



SCIELE PHARMA AND ADDRENEX PHARMACEUTICALS ANNOUNCE POSITIVE PHASE III CLINICAL RESULTS OF CLONICEL USED IN COMBINATION WITH STIMULANTS TO TREAT ADHD

Study shows Clonichel® and stimulants combined provided greater improvement in symptoms than stimulants alone

Atlanta, GA and Durham, NC (April 23, 2009) – Sciele Pharma, a Shionogi Company, and Addrenex Pharmaceuticals, Inc. today announced that a preliminary analysis showed positive results from a second Phase III trial of Clonichel®, demonstrating that the combination of Clonichel with stimulants provided statistically significant improvements in ADHD symptoms compared to stimulant used alone.

Larry Dillaha, M.D., Chief Medical Officer of Sciele Pharma, said, “We are pleased with the positive Phase III results using Clonichel in combination with stimulants. Clonichel is an important product in our development pipeline, and we are excited about the potential benefit that Clonichel may provide to children and adolescents who have ADHD.”

Based on the positive data from two Phase III trials conducted on Clonichel, Addrenex and Sciele Pharma plan to file with the U.S. Food and Drug Administration (FDA) later this year for Clonichel as both a monotherapy and as an add-on therapy to stimulant medication for children and adolescents with ADHD. The North American rights to market Clonichel are licensed to Sciele Pharma, a Shionogi Company, which is an Atlanta-based specialty pharmaceutical company.

“Our data from the first Phase III study data suggest that Clonichel may be an effective therapy for ADHD when used alone, and now we have evidence from a second study that Clonichel also has a complementary effect when used with stimulants,” said Moise Khayrallah, Ph.D., CEO of Addrenex Pharmaceuticals. “In children who are not receiving optimal benefit from stimulants such as methylphenidate or amphetamine, Clonichel may provide greater relief than using a stimulant medication alone.”

The current study of 200 children with ADHD is the second Phase III trial in a year to investigate the safety and efficacy of Clonichel, a long-acting version of clonidine hydrochloride. Both studies demonstrated that Clonichel improved an aggregate of 18 ADHD symptoms recognized by the American Psychiatric Association and used by doctors to diagnose and classify ADHD in children and adolescents.

In both studies, Clonichel showed improvement across all three symptom domains of ADHD: attention, hyperactivity, and impulsivity. Clonichel was well tolerated and had a favorable safety profile, with mild adverse events such as drowsiness. The multi-center, placebo-controlled, double blind, randomized trial was funded by Addrenex Pharmaceuticals

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Clonicef is a non-stimulant medication that selectively targets and calms the adrenergic system, a cascade of stress hormones that regulate the body's response to stress and other physiologic factors. An overactive adrenergic system can trigger emotional outbursts, irritability, mood swings and other debilitating symptoms.

About Sciele Pharma, Inc.

Sciele Pharma, Inc., a Shionogi Company, is a pharmaceutical company specializing in sales, marketing and development of branded prescription products focused on the therapeutic areas of Cardiovascular, Diabetes, Women's Health and Pediatrics. The Company's Cardiovascular and Diabetes products treat patients with high cholesterol, hypertension, high triglycerides, unstable angina and type 2 diabetes; its Women's Health products are designed to improve the health and well-being of women and mothers and their babies; and its Pediatrics products treat allergies, asthma, coughs and colds, and attention deficit and hyperactivity disorder (ADHD). Founded in 1992 and headquartered in Atlanta, Georgia, Sciele employs more than 1,000 people. The Company's success is based on placing the needs of patients first, improving health and quality of life, and implementing its business platform – an Entrepreneurial Spirit, Innovation, Execution Excellence, Simplicity, and Teamwork.

On October 9, 2008, Shionogi & Co., Ltd. and Sciele Pharma announced the completion of Shionogi's acquisition of Sciele. Sciele is now an indirect wholly owned subsidiary of Shionogi.

About Shionogi & Co., Ltd.

Shionogi & Co., Ltd. is a major research-driven Japanese pharmaceutical manufacturer. The company's primary businesses are research and development, manufacturing, marketing, and import and export sales of pharmaceuticals and diagnostics. Shionogi follows a basic policy of continually providing the superior medicines essential to people's health. For more details, please visit www.shionogi.co.jp.

About Addrenex

Addrenex specializes in the development of drugs, diagnostic tools and intervention methods aimed at normalizing adrenergic function and thereby helping patients regain control of symptoms related to adrenergic dysregulation. Adrenergic dysregulation is the root cause or major contributing factor for multiple medical conditions. Currently, Addrenex has three products in clinical trials and a library of over 400 compounds available for future development. For more information go to www.addrenex.com

Safe Harbor Statement

This press release contains forward-looking statements that are subject to risks and uncertainties that could cause actual results to materially differ from those described. Although we believe that the expectations expressed in these statements are reasonable, we cannot promise that our expectations will turn out to be correct. Our actual results could be materially different from and worse than our expectations.

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