May 14, 2013

**Notification of the results of the Phase II clinical study in the United States of HTU-520 (terbinafine hydrochloride patch), a therapeutic agent for tinea unguium.**

This is to report the results of the Phase II clinical study of HTU-520, a therapeutic product for tinea unguium (terbinafine hydrochloride patch), which is being developed by Hisamitsu Pharmaceutical Co., Inc. (Head office: Tosu-shi, Saga, Japan; President & CEO: Hirotaka Nakatomi).

In this study, the efficacy and safety of HTU-520, administered to the nails once daily for 48 weeks in patients with tinea unguium, were investigated using a placebo as the control. As a result, a statistically significant difference was confirmed for the secondary endpoint of efficacy (mycological cure; the absence of fungus as determined by a negative potassium hydroxide (KOH) examination and a negative fungal culture), but no significant difference was confirmed for the primary endpoint of efficacy (complete cure) compared with the placebo group. No serious adverse events related to HTU-520 were reported during the study.

In future, Hisamitsu will determine the direction of development of HTU-520 in the United States and Japan based on a detailed investigation of the obtained results in this study.