



## **TOPICA BEGINS PHASE 2 CLINICAL TRIAL OF POTENT ANTIFUNGAL, LULICONAZOLE, IN ATHLETE'S FOOT**

**PALO ALTO, Calif.** (April 22, 2009) - TOPICA Pharmaceuticals today announced the enrollment of patients in a Phase 2 clinical trial evaluating luliconazole for the treatment of tinea pedis (athlete's foot). Luliconazole, the company's lead product candidate, is the one of the most potent and broad spectrum molecules in the imidazole class of antifungal agents, giving it the potential to provide physicians and patients with a needed topical solution to a variety of skin and nail fungal infections.

"The initiation of this trial represents a significant milestone for TOPICA as we begin our U.S. clinical development program of this promising drug candidate, which already has been proven in millions of patients in Japan," said Greg Vontz, president and chief executive officer of TOPICA. "We expect to complete this trial by the end of this year, potentially enabling us to initiate our pivotal Phase 3 clinical trial in 2010."

Phase 3 data from clinical studies conducted in Japan demonstrated that luliconazole successfully treated tinea pedis in half the time of commonly prescribed products. Since the 2005 approval of luliconazole in Japan for the treatment of tinea infections, more than 4 million patients have been safely treated with luliconazole. TOPICA has an exclusive license to develop and market luliconazole in the Americas and Europe.

The Phase 2, multi-center, randomized, double blind, trial is evaluating the safety and optimal duration of 1 percent luliconazole cream administered once daily for 14 or 28 days in patients with tinea pedis. The primary efficacy endpoint is to achieve complete clearance of the infection at two weeks post treatment. Currently in the U.S. available prescription medications generally require treatment once or twice a day for up to four weeks to achieve this result. The company expects to enroll approximately 120 patients in the trial, which is being conducted at 5 clinical trial sites in the United States. For more details on the trial go to <http://www.topicapharma.com> and click on the link for the trials posting on [www.clinicaltrials.gov](http://www.clinicaltrials.gov).

In addition, the company is developing luliconazole for onychomycosis (nail and nail bed fungal infections) and plans to move ahead with clinical development of onychomycosis shortly. The company's successful preclinical studies of luliconazole demonstrate that it has the ability to easily penetrate the toenail achieving rapid fungal eradication in the nail bed, as measured by MedPharm's *in vitro* ChubTur® infected nail model. Luliconazole is also unique in that the molecule doesn't require devices, procedures or "delivery enhancement" to cross the nail. Onychomycosis affects approximately 35 million people in the U.S. Of those affected, it is estimated that 47 percent are not receiving treatment. The disease can cause extreme disfigurement of nails and can often result in pain. The potential annual U.S. market for onychomycosis treatment is estimated at approximately \$3.0 billion.

**About Tinea Pedis**

Tinea pedis (athlete's foot) is the most common fungal infection of the skin, affecting about one in every 10 people at any given time. Patients with the disease often experience itching and burning on the infected area. In severe cases, the disease can cause cracking, pain and bleeding. In 2008, the U.S. prescription market for tinea pedis was \$385 million equating to approximately 22 million prescriptions. The topical prescription antifungal market has been dominated in recent years by generics due to the fact that a new prescription anti-fungal agent has been not been introduced into the market in over five years.

**About TOPICA Pharmaceuticals**

TOPICA is a privately held, specialty pharmaceutical company, focused on licensing, developing, and commercializing potent topical prescription products to treat the needs of patients with serious nail and skin conditions. Taking advantage of its established trans-pacific network of scientific and industry contacts, TOPICA has in-licensed its lead-product candidate, luliconazole, a topical antifungal agent that is already on the market in Japan. TOPICA is developing it for the treatment of tinea pedis (athlete's foot) and onychomycosis (nail and nail bed fungal infections). For more information, please visit <http://www.topicapharma.com>.

For Further Information Contact:

Daryl Messinger  
WeissComm Partners  
415-946-1062  
[dmessinger@wcpglobal.com](mailto:dmessinger@wcpglobal.com)

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