Sol-Gel Announces Positive Phase 2 Clinical Trial Results for TWIN in Patients with Acne Vulgaris

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TWIN Achieved Primary and Secondary Efficacy Endpoints with Statistical Significance and a Favorable Tolerability Profile

Subject to End of Phase 2 Meeting to be Scheduled with the FDA,
Commencement of Phase 3 Program Planned for 2018

Further Validation of Sol-Gel's Silica-based Encapsulation Platform Technology

NESS ZIONA, Israel, July 20, 2017 (GLOBE NEWSWIRE) -- Sol-Gel Technologies Ltd. (Sol-Gel), 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 positive results from its Phase 2 clinical trial of its topical drug candidate TWIN, under development for the treatment of acne vulgaris (acne). TWIN is a once-daily cream containing a fixed-dose combination of the active components tretinoin and benzoyl peroxide, separately encapsulated in Sol-Gel's silica-based proprietary drug delivery platform technology.

The six-arm, randomized, double-blind, placebo-controlled Phase 2 clinical trial enrolled 726 subjects at 36 sites in the United States. The trial evaluated the efficacy, tolerability and safety of two TWIN concentrations, TWIN High and TWIN Low, containing a higher or lower concentration of encapsulated tretinoin and an identical concentration of encapsulated benzoyl peroxide. Each of tretinoin and benzoyl peroxide, the two active components in TWIN, are widely used single agent therapies for acne that historically have not been conveniently co-administered. The trial also evaluated the separate active components of TWIN; both the higher and lower concentrations of encapsulated tretinoin and encapsulated benzoyl peroxide administered as a single agent. In this trial, TWIN showed statistically significant improvements in all pre-defined co-primary and secondary efficacy endpoints, as compared to vehicle. TWIN also exhibited favorable efficacy results compared to its active components.

TWIN demonstrated excellent cutaneous tolerability with no treatment-related serious adverse events. Across the entire Phase 2 trial, four subjects treated with TWIN High and two subjects treated with TWIN Low discontinued due to related adverse events. Adverse events were primarily mild or moderate in severity.

"The results from the Phase 2 trial are a major step towards establishing Sol-Gel as a pure-play dermatology company that provides patients with innovative drug therapies for multiple skin diseases," said Mr. Mori Arkin, Chairman of Sol-Gel. "These results further substantiate the ability of our silica-based drug delivery platform technology to stabilize tretinoin in the presence of benzoyl peroxide, and demonstrate TWIN's ability to treat both inflammatory and non-inflammatory lesions associated with acne," said Dr. Alon Seri-Levy, Chief Executive Officer of Sol-Gel.

"Acne is a multifactorial disorder and is better treated with drugs affecting as many components as possible that contribute to its development. TWIN is pursuing this approach by designing a fixed-dose combination of tretinoin, which is a modulator of cellular differentiation, keratinization and inflammatory processes, and benzoyl peroxide, which is an oxidizing agent with bactericidal and keratolytic effects. Based on the Phase 2 trial efficacy, tolerability and safety results, TWIN has the potential to become a preferred treatment for acne by dermatologists and their patients," said Guy Webster, MD, PhD, Clinical Professor of Dermatology at Jefferson Medical College, Thomas Jefferson University, Philadelphia, PA and the medical monitor of the TWIN Phase 2 trial.

Based on these results and subject to an end of Phase 2 meeting to be scheduled with the U.S. Food and Drug Administration (FDA), Sol-Gel plans to initiate a Phase 3 program to evaluate the efficacy, tolerability and safety of TWIN as a potential treatment for acne in adult and adolescent patients. In addition, Sol-Gel plans to leverage the results from the encapsulated tretinoin arms of the trial to develop its single agent, encapsulated tretinoin drug product candidate, SIRS-T, primarily as a potential first-line treatment for adult and adolescent patients with acne. Subject to an end of Phase 2 meeting to be scheduled with the FDA, Sol-Gel intends to initiate a Phase 3 program to evaluate the efficacy, tolerability and safety of this drug product candidate.

