Santalis Pharmaceuticals Announces Positive Results from a Study of Pediatric Patients with Eczema (Atopic Dermatitis) Treated with the Santalia™ AD Over the Counter Therapy Regimen

SAN ANTONIO--(BUSINESS WIRE)--4th bullet of release issued February 22, 2016 should read: 68% of patients achieved an IGA score of "much improved" or “very much improved" with a minimum 2-grade improvement after eight weeks of treatment (instead of "after four weeks of treatment").

Santalis Pharmaceuticals today announced positive preliminary results from its expanded study of its Santalia™ AD product regimen (serum, cleanser and bubble bath). The Santalia™ AD OTC products all contain East Indian sandalwood oil (EISO) and colloidal oatmeal to treat the symptoms of pediatric eczema (atopic dermatitis). EISO has been demonstrated to inhibit a broad range of inflammatory pathways thought to underlie this skin condition, as well as many pathogens associated with secondary infections of eczema, such as Staphlococcus aureus (“staph”). The results of this study show Santalia™ AD to be safe, well tolerated, and efficacious for patients aged between 3 months to 12 years who have mild, moderate or severe eczema affecting a large percentage of their body surface area. The treatment regimen comprised a twice-daily application of the serum and cleanser to the affected areas and a bubble bath used three times a week.

“The results of this study are very encouraging. The Santalia™ AD kit had a significant impact on the quality of life of these patients and their parents. The results seen were better than had been previously achieved by these patients from the use of other topical treatments, including both over-the-counter and prescription drugs. This improvement is further evidenced by the number of parents asking to continue using the product kit after the study had finished. The Santalia™ AD OTC kit should be the first choice for parents before visiting the doctor’s office,” said John Browning, M.D., Assistant Professor of Pediatrics and Dermatology at Baylor College of Medicine and Chief of Dermatology at Children’s Hospital of San Antonio.

“This shows clearly the significant benefit of Santalia™ AD, a combination of EISO and colloidal oatmeal, in the OTC treatment of young children, where the choice of effective and safe products is limited,” said Paul Castella, Chief Executive Officer of Santalis Pharmaceuticals. “This OTC study provides additional support for our EISO-based prescription drug program for eczema, which we intend to start later this year with the initiation of placebo-controlled clinical studies.”
The results from the study have been submitted for publication and the Santalia™ AD OTC kit should be available for distribution at the start of 2017.

Santalia™ AD Regimen
The single-center, open-label study enrolled 25 patients, ages 3 months to 12 years with mild, moderate or severe atopic dermatitis with a mean beginning Eczema Area and Severity Index (EASI) score of 11.1 (moderate). Treatable atopic dermatitis, for this study, was defined as an EASI score ≥5 but ≤ 52. The EASI scoring system is a validated investigator-assessed instrument, which measures the severity of clinical attributes of atopic dermatitis in patients. Patients (or their caregivers) were

instructed to apply the Santalia™ AD Regimen cleanser and cream twice daily for 60 days and bubble bath at least three times weekly.

Safety, tolerability and efficacy endpoints were all included as a part of this study. Safety evaluation included an assessment of safety based on the frequency and severity of systemic and local adverse events (AEs) when the Santalia™ AD Regimen is applied to pediatric and adolescent patients with atopic dermatitis for up to 60 days. Tolerability was determined by the number and percentage of patients reporting burning, itching, scaling, erythema, dryness, or stinging of the treatment area(s). Primary efficacy was determined by the percentage of patients who had at least a 25% improvement in the EASI score at any time point during the 60 days of therapy.

Secondary efficacy endpoints included patients having a >25%-50% improvement in EASI score at Visit 6, >51% improvement in EASI score at Visit 6, and descriptive assessments of improvement in the severity and extent of disease based on the Investigator Global Assessment at Visit 6 as well as a comparison of Baseline and Visit 6 Children's Dermatitis Life Quality Index (CDLQ) or Infant Dermatitis Quality of Life Index Questionnaire (IDQoL). The Investigator Global Assessment is a 5-measure scale, from "worse" to "very much improved," recording the change in a patient's atopic dermatitis at each visit compared to the status of the condition at baseline.

Efficacy

22 out of 25 patients completed the study

82% (18/22) of patients met the primary efficacy endpoint (a 25% reduction in their EASI score)

91% (20/22) of patients experienced a reduction in their EASI score

68% of patients achieved an IGA score of "much improved" or "very much improved" with a minimum 2-grade improvement after eight weeks of treatment

61.9% of patients achieved an IGA score of "much improved" or "very much improved" with a minimum 2-grade improvement after four weeks of treatment

Patients demonstrated an average 60% reduction in EASI score over Baseline

In patient diary responses, the aggregate score for all diary responses went from 0 at study commencement to 3.1 (much Improvement) in 8 weeks

74.7% of respondents reported an aggregate score of 3 (much improvement) or 4 (very much improved) at study end

78.9% reported a reduction in both redness and an improvement in skin texture of the treated area and 73.7% reported an improvement in pain or irritation of the treatment area

Safety and Tolerability

The Santalia™ AD Regimen was generally safe and well-tolerated with no AEs found to be possibly, probably or definitely related to the study drug.

About Eczema/Atopic Dermatitis

Eczema/atopic dermatitis is a chronic skin condition involving inflammation and itching. The rash is characterized by red, oozing patches and thickening of the skin. Rubbing and scratching 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, 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 wholly-owned subsidiary of TFS Corporation, Ltd. (ASX: TFC). Santalis, and its sister company, ViroXis, 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, pharmaceutical-grade East Indian Sandalwood Oil. Santalis' product development programs are focused in oral health and dermatology, where EISO's well documented safety and anti-infective, anti-proliferative and anti-inflammatory properties are well suited to a number of prevalent and underserved conditions (such as acne, eczema, psoriasis, oral mucositis, onychomycosis, HPV skin warts and Molluscum Contagiosum). In addition to an eczema program study, Santalis has ongoing Phase 2 studies in pediatric Molluscum contagiosum, oral mucositis, and psoriasis, and is preparing to initiate a Phase 3 study for pediatric HPV skin warts.

About East Indian Sandalwood

Indian sandalwood has a history as a tradeable commodity spanning thousands of years, but is now endangered due to the illegal harvest of wild trees throughout the world. As a result, Indian sandalwood is the world's most expensive tropical hardwood. Indian sandalwood oil is a globally important ingredient in fine fragrances, cosmetics and toiletries, Indian consumer products and is used for traditional medicinal purposes (Ayurvedic and Chinese medicine). The wood is used for high quality carvings and artefacts and religious worship in the Hindu and Buddhist faiths. The global pharmaceutical market has the potential to be a significant consumer of Indian sandalwood.

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