February 5, 2014

Notification of the results of Phase II clinical study of HP-3000 in Japan (a transdermal drug for the treatment of Parkinson's disease)

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 for a transdermal drug for the treatment of Parkinson's disease in Japan (Development code: HP-3000, Active pharmaceutical ingredient: ropinirole hydrochloride, hereinafter referred to as "the product").

The efficacy and safety of the product were compared with a placebo in patients with Parkinson's disease who concomitantly used L-dopa (levodopa). As a result, a statistically significant difference was confirmed for improvement in the primary efficacy endpoint compared with the placebo group. For safety, no adverse reactions were observed that would cause major concerns in development.

The product is a transdermal formulation developed using Hisamitsu's TDDS (Transdermal Drug Delivery System) technology. We expect the product to be a new option for the treatment of Parkinson's disease by realizing its long-lasting effect by means of maintaining a stable blood concentration. A Phase II clinical study of the product was commenced last year for moderate to severe idiopathic restless leg syndrome.

Hisamitsu aims to initiate a Phase III clinical study during FY 2014.