Santalis Pharmaceuticals Obtains FDA Allowance To Start A Phase 2 Clinical Study For The Treatment Of Mild To Moderate Atopic Dermatitis (AD)

SAN ANTONIO--(BUSINESS WIRE)--Following the recent start of its pediatric and adult Phase 2 clinical study for atopic dermatitis in Australia, Santalis Pharmaceuticals today announced it has obtained allowance from the U.S. Food and Drug Administration (FDA) to initiate a multi-center, placebo controlled, double blinded, Phase 2 efficacy and tolerability study for the treatment of mild to moderate atopic dermatitis (AD), also known as eczema. Patients must be 17 years of age or older with a clinically stable diagnosis of atopic dermatitis with a total body surface area (BSA) involvement of not more than 15%. Up to 72 patients will be enrolled to determine preliminary efficacy after 28 days of a twice-a-day treatment using a unique 5% East Indian Sandalwood Oil (EISO) cream formulation.

These Phase 2 studies follow on from a prior open-label study in the U.S., which demonstrated an over-the-counter formulation of EISO in combination with colloidal oatmeal to be safe, well tolerated, and efficacious for patients aged between 3 months and 12 years who had mild, moderate or severe eczema affecting a large percentage of their body surface area. The pharmaceutical-grade EISO from TFS Corporation Ltd. (Santalis' parent company) has been demonstrated to inhibit a broad range of inflammatory and proliferative pathways thought to underlie this condition, including down-regulation of phosphodiesterase (PDE4) activity. In addition, EISO is effective in controlling many pathogens associated with secondary infections of AD, such as Staphlococcus aureus ("staph").

"It's very gratifying to have been given allowance to expand Santalis' atopic dermatitis prescription drug development program into the U.S.," said Frank Wilson, Managing Director of TFS Corporation. "We have invested significantly into developing the world's only sustainable supply of cGMP produced, pharmaceutical-grade East Indian Sandalwood Oil, which is a unique botanical drug substance."
"Atopic dermatitis continues to be difficult-to-treat condition affecting children and adults worldwide," said Ian Clements, COO of Santalis Pharmaceuticals. "We now have an opportunity to further evaluate the unique range of pharmacological attributes of EISO in treating this important dermatological condition."

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% to 90% having mild or moderate disease. It is estimated that the incidence of the disease amongst infants and children in the US is between 8% and 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 ViroXis Corp), 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, anti-proliferative and antiinflammatory properties are well suited to a number of prevalent and underserved conditions. In addition to its Phase 2 AD studies, Santalis has ongoing Phase 2 clinical programs in pediatric Molluscum contagiosum, psoriasis and oral mucositis, and is preparing to initiate a Phase 3 study for HPV skin warts.

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