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## FDA ACCEPTS TOPICA'S LULICONAZOLE IND TO BEGIN CLINICAL TRIALS IN ONYCHOMYCOSIS

-- TOPICA to Start Phase 1/2 Trial in Onychomycosis with Novel High-Concentration Luliconazole Solution --

PALO ALTO, Calif. (February 1, 2010) -- TOPICA Pharmaceuticals, a privately-held biotechnology company, today announced that the U.S. Food and Drug Administration (FDA) has accepted the company's Investigational New Drug (IND) application for the use of luliconazole, its lead product candidate, in patients with onychomycosis (nail and nail bed fungal infections). The company plans to initiate a Phase 1/2 trial in the first quarter. Luliconazole is one of the most potent and broad-spectrum topical antifungal agents in development and will be advancing to Phase 3 clinical development in the U.S. for tinea pedis (athlete's foot).

"The FDA's acceptance of our IND for luliconazole is a significant step forward in realizing our goal of bringing this product to market in the United States as the first highly effective and safe topical therapy for onychomycosis," said Greg Vontz, president and CEO of TOPICA Pharmaceuticals. "We believe the comprehensive development program completed for luliconazole in Japan, where the drug is approved for tinea infections, has greatly aided its advancement through the IND process. The FDA's guidance throughout the IND process has allowed us to effectively advance our clinical development plans to prepare for the initiation of our Phase 1/2 trial this quarter, which will support our objective of initiating a robust Phase 2/3 program in onychomycosis later this year."

The Phase 1/2 trial will be conducted in patients with moderate to severe distal subungual onychomycosis and will evaluate 28 days of treatment with luliconazole 10% solution given once daily. The safety, tolerability and pharmacokinetic profile of the luliconazole will be assessed. Patients will also be followed post treatment for 30, 60, and 90 days assessing the concentration of luliconazole in the infected nails, mycologic effectiveness and amount of new clear nail growth. Additional information about the trial can be found at [www.clinicaltrials.gov](http://www.clinicaltrials.gov).

"Luliconazole's antifungal profile suggests it has the potential to be successful in treating onychomycosis. If approved, it will provide a new treatment option for this prevalent and difficult-to-treat condition," said David Cohen, M.D., M.P.H., a leading dermatologist and Vice Chairman for Clinical Affairs at the New York University School of Medicine Department of Dermatology. "I look forward to participating with TOPICA in the development of this promising compound for onychomycosis."

### **About Luliconazole**

Luliconazole is one of the most potent and broad-spectrum topical antifungal agents. TOPICA is developing luliconazole for onychomycosis, which affects approximately 35 million people in the U.S. Currently approved therapies for onychomycosis are either ineffective or are complicated by the potential of liver toxicity and require hepatic monitoring. In numerous rigorous preclinical models of onychomycosis, luliconazole has demonstrated rapid penetration and therapeutically effective levels in the nail bed. This preclinical profile suggests luliconazole has the potential to be the first highly effective and safe topical therapy

for onychomycosis. The potential annual U.S. market for onychomycosis treatment is estimated at approximately \$3 billion.

TOPICA is also developing luliconazole for the treatment of tinea pedis, the most common fungal infection of the skin, affecting about one in every 10 people. In the U.S. more than 22 million prescriptions are written annually for tinea infections. Currently approved products for the topical treatment of tinea pedis are only modestly effective, have a high reoccurrence rate and require a month of therapy. In 2009, TOPICA announced positive results from its Phase 2 clinical trial of luliconazole for tinea pedis. The results of TOPICA's Phase 2 trial demonstrated that luliconazole was substantially more effective than approved therapies and required half the treatment time. TOPICA expects to begin its pivotal Phase 3 trials in 2010 to support approval.

TOPICA has an exclusive license from Nihon Nohyaku Co., Ltd. to develop and market luliconazole in the Americas and Europe.

### **About TOPICA Pharmaceuticals**

TOPICA is a privately-held specialty pharmaceutical company focused on licensing, developing and commercializing 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 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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