PRESS RELEASE

Merz North America (Merz Aesthetics, Inc. and Merz Pharmaceuticals, LLC) Announces the End of Court-Ordered Injunction

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Greensboro, N.C. – (BUSINESS WIRE) – Merz North America (Merz Aesthetics, Inc. and Merz Pharmaceuticals, LLC) announces that effective today, January 9, 2013, the court-ordered injunction has been lifted and patients and physicians now have access to a broader range of treatment options in neurology, dermatology and aesthetic medicine.

"The violations that led to this injunction were directly attributable to the acts of several individuals, and were entirely incompatible with Merz's culture. We accepted the injunction as a challenge to us to reinforce compliance training throughout the company and to re-imagine a company-wide compliance program. Last summer we directed all our efforts and resources toward the remediation process, and were pleased when the court agreed to a partial lift of the injunction in November 2012," said Katrina Church, Vice President - Chief Compliance Officer of Merz, Inc. "We believe that compliance policies are an investment in our company's future."

Merz North America (Merz Aesthetics, Inc. and Merz Pharmaceuticals, LLC) is now permitted to sell and promote its entire portfolio of FDA-approved products, including XEOMIN® (incobotulinumtoxinA), BELOTERO BALANCE® Dermal Filler, and Radiesse® Volumizing Filler, in the U.S. with no restrictions imposed by the court.

"Never at any point did the injunction question the quality of Merz's products," said Bill Humphries, President and Chief Executive Officer of Merz, Inc. "Although the injunction represented a challenge to our business activities, I am proud to announce that during those ten months, we continued to advance our core business, launching Naftin (naftifine hydrochloride) 2% cream, filing a NDA with the FDA for Naftin (naftifine hydrochloride) 2% gel, acquiring two novel prescription products (CUVPOSA® and Onmel™) and naming and staffing our Merz North American Leadership Team. Moving into 2013 our focus will be on sales and marketing execution in the marketplace, business development and licensing, and the organic expansion of our pipeline to better serve patients and physicians. We look forward to expanding our leadership role in dermatology within prescription antifungals, continuing our growth trajectory in movement disorders and commercializing our full suite of aesthetic products."

About XEOMIN® (incobotulinumtoxinA) for injection, for intramuscular use

INDICATIONS AND USAGE

XEOMIN® (incobotulinumtoxinA) is an acetylcholine release inhibitor and neuromuscular blocking agent indicated for the: treatment of adults with cervical dystonia, to decrease the severity of abnormal head position and neck pain in both botulinum toxin-naive and previously treated patients; treatment of blepharospasm in adults previously treated with onabotulinumtoxinA (Botox®); and temporary improvement in the appearance of moderate to severe glabellar lines associated with corrugator and/or procerus muscle activity in adult patients.

XEOMIN® should be administered no more frequently than every three months.

IMPORTANT SAFETY INFORMATION, INCLUDING BOXED WARNING

WARNING: DISTANT SPREAD OF TOXIN EFFECT

Postmarketing reports indicate that the effects of XEOMIN® (incobotulinumtoxinA) for injection, for intramuscular use, and all botulinum toxin products may spread from the area of injection to produce symptoms consistent with botulinum toxin effects. These may include asthenia, generalized muscle weakness, diplopia, blurred vision, ptosis, dysphagia, dysphonia, dysarthria, urinary incontinence and breathing difficulties. These symptoms have been reported hours to weeks after injection. Swallowing and breathing difficulties can be life threatening and there have been reports of death. The risk of symptoms is probably greatest in children treated for spasticity but symptoms can also occur in adults treated for spasticity and other conditions, particularly in those patients who have underlying conditions that would predispose them to these symptoms. In unapproved uses, including spasticity in children and adults, and in approved indications, cases of spread of effect have been reported at doses comparable to those used to treat cervical dystonia and at lower doses.

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

CONTRAINDICATIONS

XEOMIN® is contraindicated in patients with a known hypersensitivity to the active substance botulinum toxin type A or to any of the components in the formulation and in the presence of infection at the proposed injection site(s), as injection could lead to severe local or disseminated infection.

WARNINGS AND PRECAUTIONS

- **The potency units of XEOMIN® are not interchangeable with other preparations of botulinum toxin products. Therefore, units of biological activity of XEOMIN® cannot be compared to or converted into units of any other botulinum toxin products.**

- Hypersensitivity reactions have been reported with botulinum toxin products (anaphylaxis, serum sickness, urticaria, soft tissue edema, and dyspnea). If serious and/or immediate hypersensitivity reactions occur further injection of XEOMIN® should be discontinued and appropriate medical therapy immediately instituted. Patients treated with botulinum toxin may require immediate medical attention should they develop problems with swallowing, speech, or respiratory disorders.