About Sol-Gel's Phase 2 Clinical Trial of TWIN

The TWIN Phase 2 trial was a six-arm, randomized, double-blind, placebo-controlled study designed to assess the efficacy, tolerability and safety of TWIN compared to vehicle in patients aged 9 and older with facial acne vulgaris. A total of 726 subjects were enrolled in the trial at 36 sites in the United States. Inclusion criteria required 20 to 50 inflammatory lesions, 25 to 100 non-inflammatory lesions and an Investigator's Global Assessment (IGA) score of 3 or 4 ("moderate" or "severe") on a five-point scale that ranges from a score of zero, representing "clear" skin, to a score of four, representing "severe" disease. Subjects were equally randomized into six separate arms and instructed to apply the investigational drug once daily before bedtime for 12 weeks.

Co-primary efficacy endpoints were absolute changes from baseline in inflammatory and non-inflammatory lesion counts at week 12 in the intent-to-treat (ITT) population, and the proportion of patients achieving an assessment of "clear" or "almost clear" with at least a two-grade improvement from baseline on a five-grade ("clear", "almost clear", "mild", "moderate" and "severe") IGA scale at week 12 in the ITT population. The secondary efficacy endpoints were the percent changes in the number of inflammatory and non-inflammatory lesions at week 12 in the ITT population. The clinical trial also evaluated the contribution of each active component to the efficacy of TWIN.

The following table summarizes the efficacy results in the TWIN Phase 2 clinical trial:

Trial Arm	**Success Rate in IGA at Week 12 (ITT)**	**Mean Change from Baseline at Week 12 (ITT)**			
		Inflammatory Lesions		**Non-Inflammatory Lesions**	
		Absolute	**Percent**	**Absolute**	**Percent**
TWIN High	39.7 %[1]	-16.9[1]	-64.0 %[1]	-23.6[1]	-53.3 %[1]

TWIN Low	27.4	%[2]	-17.0[1]	-60.8	%[1]	-23.7[1]	-54.9	%[1]
Encapsulated tretinoin High	31.7	%	-14.9	-57.1	%	-23.8	-57.1	%
Encapsulated tretinoin Low	24.9	%	-13.9	-51.7	%	-17.8	-44.6	%
Encapaulated benzoyl peroxide	22.1	%	-13.8	-49.4	%	-16.2	-37.7	%
Vehicle	12.3	%	-11.5	-42.2	%	-13.7	-32.4	%

[1] *p* -value relative to vehicle < 0.001

[2] *p* -value relative to vehicle = 0.006

About Acne Vulgaris

Acne vulgaris is a common multifactorial skin disease that according to the American Academy of Dermatology affects approximately 40 to 50 million people in the United States. The disease occurs most frequently during childhood and adolescence (affecting 80% to 85% of all adolescents) but it may also appear in adults. Acne 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 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 Sol-Gel Technologies (www.sol-gel.com)

Sol-Gel Technologies Ltd. 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 aims to leverage its proprietary, silica-based microencapsulation delivery systems in the development of innovative topical drug products. The silica-based proprietary delivery systems are designed to enhance the efficacy, safety and stability of topical drugs. With topical drugs, there is often a trade-off between high efficacy, and compromised tolerability. Sol-Gel's delivery system is designed to provide an optimal solution by entrapping active ingredients in an inert silica shell. While Sol-Gel's microcapsules create an unnoticeable barrier between the active ingredient and the skin, they allow the entrapped active ingredients to gradually migrate through the pores of the microcapsules and to deliver effective doses into the skin in a controlled manner. Sol-Gel was co-founded by Professor David Avnir and Dr. Alon Seri-Levy and is wholly owned by Mr. Mori Arkin through his holdings in Arkin Dermatology Ltd.

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