



TOPICA ANNOUNCES POSITIVE PHASE 2 CLINICAL RESULTS FOR LULICONAZOLE, A POTENT TOPICAL ANTIFUNGAL

-- Novel Dose Validated in Phase 2 Trial Shows Robust Mycologic Efficacy --

PALO ALTO, Calif. (October 06, 2009) - TOPICA Pharmaceuticals, a privately-held biotechnology company, today announced positive results from its Phase 2 clinical study evaluating luliconazole, one of the most potent and broad spectrum topical antifungal agents, in patients with tinea pedis (athlete's foot). The study was designed to assess the effectiveness of 1% luliconazole cream applied once daily for 14 days compared with once daily for 28 days. The study met its primary efficacy endpoint demonstrating that luliconazole, when applied once daily for 14 days, was able to achieve "complete clearance," as evaluated by a clear clinical score and negative mycology assessment (negative fungal culture and negative potassium hydroxide (KOH) test) equivalent to the 28-day dosing regimen.

"These Phase 2 results suggest that luliconazole may be able to treat tinea pedis in half the time, compared with commonly prescribed products in the U.S., which require treatment once or twice a day for four weeks. For tinea pedis patients, these results may translate to a significantly easier treatment plan to follow, which should improve clinical outcomes. It is impressive to see that even four weeks after treatment ends with luliconazole, its antifungal effects continued to persist," said Terry M. Jones, M.D., a board certified dermatologist and leading enroller in the phase 2 trial.

The multi-center, randomized, double blind, trial evaluated the safety and optimal duration of 1% luliconazole cream administered once daily for 14 or 28 days in patients with moderate to severe tinea pedis. The Phase 2 results demonstrated:

- At day 42, the 14-day dose resulted in a 53.7 percent complete clearance rate compared with a placebo rate of 4.5 percent ($p=0.0001$);
- At day 42, the 28-day dose resulted in a 45.7 percent complete clearance rate compared with a placebo rate of 10 percent ($p=0.0071$);
- There was no statistical difference in complete clearance between the 14 or 28 day once daily dosing regimen ($p=0.4928$);
- The mycologic results improved over time post treatment. Specifically, the 14-day dose resulted in a 78 percent mycologic cure at day 28 and 82.9 percent at day 42, demonstrating the long-lasting mycologic effect of luliconazole; and
- No serious or drug-related adverse events were reported in the study.

"We are very pleased with these results, which validate our clinical development plans for luliconazole and move us one step closer toward our goal of bringing highly differentiated products to market. The encouraging mycologic results also add to our growing confidence in luliconazole and its potential to treat both tinea pedis, onychomycosis and other topical fungal infections," said Greg Vontz, president and chief executive officer of TOPICA. "With more than

22 million prescriptions written for topical anti-fungal products in 2008, we believe a well differentiated product, such as luliconazole, could be of significant use to clinicians.”

In addition to the Phase 2 results, the company's successful preclinical studies of luliconazole in onychomycosis (fungal infections of the nail) demonstrate that it has the ability to easily penetrate toenails achieving rapid fungal eradication in the nail bed, as measured by MedPharm's in vitro ChubTur® infected nail model. TOPICA plans to file an IND for onychomycosis before the end of 2009. Onychomycosis affects approximately 35 million people in the U.S. 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 \$3.0 billion. The utility of currently approved oral therapies for onychomycosis are limited by their side effect profile and the approved topical therapy has minimal efficacy.

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. Forty-five percent of tinea pedis patients are infected for more than 10 years and 70 percent of Americans will contract tinea pedis in their lifetimes.

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 luliconazole for the treatment of tinea pedis (athlete's foot) and onychomycosis (fungal infections of the nail). For more information, please visit <http://www.topicapharma.com>.

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