This material is an English translation of the press release announced on February 27, 2018 in Japanese, and the Japanese release is given priority about the content and the interpretation.

February 27, 2018

Notification of the results of Phase III 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; Chairman and CEO: Hirotaka Nakatomi, hereinafter referred to as "Hisamitsu Pharmaceutical") announces that the transdermal patch for the treatment of Parkinson's disease (Development code: HP-3000, generic name: ropinirole hydrochloride, hereinafter referred to as "the investigational product") achieved the primary endpoint of the Phase III clinical study in Japan.

In this study, the efficacy and safety of administration of the investigational product once per day was compared with a placebo and with a positive drug (oral drug) in patients with Parkinson's disease who concomitantly use L-dopa (levodopa). As a result, an improvement in primary endpoints for efficacy was observed with a statistically significant difference when compared with the placebo group, and non-inferiority was confirmed when compared with the positive drug (oral drug). For safety, no adverse reactions were observed that would cause major concerns in development.

The investigational product is a transdermal formulation developed using Hisamitsu's TDDS (Transdermal Drug Delivery System) technology and expected to realize its long-lasting effect by means of maintaining a stable blood concentration. Hisamitsu Pharmaceutical will contribute improvement of Quality of Life of the patients with Parkinson's disease through the development of HP-3000.

In the future, we aim to apply for manufacturing and marketing approval during FY2018.



Delivering Patch Culture Hand by Hand

Hisamitsu Pharmaceutical Co., Inc. was established in 1847 and has marked its 170th anniversary since its foundation thanks to the support of many people.