



TOPICA Announces Positive Phase 2 Data for Luliconazole in Athlete's Foot
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TOPICA Announces Positive Phase 2 Clinical Results for Luliconazole, a Potent Topical Antifungal; -- Novel Dose Validated in Phase 2 Trial Shows Robust Mycologic Efficacy --
Press release
6 October 2009

Note: This press release was posted to AlphaTrade Finance, AOL Money News, Arizona Republic, Atlanta Business Chronicle, Austin Business Journal, Baltimore Business Journal, BioAlabama.com, BioWorld Online, Birmingham Business Journal, Bizjournals.com, Boston Business Journal, Breitbart.com, Business First of Buffalo, Business First of Columbus, Business First of Louisville, Forbes.com, Healthcare Industry Today, KAIT8.com, Kansas City Business Journal, KATC.com, ArizonasOwn.com, KCAUTV.com, KCBA.com, KCBD.com, KCOY.com, KESQ.com, Fox14TV.com, KFVS12.com, KGUN9.com, Los Angeles Business Journal, MedicalDevices.org, Memphis Business Journal, Minneapolis/St. Paul Business Journal, Montana's News Station, Nashville Business Journal, Nebraska TV, New Mexico Business Week, News Blaze, Orlando Business Journal, Pacific Business News, Pharmaceutical Industry Today, Pharmahorizons, Philadelphia Business Journal, Pittsburgh Business Times, Portland Business Journal, Puget Sound Business Journal, Reuters, Sacramento Business Journal, TecTrends, WAAY-TV, WAFB.com, WAAF.com, WALB.com, Medical NewsToday, PipeLineReview.com, News-Medical.net

TOPICA reports encouraging Phase II results for topical antifungal luliconazole in athlete's foot

M2 Pharma
6 October 2009

Clinic Roundup
BioWorld Today
7 October 2009

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6 October 2009

6 October 2009 - US-based biotechnology company TOPICA Pharmaceuticals reported today favourable results from its Phase II study evaluating luliconazole, a broad spectrum topical antifungal agent, 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.

The multi-centre, randomised, 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.

At day 42, the 14-day dose resulted in a 53.7% complete clearance rate compared with a placebo rate of 4.5% ($p=0.0001$). At day 42, the 28-day dose resulted in a 45.7% complete clearance rate compared with a placebo rate of 10% ($p=0.0071$). 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% mycologic cure at day 28 and 82.9% at day 42, demonstrating the long-lasting mycologic effect of luliconazole. No serious or drug-related adverse events were reported in the study.

In addition to the Phase II 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 this year.

Clinic Roundup

BioWorld Today

7 October 2009

Topica Pharmaceuticals Inc., of Palo Alto, Calif., reported Phase II data showing that luliconazole, a broad spectrum antifungal agent, met its primary endpoint, demonstrating that once-daily application for 14 days achieved complete clearance in patients with tinea pedis (athlete's foot), equivalent to the 28-day dosing regimen. Data indicated that, at day 42, the 14-day dose resulted in 53.7 percent complete clearance vs. 4.5 percent in the placebo arm, while the 28-day dose resulted in 45.7 percent complete clearance rate vs. 10 percent in the placebo group.