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## ASX Release

### **TFS to trial treatment for cancer side effect after receipt of US FDA allowance**

#### **Highlights:**

- TFS's US-based subsidiary, Santalis Pharmaceuticals, has been granted FDA allowance to commence trials of an oral rinse to treat Oral Mucositis
- Oral Mucositis is an acute inflammation and ulceration of the surface of the mouth and throat common among cancer patients receiving chemotherapy and radiation therapy
- Santalis has also received allowance to expand a Phase 2 study in the treatment of *Molluscum Contagiosum Virus*, a contagious and highly prevalent skin virus, particularly in children

TFS Corporation Limited ("TFS", ASX: TFC), the world's largest owner and manager of commercial Indian sandalwood plantations, is pleased to announce it that has received US regulatory allowance to commence a study into the prevention and treatment of a cancer-associated mouth condition using the Company's pharmaceutical grade East Indian Sandalwood oil ("EISO").

TFS's recently acquired US subsidiary, Santalis Pharmaceuticals ("Santalis"), has received US Food and Drug Administration ("FDA") allowance for Santalis's new Investigational New Drug ("IND") application to initiate a Phase 2 study for the prevention and treatment of Oral Mucositis ("OM").

The proposed treatment uses an oral rinse formulation that contains EISO as the active ingredient. The Phase 2 study is expected to enrol its first patient before the end of 2015.

The Single-Center, Open-Label, Phase 2 Trial is designed to evaluate the efficacy, safety and tolerability of the EISO oral rinse in up to 15 patients who are expected to develop significant OM as part of their treatment for head and neck cancer. The trial is expected to be concluded and assessed by the end of FY17.

OM is an acute inflammation and ulceration of the surface of the mouth and throat, common in cancer patients as a side effect of chemotherapy and radiation treatment. It is estimated that approximately 400,000 cases of OM are diagnosed globally each year and current treatments are largely only supportive.

"The US FDA allowance marks TFS's entry into the market for the treatment of the numerous and often debilitating side effects caused by cancer treatment," TFS CEO Frank Wilson said.

"This is an important first step into a market where there is both a clinical need and commercial opportunity for TFS's pharmaceutical grade East Indian Sandalwood Oil."

The OM trial is the second IND allowed by the US FDA using EISO, with the first relating to the treatment of HPV skin warts. The IND for the treatment of HPV skin warts previously received US FDA allowance to expand to include a 60 patient Phase 2 randomized placebo controlled clinical trial for the treatment of *Molluscum Contagiosum Virus* ("MCV") in children over the age of 2 years.

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MCV is a highly prevalent and contagious skin virus (pox virus) that causes a diffuse rash with multiple wart-like nodules. There are no currently approved drugs to treat this condition, while cryo-therapy or blistering treatments are painful and can result in scarring. Santalis expects to enrol its first patient in the MCV trial before the end of 2015.

These trials will be funded from existing research and development budgets which are included within TFS's current market guidance.

"Progressing these Investigational New Drugs is part of a broader strategy to significantly expand the portfolio of clinical stage drugs containing East Indian Sandalwood Oil in development," Mr Wilson said.

"The pharmaceutical market is a high value market and Santalis and ViroXis, which are now 100% owned by TFS and operating under the Santalis name, are providing the vehicle to increase our exposure to that market."

### **About Oral Mucositis**

Oral Mucositis (OM) is an acute inflammation and ulceration of the surface of the mouth and throat in cancer patients caused by chemotherapy and radiation treatment, which disrupt rapidly dividing epithelial progenitor cells. It is estimated that approximately 400,000 cases of OM are diagnosed each year in the United States of America alone. OM can be an intensely painful condition that often leads to difficulties swallowing food and fluids, potentially leading to dehydration and malnutrition. OM can also lead to delays in cancer treatments, through chemotherapy dose reductions, breaks in radiation treatment, cessation of cancer therapy, hospitalization and reliance on parenteral nutrition. There are limited treatment options once OM is established and prevention is a major medical and patient unmet medical need. OM is seen most often in patients receiving radiation therapy for head and neck cancer, and in patients receiving high-dose chemotherapy conditioning prior to hematopoietic stem cell transplantation. However, any patient receiving cancer treatment is at risk.

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## **ABOUT TFS**

TFS Corporation Ltd ("TFS", ASX: TFC) is an owner and manager of Indian sandalwood plantations in northern Australia. As part of its vision to be a vertically integrated producer of sandalwood products, TFS owns a significant proportion of the plantations in its own right. TFS also operates sandalwood processing and oil distribution facilities from Albany, Western Australia.

TFS was originally founded to exploit the success of government trials into the plantation growth of Indian sandalwood in the Ord River Irrigation Area (ORIA) of north-east Western Australia.

TFS now manages the largest area of commercial Indian sandalwood plantations in the world, with over 10,500 hectares planted of which TFS owns directly and indirectly nearly 3,500 hectares. TFS plantations are managed on behalf of both institutional, high net worth and MIS investors.

In 2014, TFS completed its first commercial harvest of its Indian sandalwood plantations and, via its subsidiary Santalis Pharmaceuticals, entered into a supply agreement for pharmaceutical grade oil with Galderma, a leading global dermatology company wholly owned by Nestle.

The company listed on the Australian Stock Exchange in December 2004. Since March 2014, TFS has been an ASX300 company.

TFS is committed to adopting and maintaining the highest environmental and ethical standards in all aspects of its business.

## **ABOUT SANTALIS PHARMACEUTICALS**

Santalis Pharmaceuticals, Inc. is a wholly-owned subsidiary of TFS Corporation Ltd. 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's cultivated, sustainable, pharmaceutical-grade East Indian Sandalwood Oil. Santalis's initial product offerings are focused in dermatology, where EISO's well documented anti-infective, anti-inflammatory and non-irritating properties are well suited to a number of prevalent and under-served conditions (such as acne, eczema, psoriasis, oral mucositis, onychomycosis, HPV skin warts and *Molluscum Contagiosum Virus*).

## **ABOUT 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 which continues to increase in price each year.

Indian sandalwood oil is a globally important ingredient in fine fragrances, cosmetics and toiletries, Indian consumer products and for medicinal purposes (Ayurvedic and Chinese medicine) and the wood is used for high quality carvings and artefacts and religious worship in the Hindu and Buddhist faiths. The efficacy of Indian sandalwood is being tested by US dermatology companies for a range of skin conditions and the global pharmaceutical market has the potential to be a significant consumer of Indian sandalwood oil.