- Treatment with XEOMIN® and other botulinum toxin products can result in swallowing or breathing difficulties. Patients with pre-existing swallowing or breathing difficulties may be more susceptible to these complications. When distant effects occur, additional respiratory muscles may be involved Deaths as a complication of severe dysphagia have been reported after treatment with botulinum toxin. Dysphagia may persist for several months, which may require use of a feeding tube. Aspiration may result from severe dysphagiaThese reactions can occur within hours to weeks after injection with botulinum toxin. *[See Boxed Warning]*.

- **Cervical Dystonia**: Patients with smaller neck muscle mass and patients who require bilateral injections into the sternocleidomastoid muscles are at greater risk of dysphagia. Limiting the dose injected into the sternocleidomastoid muscle may decrease the occurrence of dysphagia.

- **Blepharospasm**: Injection of XEOMIN® into the orbicularis oculi muscle may lead to reduced blinking and corneal exposure with possible ulceration or perforation. Lower lid injections should not be repeated if diplopia occurred with previous botulinum toxin injections.

- **Glabellar Lines:** Do not exceed the recommended dosage and frequency of administration of XEOMIN®. In order to reduce the complication of ptosis the following steps should be taken:
  - Avoid injection near the levator palpebrae superioris, particularly in patients with larger brow depressor complexes.
  - Corrugator injections should be placed at least 1 cm above the bony supraorbital ridge.

- Individuals with peripheral motor neuropathic diseases, amyotrophic lateral sclerosis, or neuromuscular junctional disorders (e.g., myasthenia gravis or Lambert-Eaton syndrome) should be monitored particularly closely when given botulinum toxin. Patients with neuromuscular disorders may be at increased risk of clinically significant effects including severe dysphagia and respiratory compromise from typical doses of XEOMIN®.

- XEOMIN® contains albumin. Based on effective donor screening and product manufacturing processes, it carries an extremely remote risk for transmission of viral diseases and Creutzfeldt-Jakob disease (CJD). No cases of transmission of viral diseases or CJD have ever been reported for albumin.

ADVERSE REACTIONS

Cervical Dystonia: The most commonly observed adverse reactions (incidence ≥10% of patients and twice the rate of placebo) for XEOMIN® 120 Units and XEOMIN® 240 Units, respectively, were: dysphagia (13%, 18%), neck pain (7%, 15%), muscle weakness (7%, 11%), and musculoskeletal pain (7%, 4%).

Blepharospasm: The most common adverse reactions (incidence ≥10% of patients and twice the rate of placebo) for XEOMIN® were eyelid ptosis (19%), dry mouth (16%), visual impairment (12%), diarrhea (8%), and headache (7%).

Glabellar Lines: The most common adverse reaction (incidence ≥ 2% of patients and greater than placebo) for XEOMIN® was Headache (5.4%).

DRUG INTERACTIONS

Concomitant treatment of XEOMIN® and aminoglycoside antibiotics, spectinomycin, or other agents that interfere with neuromuscular transmission (e.g., tubocurarine-like agents), or muscle relaxants, should be observed closely because the effect of XEOMIN may be potentiated.

The effect of administering different botulinum toxin products at the same time or within several months of each other is unknown. Excessive neuromuscular weakness may be exacerbated by administration of another botulinum toxin prior to the resolution of the effects of a previously administered botulinum toxin.

USE IN PREGNANCY

Pregnancy Category C: There are no adequate and well-controlled studies in pregnant women. XEOMIN® should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

PEDIATRIC USE

The safety and effectiveness of XEOMIN® in patients less than 18 years of age have not been established.

Please see Full Prescribing Information for more information on XEOMIN® (incobotulinumtoxinA) for injection, for intramuscular use, including complete Boxed WARNING, available at www.Xeomin.com and at www.XeominAesthetics.com.

About ONMEL™

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.merzusa.com.

XEOMIN® is a registered trademark of Merz Pharma GmbH & Co. KGaA.
BELOTERO BALANCE® is a registered trademark of Merz Pharma GmbH & Co. KGaA.
RADIESSE® Volumizing Filler is a registered trademark of Merz Aesthetics, Inc.
Botox® is a registered trademark of Allergan, Inc.

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.

U.S. brands include Belotero Balance®, Radiesse® Volumizing Filler, Asclera® (polidocanol) Injection, Xeomin® (incobotulinumtoxin A), CUVPOSA® glycopyrrolate (1 mg/5 mL) oral solution, Onmel™ (itraconazole), Naftin®, Mederma®, Aqua Glycolic®, and Appearex®. For more information about Merz or the Company's products, please visit www.merzusa.com or www.merzaesthetics.com/en-US/.

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