Sol-Gel Technologies Collaboration Partner Filed First-to-File Paragraph IV Certification for Duobrii®

September 3, 2020

- *Patent challenge initiated by Bausch Health Companies*

NESS ZIONA, Israel, Sept. 03, 2020 (GLOBE NEWSWIRE) -- Sol-Gel Technologies, Ltd. (NASDAQ: SLGL), a clinical-stage dermatology company focused on identifying, developing and commercializing branded and generic topical drug products for the treatment of skin diseases, today announced that Bausch Health Companies, Inc. (NYSE:BHC) initiated patent infringement action in the U.S. District Court for the District of New Jersey on August 31, 2020 with regards to Perrigo Company plc ("Perrigo") (NYSE; TASE: PRGO) Abbreviated New Drug Application ("ANDA") for a generic version of Duobrii® (halobetasol propionate and tazarotene) lotion, for the treatment of plaque psoriasis in adults[1].

On July 23, 2020, Sol-Gel's partner Perrigo filed a Notice of first-to-file Paragraph IV Certification asserting that certain U.S. patents, each of which is listed in the FDA's Orange Book for Duobrii® (halobetasol propionate and tazarotene) lotion, are either invalid, unenforceable and/or will not be infringed by the commercial manufacture, use or sale of Perrigo's generic lotion.

Development of halobetasol propionate and tazarotene lotion is covered under a previous collaboration between Sol-Gel and Perrigo. Consistent with Sol-Gel's prior agreements with Perrigo, Perrigo will seek regulatory approval with the U.S. Food and Drug Administration ("FDA") for the generic product candidate. If approved by the FDA, Perrigo will lead the commercialization efforts for the generic product candidate in the United States. Sol-Gel and Perrigo will share the development costs and any gross profits generated from potential sales of the generic product candidate.

Annual market sales of Duobrii® for the last 12 months ended July 2020 amounted to $88.4 million[2].

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 microencapsulation 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.

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 that Perrigo will seek regulatory approval of the generic product candidate. 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, risks relating to the effects of COVID-19 (coronavirus), the timing of a launch of a branded tapinarof product and the launch of a branded topical roflumilast in the U.S., risks related to the timing of the submission of an NDA for Epsolay and an NDA for Twyneo 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 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 24, 2020 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] The patents-in-suit are U.S. Patent Nos. 8,809,307; 10,478,502; 10,251,895; and 10,426,787.

[2] Source: Symphony Health

Source: Sol-Gel Technologies Ltd.