PRESS RELEASE

NAFTIFINE HYDROCHOLORIDE GEL 2% DATA PRESENTED AT THE 71ST ANNUAL MEETING FOR THE AMERICAN ACADEMY OF DERMATOLOGY (AAD)

Merz North America
Rachel Chase
Corporate Communications
4215 Tudor Lane
Greensboro, NC 27410
Office (336) 217-2423
Cell (336) 501-0919
rchase@merzusa.com

www.merzaesthetics.com/en-US
www.merzusa.com
www.merzcanada.com

Greensboro, N.C. – (BUSINESS WIRE) – Today at the 71st Annual Meeting for the American Academy of Dermatology (AAD) in Miami, FL, Merz North America (U.S. affiliate of Merz Pharma Group) announced the findings from new data on naftifine hydrochloride gel 2%. Data presented discussed the ability of naftifine hydrochloride gel 2% to be both efficacious and tolerable in the treatment for interdigital-type and moccasin-type Tinea pedis.

The first poster titled, "Naftifine Hydrochloride Gel 2% is Effective as a Topical Therapy for Moccasin-Type Tinea Pedis," was designed to evaluate the efficacy of Naftifine Hydrochloridegel 2% applied once daily for two weeks compared to the vehicle at end of treatment and at two and four weeks post-treatment in subjects with moccasin-type tinea pedis. It concluded that two weeks application of topical naftifine gel 2% is an effective monotherapy treatment for moccasin-type tinea pedis. [Verma, et. al.; e-poster Presented in Center 2 on Sunday, March 3, 2013 at 9:15AM EST].

"Naftifine hydrochloride (naftifine) is a topical antifungal of the allylamine class, displaying fungicidal and fungistatic activity. Naftifine is generally used to treat interdigital type tinea pedis; however, systematic therapy is often prescribed by healthcare providers for moccasin-type tinea pedis," said Alan B. Fleischer Jr, MD, Executive Director of Dermatology at Merz. "Well-controlled clinical data on topical antifungal therapy for moccasin-type tinea pedis is limited."

The second poster titled, "Naftifine Hydrochloride Gel 2% is Efficacious and Safe for the Treatment of Tinea Pedis: Results from a Randomized, Multicenter, Double-Blind, Vehicle-Controlled Study," was designed to evaluate the efficacy and safety of two weeks once daily application of Naftifine Hydrochloride Gel 2% in the treatment of tinea pedis. It concluded that once daily Naftifine Hydrochloride Gel 2% for two weeks is well tolerated and is effective in treating tinea pedis. [Verma, et. al.; e-poster Presented in Center 2 on Sunday, March 3, 2013 at 9:20AM EST].

"Tinea pedis is the most common chronic fungal infection. Naftifine displays fungicidal activity and clinically significant anti-bacterial and anti-inflammatory effects," said Alan B. Fleischer Jr, MD, Executive Director of Dermatology at Merz. "These studies show continued efficacy for weeks following the end of treatment which is consistent with its demonstrated depot effect in the skin for at least four weeks."

Merz has a NDA under FDA review for Naftifine hydrochloride Gel 2% and expects a decision by FDA on the application this summer.

Additional FDA approved antifungal prescription products available from Merz in the U.S. include ONMEL™ (intraconazole), Naftin® (naftifine HCL) Cream 2%, and Naftin® (naftifine HCL) Gel 1%.

About ONMEL™ (itraconazole)

ONMEL™ (itraconazole), an azole antifungal, was approved by the FDA in April 2010 and is indicated for the treatment of onychomycosis of the toenail caused by

Trichophyton rubrum or *T. mentagrophytes* in non-immunocompromised patients. Recommended dosing is one 200mg tablet once daily for 12 consecutive weeks.

IMPORTANT SAFETY INFORMATION

WARNING: CONGESTIVE HEART FAILURE, CARDIAC EFFECTS AND DRUG INTERACTIONS

Do not administer ONMEL™ for the treatment of onychomycosis in patients with evidence of ventricular dysfunction such as congestive heart failure (CHF) or a history of CHF. When itraconazole was administered intravenously to dogs and healthy human volunteers, negative inotropic effects were seen. If signs or symptoms of congestive heart failure occur during administration of ONMEL™, discontinue administration.

Drug Interactions: Co-administration of cisapride, pimozide, quinidine, dofetilide, levacetylmethadol (levomethadyl), felodipine, oral midazolam, nisoldipine, triazolam, lovastatin, simvastatin, ergot alkaloids such as dihydroergotamine, ergometrine (ergonovine), ergotamine and methylergometrine (methylergonovine) or methadone with ONMEL™ is contraindicated. ONMEL™, a potent cytochrome P450 3A4 isoenzyme system (CYP3A4) inhibitor, may increase plasma concentrations of drugs metabolized by this pathway. Serious cardiovascular events, including QT prolongation, torsades de pointes, ventricular tachycardia, cardiac arrest, and/or sudden death have occurred in patients using cisapride, pimozide, levacetylmethadol (levomethadyl), methadone or quinidine concomitantly with itraconazole and/or other CYP3A4 inhibitors.

