Sol-Gel Technologies Announces FDA Approval for Perrigo's Generic Acyclovir Cream, 5%

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Sol-Gel and Perrigo will equally share the gross profits generated from sales of the product

NESS ZIONA, Israel, Feb. 06, 2019 (GLOBE NEWSWIRE) -- Sol-Gel Technologies Ltd. (NASDAQ: SLGL) (Sol-Gel or the Company), 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 Perrigo has received final approval from the U.S. Food and Drug Administration (FDA) for the first generic version of Zovirax® (acyclovir) cream, 5%. The product was developed in a collaboration between Sol-Gel and Perrigo in which they shared development costs and will equally share the gross profits generated from sales of the product.

Acyclovir is a herpes simplex virus (HSV) nucleoside analogue DNA polymerase inhibitor indicated for the treatment of recurrent herpes labialis (cold sores) in immunocompetent adults and adolescents 12 years of age and older. Annual market sales of Zovirax cream, 5%, for the latest 12 months ending December 2018 were approximately $92 million as measured by IQVIA™.

"This approval reinforces our strategy of building an attractive generic pipeline of complex topical drug products side-by-side with a portfolio of innovative drug products, two of which are undergoing pivotal trials in the U.S.," commented Dr. Alon Seri-Levy, the Chief Executive Officer of Sol-Gel. "The approval of acyclovir cream is in addition to the tentative approval received last January for our generic product candidate, ivermectin cream, 1%, which is also in collaboration with Perrigo and which we view as a significant asset."

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's current product candidate pipeline consists of late-stage branded product candidates that leverage our proprietary, silica-based microencapsulation technology platform, and several generic product candidates across multiple 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. These statements are neither promises nor guarantees, but involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statement, including but not limited to, the following: the fact that we have and expect to continue to incur significant losses; our need for additional funding, which may not be available; our ability to complete the development of our product candidates; 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; our ability to rely on data from our Phase II TWIN trial to advance the development of SIRS-T; our ability to commercialize our product candidates; our ability to obtain and maintain adequate protection of our intellectual property; our ability to manufacture our product candidates in commercial quantities, at an adequate quality or at an acceptable cost; our ability to establish adequate sales, marketing and distribution channels; acceptance of our product candidates by healthcare professionals and patients; the possibility that we may face third-party claims of intellectual property infringement; 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; 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; potential product liability claims; potential adverse federal, state and local government regulation in the United States, Europe or Israel; and 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 26, 2018 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. While we may elect to update such forward-looking statements at some point in the future, we disclaim any obligation to do so, even if subsequent events cause our views to change.

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