



Santalalis Pharmaceuticals Enrolls First U.S. Subject Into a Phase 2 Clinical Study of Mild to Moderate Atopic Dermatitis

SAN ANTONIO--([BUSINESS WIRE](#))--[Santalalis Pharmaceuticals](#) has announced enrollment of the first U.S. subject into a multi-center, placebo-controlled, double-blind, safety, tolerability and efficacy study of a unique 5% Sandalwood Album Oil (SAO), also known as East Indian Sandalwood Oil (EISO), cream formulation for the treatment of atopic dermatitis (AD), also known as eczema.

Subjects will be 18 to 65 years old with a clinically stable diagnosis of atopic dermatitis with a total body surface area (BSA) involvement of 2-15%. Up to 60 subjects will be enrolled to determine preliminary efficacy after 28 days of twice-a-day treatment. This study follows on from a prior open-label pediatric study and complements a similar Phase 2 study in Australia announced previously.

Atopic dermatitis is a chronic skin condition involving inflammation, dryness and itching. This disease can lead to skin damage and secondary bacterial infections. Approximately 18 to 25 million people in the United States are believed to suffer from atopic dermatitis, 80-90% of whom have mild or moderate disease.

There is currently no cure for atopic dermatitis and current therapies are primarily palliative, focused on reduction of symptoms (redness, itching, etc.). Moisturizers, anti-inflammatory drugs, phototherapy and other approaches are often used but long-term use of many of the current treatments is often not effective or can lead to complicating side effects. There is a need for topical treatments that are effective and safe enough for chronic use.

The pharmaceutical-grade SAO from [Quintis](#) (ASX: QIN, Santalis' parent company) has been demonstrated to inhibit inflammatory and proliferative pathways thought to underlie this condition, including down-regulation of phosphodiesterase 4 (PDE4) activity and direct inhibition of several isoforms of the enzyme. In addition, SAO is effective in controlling many pathogens associated with secondary infections of AD, such as *Staphylococcus aureus* ("Staph").

"Treatment of atopic dermatitis and its complications remains a challenge," said Dr. John Browning, Chief of Dermatology at Children's Hospital of San Antonio and Lead Investigator for the study. "We're excited to be participating in this new clinical trial and hopeful that this study will lead to new safe and effective therapy options for those suffering from AD."

Ian Clements, Chief Operating Officer of Santalis Pharmaceuticals, remarked: "This is another milestone in our on-going efforts to bring novel medicines to market based on traditional botanical uses. The unique biological properties of our drug candidate, SAO, make it an attractive candidate to develop in this potential indication."

ABOUT SANTALIS PHARMACEUTICALS

Santalís Pharmaceuticals, Inc. is a wholly-owned subsidiary of Quintis Ltd., (ASX:QIN). Santalis is developing scientifically- and clinically-validated over-the-counter and prescription products that utilize Quintis' cultivated, sustainable, pharmaceutical grade Sandalwood Album Oil (SAO). Santalis' product development programs are focused in dermatology and oral health, where SAO's well documented safety and anti-infective, anti-proliferative and anti-inflammatory properties are well suited to a number of prevalent and under - served conditions. In addition to the atopic dermatitis studies, Santalis has ongoing Phase 2 studies in pediatric Molluscum contagiosum, adult psoriasis, oral mucositis, and is preparing to initiate a Phase 3 study for pediatric HPV skin warts.

<http://www.santalispharma.com>

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