Notification on the commencement of Phase II clinical study of HP-3000 in Japan (a transdermal drug 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 commencement of the Phase II clinical study for a transdermal drug 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 product is a transdermal preparation developed using Hisamitsu's TDDS (Transdermal Drug Delivery System) technology. With the expectation that the efficacy of the product will be sustained by maintaining the blood concentration in a stable manner, a Phase II clinical study of the product was commenced last year for Parkinson's disease.

On this occasion, a Phase II clinical study will be conducted with the expectation for the efficacy of the product in idiopathic restless legs syndrome. The study will investigate the efficacy and safety of the product by once daily administration of the product or placebo in patients with moderate to severe idiopathic restless legs syndrome.

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