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Results of a Japanese Phase III Clinical Study of HTU-520 (Terbinafine Hydrochloride Patch): A Therapeutic Agent for Tinea Unguium

We report the results of a Japanese phase III clinical study of HTU-520 (terbinafine hydrochloride patch), a therapeutic agent for tinea unguium, currently under development by Hisamitsu Pharmaceutical Co., Inc. (President and Chief Executive Officer, Hirotaka Nakatomi).

The safety and efficacy of HTU-520 against placebo were investigated in patients with tinea unguium in whom 1 patch of HTU-520 was applied to the nail once daily for 52 weeks. However, expected results were not obtained with respect to efficacy.

HTU-520 is a preparation containing terbinafine hydrochloride, which is intended to treat “tinea unguium”, a mycosis that infects nails. We have been undertaking the development of HTU-520 in Japan and the United States, assuming that the efficacy and safety would result from the distribution of the drug in the nail at a high concentration, which is facilitated by the characteristic property of the patches.

We will determine whether or not to continue development in Japan on the basis of subsequent thorough investigation of the results obtained from this study. In the United States, we intend to start a phase III clinical study within 2013, as planned.