SEBACIA

U.S. FDA Clears Sebacia Microparticles for the Treatment of Mild to Moderate Inflammatory Acne

U.S. Commercial Launch of Cash-Pay Product Anticipated in Mid-2019

Duluth, GA – September 17, 2018 – Sebacia, Inc., a privately held, commercial stage dermatology and aesthetics company, today announced that the U.S. Food and Drug Administration (FDA) has granted clearance for its lead product, Sebacia Microparticles. This significant achievement is a milestone in the treatment of acne and follows the company's completion of its pivotal study, which clearly demonstrated clinical efficacy and safety of Sebacia Microparticles, and its 510(k) submission to the FDA in June 2018.

FDA-cleared Sebacia Microparticles selectively targets the sebaceous (oil-producing) glands, offering dermatologists a truly innovative acne therapy. In the U.S., Sebacia Microparticles is indicated for use as an accessory to 1064 nm lasers to facilitate photothermal heating of sebaceous glands for the treatment of mild to moderate inflammatory acne vulgaris. In the EU, Sebacia Microparticles is CE marked and sold in select markets.

The U.S. FDA clearance of Sebacia Microparticles is based on results from a U.S. pivotal, randomized, controlled, blinded trial evaluating 168 patients with mild to moderate acne using either Sebacia Microparticles with laser or with laser alone. In this study, the Sebacia Microparticles treatment arm demonstrated a 53% median reduction in inflammatory lesion count (ILC), compared to 45% median reduction achieved by the laser treatment alone. The study achieved its primary endpoint of demonstrating non-inferiority at 12 weeks. It also achieved several secondary endpoints including 30.1% of patients treated with Sebacia Microparticles achieving a clear or almost clear IGA score (Investigator's Global Assessment of acne severity) – a significant accomplishment for an FDA-cleared acne product. All reported adverse events, regardless of study treatment were of mild to moderate intensity. There were no severe adverse events nor were there any serious and/or unanticipated adverse events related to study treatment.

Jill S. Waibel, MD, board-certified dermatologist practicing at Miami Dermatology and Laser Institute and a Sebacia clinical trial investigator, said, "The clinical results demonstrated by the U.S. pivotal study were exceptional in showing Sebacia Microparticles' ability to provide a clinically meaningful reduction in acne requiring fewer treatments compared to laser alone. We have not seen any truly innovative acne therapies developed for more than two decades and with this clearance, Sebacia Microparticles offers a new option for the millions of mild to moderate acne sufferers. Dermatologists are seeking new options for first-line therapies to offset the concerns of antibiotic resistance in this patient population. I expect Sebacia Microparticles to further enhance patient and physician optionality while seamlessly integrating into the AAD-recommended polytherapeutic approach to managing acne."

Anthony Lando, Chief Executive Officer, said, "This FDA clearance further validates Sebacia Microparticles as an effective option for many who struggle with self-esteem and quality of life limitations caused by acne. By facilitating a more convenient use of laser systems, dermatologists now have another option when weighing trade-offs such as efficacy, side effects, antibiotic resistance and patient compliance in determining the optimum treatment protocol for their patient. With FDA clearance, Sebacia

Microparticles is now commercially cleared in both the U.S. and the EU – the two largest dermatology markets in the world. We look forward to providing updates on our commercialization strategy in the coming months."

R. Rox Anderson, MD, Professor of dermatology at Harvard Medical School, Director of the Wellman Center for Photomedicine at Massachusetts General Hospital, and a member of Sebacia's Medical Advisory Board, commented, "Acne is a complicated skin disease that depends on having active sebaceous glands. Applying light-absorbing gold particles that are able to reach these glands, allows them to be selectively targeted with pulses of light."

About Sebacia

Sebacia, Inc. is a private medical device and aesthetics company focused on creating advanced topical therapies for the treatment of dermatological conditions, with a primary focus on a novel procedure-based acne treatment. Sebacia's goal is to provide a better alternative to the daily use of topical and systemic drugs currently available for the treatment of acne. Sebacia's patented microparticles technology was invented at Rice University, and the proprietary dermatology applications were further developed with researchers from the Wellman Center of Photomedicine at Massachusetts General Hospital. Investors in the company include Accuitive Medical Ventures, Domain Associates, Partners Innovation Fund, Salem Partners and Versant Ventures.

Sebacia, Inc. is located in Duluth, Georgia. More information is available at www.sebacia.com or follow us at www.twitter.com/SebaciaNews and https://www.facebook.com/sebaciainc/.