



Sol-Gel's Collaboration Partner First-to-File ANDA Drug Product Generic to Zoryve® Cream

April 1, 2024

Patent challenge initiated by Arcutis Biotherapeutics

NESS ZIONA, Israel, April 01, 2024 (GLOBE NEWSWIRE) -- Sol-Gel Technologies, Ltd. (NASDAQ: SLGL), a dermatology company pioneering treatments for patients with severe skin conditions, conducting a Phase 3 clinical trial of SGT-610 (patidegib gel, 2%) for Gorlin syndrome, and with two approved large-category dermatology products, TWYNEO® and EPSOLAY®, today announced that Padagis Israel Pharmaceuticals Ltd ("Padagis"), Sol-Gel's collaboration partner, submitted a first-to-file Abbreviated New Drug Application ("ANDA") to the U.S. Food and Drug Administration ("FDA") for Roflumilast Cream, 0.3%, a drug product generic to Zoryve® Cream (roflumilast cream, 0.3%), indicated for the treatment of plaque psoriasis in patients six years of age and older. On March 26, 2024, Arcutis Biotherapeutics, Inc. (Nasdaq: ARQT) ("Arcutis") initiated a patent infringement action in the U.S. District Court for the District of New Jersey regarding the Padagis Roflumilast Cream, 0.3% ANDA.

Annual market sales for Zoryve Cream, 0.3% were approximately \$95 million in the 12 months ended in January 2024, as measured by IQVIA. Should its ANDA for Roflumilast Cream, 0.3% be approved by the FDA, Padagis believes that its product may be entitled to 180 days of generic market exclusivity. If approved, Sol-Gel and Padagis will share gross profit generated from potential sales of Roflumilast Cream, 0.3% (calculated after the deduction of certain development costs).

"According to recent leading analysts' reports, Zoryve Cream is estimated to generate net revenue exceeding \$500 million by the end of 2030. Submissions such as Padagis's Roflumilast Cream, 0.3% ANDA demonstrate the historic value of Sol-Gel's partnership with Padagis. Though Sol-Gel exited the majority of the partnership in the generic divestment deal announced on November 4, 2021, the Roflumilast Cream, 0.3% project was maintained because of the potential value to both companies," stated Mr. Mori Arkin, Executive Chairman of the Board of Sol-Gel.

Mr. Arkin continued, "Given the market potential of Padagis's ANDA product, Sol-Gel is exploring all options to maximize the value of this opportunity."

As reported by Arcutis, Q4/2023 net product revenues for Zoryve Cream were \$13.5 million, a 357% increase compared to the fourth quarter of 2022 and a 67% increase compared to the third quarter of 2023, driven by sequential improvement in gross-to-net in the mid 60% range, as well as sustained demand growth.

About Sol-Gel Technologies

Sol-Gel Technologies, Ltd. is a dermatology company focused on identifying, developing and commercializing or partnering drug products to treat skin diseases. Sol-Gel developed TWYNEO which is approved by the FDA for the treatment of acne vulgaris in adults and pediatric patients nine years of age and older; and Epsolay, which is approved by the FDA for the treatment of inflammatory lesions of rosacea in adults. Both drugs are exclusively licensed to and commercialized by Galderma in the US, and Searchlight in Canada.

The Company's pipeline also includes Phase 3 clinical trial of Orphan and breakthrough drug candidate SGT-610, which is a new topical hedgehog inhibitor being developed to prevent the new basal cell carcinoma lesions in patients with Gorlin syndrome that is expected to have an improved safety profile compared to oral hedgehog inhibitors as well as topical drug candidate SGT-210 under investigation for the treatment of rare hyperkeratinization disorders.

For additional information, please visit our new website: 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 obtaining regulatory approval for the generic drug product to Zoryve® Cream (roflumilast cream, 0.3%), and the market potential of the Zoryve® Cream, and of the generic drug product to Zoryve® Cream (roflumilast cream, 0.3%). 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, a delay in the timing of our clinical trials, the success of our clinical trials, and an increase in our anticipated costs and expenses, 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 collaborators' ability to commercialize our pharmaceutical product candidates; (vi) our ability to obtain and maintain adequate protection of our intellectual property; (vii) our collaborators' ability to manufacture our product candidates in commercial quantities, at an adequate quality or at an acceptable cost; (viii) our collaborators' 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; (xvi) general market, political and economic conditions in the countries in which the Company operates; and, (xvii) the current war between Israel and Hamas and any deterioration of the war in Israel into a broader regional conflict involving Israel with other parties. These factors 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 13, 2024, 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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