Oct 23, 2014

Notification of the results of Phase II clinical study of HP-3000 in Japan
(a transdermal system for the treatment of idiopathic restless legs syndrome)

Hisamitsu Pharmaceutical Co., Inc. (Head office: Tosu city, Saga Prefecture, Japan: President and CEO: Hirotaka Nakatomi, hereinafter referred to as “Hisamitsu”) hereby announces the results of the Phase II clinical study on a transdermal system for the treatment of idiopathic restless legs syndrome in Japan (development code: HP-3000, active pharmaceutical ingredient: ropinirole hydrochloride, hereinafter referred to as “the product”).

The efficacy and safety of administration of the product once per day were compared with a placebo in patients with moderate to severe idiopathic restless legs syndrome. As a result, the effectiveness of the product was confirmed in the primary efficacy endpoint. For safety, no serious adverse reactions were observed.
Based on the above results, in addition to verifying the efficacy in a Phase III clinical study, Hisamitsu will confirm the stability and efficacy in long-term administration.

The product is a systemic transdermal tape formulation developed by utilizing Hisamitsu’s TDDS (Transdermal Drug Delivery System) technology. Hisamitsu expect it to be a new option for the treatment of idiopathic restless legs syndrome by realizing its long-lasting effect by means of maintaining a stable blood drug concentration. A Phase III clinical study for treatment of Parkinson's disease is also scheduled to begin this fiscal year.

Hisamitsu aims to initiate a Phase III clinical study during FY 2015.