

April 18, 2013

Meiji Initiates Phase 1 Clinical Trial of ME1111 in U.S. for Topical Treatment of Onychomycosis

Meiji Seika Pharma Co., Ltd. (Headquarters: Tokyo, Japan, President: Masahiko Matsuo, hereinafter “Meiji”) announced today that it has initiated a Phase 1 clinical trial of ME1111 in the United States for topical treatment of onychomycosis.

ME1111 is discovered by Meiji and categorized in a new class of compound with a unique mode of action. Nonclinical studies show that ME1111 has strong fungicidal activity against dermatophytes, common causative organisms of onychomycosis, such as *Trichophyton rubrum* and *Trichophyton mentagrophytes*. In addition, ME1111 can readily penetrate into the nail. These profiles are suitable for a new topical medication for onychomycosis.

The Phase 1 clinical trial aims to evaluate safety, tolerability and pharmacokinetics of ME1111 in patients with onychomycosis once daily dosed by the topical use for 28 days. A subsequent Phase 2 clinical trial to evaluate effectiveness and safety will be conducted in the United States.

About Onychomycosis

Onychomycosis is a progressive fungal infection of nail and nail bed, which leads to the destruction and deformity of nails, and eventually causes pain and discomfort, as well as reducing quality of life. The disease affects approximately 10% of world’s adult population and prevalence of the disease increases in the elderly population.