Please see Full Prescribing Information, including Medication Guide for more information.

CONTRAINDICATIONS

- Do not administer for the treatment of onychomycosis in patients with evidence of ventricular dysfunction such as congestive heart failure (CHF) or a history of CHF.
- Do not administer for the treatment of onychomycosis to pregnant patients or to women contemplating pregnancy.
- Co-administration of cisapride, dofetilide, ergot alkaloids such as dihydroergotamine, ergotamine, ergometrine (ergonovine), and methylergometrine (methylergonovine); felodipine, levacetylmethadol (levomethadyl), lovastatin, methadone, oral midazolam, nisoldipine, pimozide, quinidine, simvastatin, and triazolam with ONMEL™ is contraindicated.
- Anaphylaxis and hypersensitivity have been reported with use of itraconazole. ONMEL™ is contraindicated in patients who have shown hypersensitivity to itraconazole products.

WARNINGS AND PRECAUTIONS

- Cases of CHF, peripheral edema, and pulmonary edema have been reported with itraconazole administration among patients being treated for onychomycosis and/or systemic fungal infections.
- Cardiac Dysrhythmias
- Cardiac Disease
- Hepatic Effects

- Calcium Channel Blockers
- Neuropathy
- Hearing Loss

ADVERSE REACTIONS

- Most common adverse reactions observed in the treatment phase of the onychomycosis clinical trial (>1%) are upper respiratory tract infections, increased hepatic enzymes, hypoacusis, headache, abdominal pain, diarrhea, nausea, fatigue, arrhythmia, cough, sore throat and back pain.
- Itraconazole has been associated with rare cases of serious hepatotoxicity, including liver failure and death.

To report SUSPECTED ADVERSE REACTIONS, contact Merz Pharmaceuticals, LLC at 1-877-743-8454 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

DRUG INTERACTIONS

- Concomitant administration of ONMEL™ Tablets with certain drugs metabolized by the cytochrome P450 3A4 isoenzyme system (CYP3A4) or transported by P-glycoprotein may result in increased plasma concentrations of those drugs, leading to potentially serious and/or life-threatening adverse events.
- Drug Interactions with the following drugs or classes of drugs may occur: Antiarrhythmics, Anticonvulsants, Anti-HIV Agents, Antimycobacterials, Antineoplastics, Antipsychotics, Benzodiazepines, Calcium Channel Blockers, Gastric Acid Suppressors/Neutralizers, Gastrointestinal Motility Agents, HMG CoA-Reductase Inhibitors, Macrolide Antibiotics, Oral Hypoglycemic Agents, Polyenes, Opiate Analgesics. Not all drug interactions are included in Highlights. See Full Prescribing Information for complete listing.

USE IN CERTAIN POPULATIONS

- Pregnancy: Based on animal data, may cause fetal harm.
- Nursing Mothers: Itraconazole is excreted in human milk.
- Pediatric Use: The efficacy and safety have not been established in pediatric patients. No pharmacokinetic data are available in children.

Please see full Prescribing Information for ONMEL™, including Boxed WARNING, available at www.onmel.com.

About Merz North America

Merz North America is a specialty healthcare company that develops and commercializes innovative treatment solutions in aesthetics, dermatology and neurology in the U.S. and Canada. Our ambition is to become a recognized leader in the treatment of movement disorders, and in aesthetics and dermatology. Our future is promising, and we are committed to advancing new therapeutic options and improving patients' lives. For more than 100 years, the development of our products has been based on Merz's commitment to providing innovative medical approaches that earn trust of patients, physicians and partners worldwide. Globally, the companies of Merz Pharma Group are focused on medications for treating neurological and psychiatric illnesses, and they have assumed a leading role in the field of Alzheimer's disease research. Founded in 1908, Merz Pharma Group is a privately owned company headquartered in Frankfurt, Germany.

For more information about Merz or the Company's products, please visit www.merzusa.com or www.merzaesthetics.com/en-US/.

NAFTIN® (naftifine hydrochloride) is a registered trademark of Merz Pharmaceuticals, LLC.
ONMEL™ (itraconazole) is a trademark of Merz Pharmaceuticals, LLC.

Your Contact:
Merz North America
Rachel Chase
Corporate Communications
4215 Tudor Lane
Greensboro, NC 27410
Office (336) 217-2423
Cell (336) 501-0919
rchase@merzusa.com