



## **ViroXis Corporation Initiates Phase II Clinical Trial of Novel Botanical Topical Treatment for HPV Skin Warts**

ViroXis Corporation today announced that the US Food and Drug Administration (FDA) granted approval for the Company's investigational new drug (IND) application and planned clinical development of a drug substance derived from East Indian Sandalwood oil (EISO) for the topical treatment of Human Papilloma Virus (HPV), common warts of the skin. ViroXis' EISO-derived product is being developed in accordance with the FDA's 2004 Guidance for Development of Botanical Drugs.

"The FDA's swift approval of our IND provides validation of ViroXis' mission to be a leader in the development of botanically-derived topical drugs and strongly supports our proposed clinical development plan for EISO," said Ian Clements, President and CEO of ViroXis. "Based on promising data in previous clinical trials with sandalwood, we are optimistic that the anti-viral activity and safety profile of this essential oil will lead to a new and effective treatment for this highly prevalent, painful and difficult to treat condition, for which there are currently no approved prescription products."

### **Trial Design**

The company's FDA Phase II clinical trial will be a double-blinded, placebo-controlled, dose range-finding trial with four arms looking at safety and efficacy of three doses of EISO in an ointment base. The patients will be adults, 18 years and above. Trial participants will be treated for up to three months and followed for an additional three months of follow up. The primary efficacy endpoint will be complete resolution of warts.

### **About East Indian Sandalwood Oil (EISO)**

EISO has previously been successfully studied in Phase I and Phase II investigator sponsored clinical trials in adults and children for the topical treatment of warts. The positive results of these initial trials lead to the issuance of three US patents for the treatment of HPV and other skin diseases.

East Indian Sandalwood oil is produced by steam distillation from the heartwood of the Santalum album tree. The essential oil is widely used in the food and fragrance industry and has been used in traditional medicine for centuries, particularly in India. EISO has been adopted in the West to treat a number of diseases and conditions, and it has been shown to be active against a variety of pathogens in addition to human papillomavirus.

Wild sources of the sandalwood tree, which is indigenous to India, are becoming increasingly scarce and supply of the oil is dwindling. To overcome this issue, ViroXis will be using sandalwood oil from trees harvested from sustainable commercial plantations in North Western Australia for its marketed drug products. ViroXis has an exclusive supply agreement with Tropical Forestry Services Corp. Ltd. (TFS) of Perth, Australia for supply of pharmaceutical grade EISO for healthcare uses. TFS, an Australian listed company (ASX: TFC), manages the largest sustainable supply of East Indian Sandalwood in the world and has won numerous awards for its ecological and environmental stewardship.

### **About HPV virus and Common Warts**

Common warts are caused by the transmissible HPV virus and there is currently no approved prescription product for treatment of problematic warts. Typical therapies involve cutting, freezing or the use of chemical blistering agents that are painful and often cause scarring. A painless and effective treatment for this common skin condition would be a welcome addition to the therapeutic options currently available to dermatologists.

### **About Series A & State of Texas Emerging Technology Fund (ETF)**

Essential to supporting ViroXis' clinical program has been Series A funding from the locally-based Targeted Technology Fund and a subsequent investment from the State of Texas' Emerging Technology Fund (ETF).

Alan Dean, Chairman of ViroXis and CEO of the Targeted Technology Fund, stated that "The fact that ViroXis was able to achieve this significant regulatory development milestone so quickly and with minimal capital expenditure is a testament to the efficiency with which the company has been operating. We are optimistic and very excited about the future prospects for the company's drug development efforts."

Startech, the regional organization body for the ETF, was instrumental in coordinating the State's investment in ViroXis, which was made after three rounds of presentations and due diligence at the local and state level. Jim Poage, Startech's CEO, reiterated that "The mission of the ETF is to provide much needed venture capital to entrepreneurial life science companies at critical times in their development to help secure their future growth and the future of high technology jobs in Texas. Clearly, their decision to support ViroXis' regulatory program has been vindicated by this news".

### **About ViroXis**

ViroXis' mission is to develop and commercialize novel, safe and effective prescription and over-the-counter botanical products for the treatment of virally-induced skin conditions. The Company has been funded by a combination of venture funding from the San Antonio-based Targeted Technology Fund and a \$2.5 million investment from the State of Texas Emerging Technology Fund (ETF). Botanically-derived drugs have formed the backbone of the pharmaceutical industry and the recently implemented FDA botanical guidelines aim to streamline the development of drugs, such as ViroXis' lead drug candidate, that are a mixture of plant-derived compounds rather than a single chemical entity, and that have a historical record of safe human use. ViroXis was the recipient of the 2009 Michael E. DeBakey Award from the RICE Alliance Life Sciences Ventures Forum as the most promising Life Science company in Texas.