Sol-Gel Provides Product Pipeline Updates and Anticipated Milestones for 2020

February 5, 2020

NESS ZIONA, Israel, Feb. 05, 2020 (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 provided a pipeline update and anticipated milestones for 2020.

"2019 proved to be a transformational year, marked by our significant clinical progress, including positive Phase 3 results for our Epsolay® and Twyneo® programs," said Alon Seri-Levy, Sol-Gel's Chief Executive Officer. "We are eager to build on this progress in 2020, with the addition of new pre-clinical programs for the treatment of psoriasis and other dermatological disorders. We are excited by the prospect of making a change in the lives of severely afflicted patients in the U.S. and worldwide, while preparing for two key NDA submissions for the treatment of papulopustular rosacea and acne vulgaris."

Product Pipeline Updates for 2020:

- **SGT-210: Indication Expansion**
  - SGT-210 (erlotinib gel) is currently in a Phase 1 study in punctuate palmoplantar keratoderma type 1, with safety results expected in the first half of 2021.
  - The Company is also planning to initiate pre-clinical studies to evaluate SGT-210 in plaque psoriasis, superficial squamous cell carcinoma and in combination with roflumilast to address various inflammatory conditions, such as hidradenitis suppurativa and prurigo nodularis.

- **Tapinarof and Roflumilast: Proprietary Development Programs**
  - In recent months, including applications planned for February, the Company drafted and filed 15 provisional patent applications for tapinarof, an aryl hydrocarbon receptor agonist, and roflumilast, a PDE4 inhibitor for use in various dermatological indications, with a focus on unmet needs.
  - The Company plans to develop both tapinarof and roflumilast for the treatment of psoriasis, with the potential for use as mono or combination therapy.

"Tapinarof has proven to be an exciting and promising compound that has achieved the best clinical results to date in the treatment of psoriasis for a non-steroidal, topical product in a Phase 2b clinical program conducted by the originator of the drug. We continue to track the originator's progress and anticipate an NDA filing in 2021, following the completion of Phase 3 trials," commented Mori Arkin, Sol-Gel's Chairman of the Board of Directors.

Continued Mr. Arkin: "Given the development pedigree of this asset, we believe that by standing on the shoulders of giants, we can potentially improve the efficacy and expand the indications of these products. Strategically, given our extensive IP research, we believe we will be able to launch our first branded tapinarof product in the U.S. in approximately 5.5 years following the approval of the originators tapinarof branded product. With respect to topical roflumilast, we estimate a significantly shorter timeline between launch of the first branded topical roflumilast and our branded product. However, regardless of our convictions, there is inherent risk in drug development including clinical, legal, and regulatory with no guarantee on our launch timeline."

Anticipated Milestones in 2020:

- **NDA Submission of Epsolay in First Half of 2020**
  - Following positive Phase 3 data in July 2019, Sol-Gel remains on track to submit the NDA for Epsolay (microencapsulated benzoyl peroxide cream, 5%) for the treatment of papulopustular rosacea in the first half of 2020.

- **NDA Submission of Twyneo in Second Half of 2020**
  - Following positive Phase 3 data in December, Sol-Gel remains on track to submit the NDA for Twyneo (microencapsulated benzoyl peroxide 3% and microencapsulated tretinoin 0.1% cream) for acne vulgaris in the second half of 2020.

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 Twyneo, for the treatment of acne vulgaris, and Epsolay, for the treatment of papulopustular rosacea. The Company's pipeline also includes SGT-210, an early-stage topical epidermal growth factor receptor inhibitor, erlotinib, for the treatment of punctate 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 upcoming events and presentations, the clinical progress of our product candidates, plans and timing for the release of clinical data, our expectations surrounding the progress of our generic product pipeline, and the sufficiency of our cash resources to meet our operating and capital expenditure requirements. 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 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 21, 2019 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 to changes in our expectations.

For further information, please contact:
Sol-Gel Contact:
Gilad Mamlok
Chief Financial Officer
+972-8-9313433

Source: Sol-Gel Technologies Ltd.

Source: Sol-Gel Technologies Ltd.