San Antonio biotech company Viroxis clears a big regulatory hurdle

San Antonio-based Viroxis Corp. has cleared one of the biggest hurdles in its bid to take its new anti-wart drug compound to market.

The U.S. Food and Drug Administration has approved Viroxis' application for Phase II clinical testing to treat patients with its new compound a substance derived from East Indian Sandalwood oil for the topical treatment of the Human Papilloma Virus (HPV), or common warts of the skin.

Viroxis, which received a $2.5 million grant last year from the Texas Emerging Technology Fund, is one of several local biotech companies benefiting from the city's efforts to promote its growing biotech sector, which is credited with having a $16.3 billion annual impact on the local economy.

Some 20 million people in the United States are believed to be infected with HPV, says Paul Castella, a co-founder and director of Viroxis. Currently, there are no prescription treatments for skin warts and the over-the-counter treatments that are available tend to be too harsh.

"Current treatments either burn or freeze the growth, but don't treat the virus," Castella says. "The problem is that those treatments are not always suitable for children or for warts in sensitive places, such as on the face."

The Phase II trial will take about 18 months to complete, after which the firm could move into a Phase III trial as the final step before gaining FDA approval to take the product to market.

Ian Clements, president and CEO of Viroxis, says provided everything goes well, Viroxis hopes to have a product on the market by 2014.

"The FDA's swift approval of our IND (investigational new drug application) provides validation of Viroxis' business model and the proposed clinical development plan for (the new compound)," Clements says. " Based on our prior clinical experience with sandalwood, we are optimistic that the advantageous anti-viral activity and safety profile of this essential oil will lead to a new treatment for this highly prevalent, painful and difficult to treat condition, for which there are currently no approved prescription products."

For its Phase II trial, the company is planning a double-blinded, placebo-controlled, dose range-finding experiment that will look at the safety and efficacy of three doses of the compound in an ointment base. The patients will be adults, 18 years and above.

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.

The sandalwood tree is indigenous to India, but as its popularity has grown, it has become increasingly scarce and the supply of oil is dwindling.

To overcome this issue, Clements says, Viroxis will be using sandalwood oil from trees harvested from sustainable commercial plantations in Northwestern Australia for its marketed drug products.

Viroxis has an exclusive supply agreement with Tropical Forestry Services Corp. Ltd. of Perth, Australia, which manages the largest sustainable supply of East Indian Sandalwood in the world.

Regulatory achievement

Viroxis is among the first companies to gain FDA approval for a botanically-derived topical drug, Clements says.

Approval for the Phase II study is the first step in a number of clinical developments Viroxis is planning to support its long-term plans for using sandalwood-based drugs to treat a range of viral skin diseases.

Clements says a key to the company's success so far has been its ability to keep costs down and the support it has received from a locally based venture capital fund.

Viroxis has raised about $750,000 via investments by the Targeted Technology Fund I. The fund was formed in the spring of 2008 by the Texas Research and Technology Foundation to capitalize on growth in the biomedical sector.

The fund initially made a $500,000 loan to Viroxis in 2010, according to a filing the privately-held Viroxis made with the U.S. Securities and Exchange Commission. That debt was converted later that year to equity as part of a private offering that also raised an additional $250,000 in equity.

Alan Dean, chairman of Viroxis and CEO of the Targeted Technology Fund, says he is very optimistic about the company's future drug development efforts.

"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," Dean says.

Startech, the regional organization body for the Emerging Technology Fund, has helped to coordinate the state's investment in Viroxis, which was made after three rounds of presentations and due diligence at the local and state level, according to Jim Poage, Startech's CEO.

"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," Poage says. "Clearly, their decision to support Viroxis' regulatory program has been vindicated by this news."

Arjun Sanga, executive director of South Texas Technology Management, a regional technology transfer office that serves the University of Texas Health Science Center at San Antonio and the

University of Texas at San Antonio, says gaining FDA approval for a Phase II trial is a significant achievement for a small biotech company and represents a major milestone.

"It is rare," Sanga says. "If you think about it like a big funnel, you start with thousands of compounds that people are looking at for possible benefits and by the time you get to the point where they are ready to start human testing, you have narrowed the number down to a small handful."

Sanga says he is not aware of any spin-off companies from the Health Science Center that are currently in a Phase II trial for a pharmaceutical product.
"This just shows that they have done a significant amount of work to get to this point," he says.

Corey Levenson, chief scientific officer for Viroxis, says he was pleased the FDA has allowed the company to move forward without requiring more animal testing. The FDA has recently implemented new guidelines aimed at streamlining the development of botanical drugs, such as the one Viroxis is developing.

The new drug is a mixture of plant-derived compounds rather than a single chemical entity, and it has a historical record of safe human use in the fragrance and food industry, Levenson notes.

Sandalwood oil has traditionally been used in India as a flavoring agent and is widely used by the fragrance industry. It has also been used for centuries as an herbal medicine in various folk remedies. But not until recently has there been a serious effort to isolate its true medicinal qualities, Levenson says.