerability profile in subjects nine years of age and older with facial acne vulgaris. TWYNEO is the first FDA-approved fixed-dose combination of tretinoin and benzoyl peroxide. For more information, visit www.sol-gel.com.

About Acne Vulgaris
Acne vulgaris is a common multifactorial skin disease that according to the American Academy of Dermatology affects up to 50 million people in the U.S. The disease occurs most frequently during childhood and adolescence (affecting 80% to 85% of all adolescents) but it may also appear in adults. Acne vulgaris 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 vulgaris 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 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. The formulation of 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.

Indications and Usage
TWYNEO is a combination of tretinoin, a retinoid, and benzoyl peroxide indicated for the topical treatment of acne vulgaris in adults and pediatric patients 9 years of age and older.

IMPORTANT SAFETY INFORMATION
CONTRAINDICATIONS: History of serious hypersensitivity reaction to benzoyl peroxide or any component of TWYNEO.

WARNINGS AND PRECAUTIONS

- Hypersensitivity: Severe hypersensitivity reactions, including anaphylaxis and angioedema, have been reported with use of benzoyl peroxide products.
- Skin Irritation: Pain, dryness, exfoliation, erythema, and irritation may occur with use of TWYNEO. Avoid application of TWYNEO to cuts, abrasions, eczematous or sunburned skin.
- Photosensitivity: Minimize unprotected exposure to sunlight and sunlamps. Use sunscreen and protective clothing when sun exposure cannot be avoided.

ADVERSE REACTIONS: The most common adverse reactions (incidence ≥ 1%) are pain, dryness, exfoliation, erythema, dermatitis, pruritus and irritation (all at the application site).
Please see full Prescribing Information here.

About EPSOLAY
EPSOLAY is an investigational topical cream containing benzoyl peroxide, 5%, for the treatment of inflammatory lesions of rosacea, also known as papulopustular rosacea, in adults. If approved, EPSOLAY has the potential to be the first FDA-approved single-active benzoyl peroxide prescription drug product. The benzoyl peroxide in EPSOLAY is in a solid form that is incorporated into silica-based microcapsules. EPSOLAY is not approved by the FDA and the safety and efficacy have not been established.

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 leverages its proprietary microencapsulation technology platform for TWYNEO, which is approved for the treatment of acne vulgaris in adults and pediatric patients 9 years of age and older; and EPSOLAY, under investigation for the treatment of inflammatory lesions of rosacea with an NDA filed with the FDA and a PDUFA goal date that was 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 as a result of COVID-19 travel restrictions. Both product candidates are exclusively licensed for U.S. commercialization with Galderma.

The Company's pipeline also includes early-stage topical drug candidates SGT-210 (erlotinib gel) under investigation for the treatment of palmoplantar keratoderma, SGT-310 (tapinarof cream, 1%) and SGT-510 (roflumilast) 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 FDA approval of EPSOLAY and statements regarding the progress on our innovative earlier stage programs. 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 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 further delay in receipt of approval, if any, of the NDA for EPSOLAY, the risk that we don't progress on our innovative earlier stage programs, 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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[1]Bickers DR, Lim HW, Margolis D, Weinstock MA, Goodman C, Faulkner E *et al.* The burden of skin diseases: 2004 a joint project of the American Academy of Dermatology Association and the Society for Investigative Dermatology. Journal of the American Academy of Dermatology 2006;55:490-500.

Source: Sol-Gel Technologies Ltd.