Santalis Pharmaceuticals Initiates a Phase 2 Study of Mild, Moderate and Severe Atopic Dermatitis - Enrolls First Patient Into Its Australian Clinical Trial Site

SAN ANTONIO--(BUSINESS WIRE)--Santalis Pharmaceuticals today announced it has enrolled its first patient into a single-center, placebo-controlled, double-blinded, safety, efficacy and tolerability study using a unique 5% East Indian Sandalwood Oil (EISO) cream formulation for the treatment of atopic dermatitis (AD), also known as eczema. Patients will be 3 months to 65 years of age with a clinically stable diagnosis of atopic dermatitis with a total body surface area (BSA) involvement of 2-15%. Up to 60 patients will be enrolled to determine preliminary efficacy after 28 days of the twice-a-day treatment. This study follows on from a prior open-label study, which demonstrated an OTC formulation of EISO to be safe, well-tolerated, and efficacious for patients aged between 3 months and 12 years who have mild, moderate or severe eczema affecting a large percentage of their body surface area. The pharmaceutical-grade EISO from TFS (Santalis' parent company) has been demonstrated to inhibit inflammatory and proliferative pathways thought to underlie this condition, including down-regulation of PDE4 activity and direct inhibition of several isoforms of the enzyme. In addition, EISO is effective in controlling many pathogens associated with secondary infections of AD, such as Staphlococcus aureus ("Staph").

"We see many patients looking for new drugs that can work in this problematic skin condition," said Professor Kurt Gebauer, Lead Investigator at the Fremantle Dermatology Group conducting the study. "New, efficacious and safe topical products that can be used over prolonged periods of time are very much in need and we are very pleased we can help both patients and a local company with a potentially game-changing new treatment."

"It's very pleasing to have local clinical support for Santalis' prescription drug development program," said Frank Wilson, Managing Director of TFS Corporation. "We have invested significantly into developing a unique drug substance with the world's only sustainable supply of cGMP produced, pharmaceutical-grade East Indian Sandalwood Oil."

"Australia is an important clinical development location for Santalis, as EISO is already a Listed Medicine with the Therapeutic Goods Administration" said Dr. Paul Castella, CEO of Santalis Pharmaceuticals, "Therefore, unlike many other drugs in development, we can quickly complete clinical studies and learn more about EISO's clinical utility. In addition, we can present the clinical data to other regulatory authorities such as the US FDA and European EMA, speeding up the regulatory process in these countries."

About Atopic Dermatitis (AD)/Eczema

Atopic dermatitis is a chronic skin condition involving inflammation and itching. Drying of the skin is also very common. This disease is characterized by redness, swelling, weeping, cracking, crusting and scaling of the skin. Rubbing and scratching can lead to skin damage and secondary bacterial infections. Multiple factors can trigger the onset of, or worsen, atopic dermatitis, including low humidity, exposure to detergents or other chemicals, cold weather and seasonal allergies. Approximately 18 to 25 million people in the United States are believed to suffer from atopic dermatitis, with 80-90% of having mild or moderate disease. It is estimated that the incidence of the disease amongst infants and children in the US is 8-18%. Though most common in the pediatric population, about half of childhood cases carry over into adulthood. 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. Long-term use of many of the current treatments is often not effective or can lead to complicating side effects.

ABOUT SANTALIS PHARMACEUTICALS

Santalis Pharmaceuticals, Inc. is a whollyowned subsidiary of TFS Corporation, Ltd. (ASX:TFC). Santalis, and its sister company, Santalis Healthcare Corporation (formerly known as ViroXis Corporation), were acquired by TFS in July 2015 and are developing scientifically- and clinically-validated over-the-counter and prescription products that utilize TFS' cultivated, sustainable, pharmaceuticalgrade East Indian Sandalwood Oil. Santalis' product development programs are focused in dermatology and oral health, where EISO's well documented safety and antiinfective, antiproliferative and antiinflammatory properties are well suited to a number of prevalent and underserved conditions. In addition to the psoriasis study, Santalis has ongoing Phase 2 studies in pediatric Molluscum contagiosum, psoriasis and oral mucositis, and is preparing to initiate additional Phase 2 studies for AD and psoriasis, and a Phase 3 study for pediatric HPV skin warts.

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