Phase III Clinical Trial Results for Overactive Bladder Drug HOB-294 (Oxybutynin Hydrochloride, Transdermal Therapeutic Formulation)

Please be informed of the domestic phase III clinical trial results for overactive bladder drug HOB-294 (oxybutynin hydrochloride, transdermal therapeutic formulation), under development by Hisamitsu Pharmaceutical Co., Inc. (Hirotaka Nakatomi, representing director and president).

We investigated efficacy and safety of HOB-294 when dosed once daily for 12 weeks in patients with overactive bladder using placebo and active control. Consequently, 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 active control. There were no serious adverse reactions with respect to safety.

HOB-294 is a transdermal therapeutic formulation used to treat "overactive bladder," which causes an urge to urinate and frequent urination. We have domestically promoted the development with expectation of the persistence of drug efficacy by stably maintaining drug levels in the blood.

In the future, we aim to apply for manufacturing and marketing approval during fiscal 2012.