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Phase II study results of HOB-294（transdermal oxybutynin hydrochloride）for treatment of overactive bladder

In this report Hisamitsu Pharmaceutical Co. Ltd.（Hirotaka Nakatomi, President & Chief Executive Officer）publishes the domestic phase II study results of HOB-294 (transdermal oxybutynin hydrochloride) under development for treatment of overactive bladder.

HOB-294 is a transdermal product containing oxybutynin hydrochloride intended for treatment of "overactive bladder" with symptoms such as micturition urgency and pollakiuria.

HOB-294, under development in Japan, is expected for long-term efficacy by maintaining of stable blood drug concentrations and decreased incidence of metabolite-induced adverse drug reactions by avoiding the liver first-pass effect, which are benefits of the characteristics of the transdermal formulation.

This phase II clinical study was an 8-week placebo-controlled double-blind study in patients with overactive bladder. HOB-294 or placebo was administered once daily in this study with a primary endpoint of improvement of symptoms.

The data analysis confirmed dose-response of HOB-294 and demonstrated a statistical difference of improvement in the primary endpoint of efficacy between the HOB-294 and placebo groups. For safety no serious adverse event was observed.

Based on these results Hisamitsu will advance to the subsequent phase III clinical study.