August 25, 2009

Results of a Phase II clinical study of HTU-520 (terbinafine hydrochloride, patch), a therapeutic agent for tinea unguium

This is to notify the results of a domestic Phase II clinical study of a therapeutic agent for tinea unguium, HTU-520 (terbinafine hydrochloride, patch), which is being developed by Hisamitsu Pharmaceutical Co., Inc. (President & Chief Executive Officer: Hirotaka Nakatomi).

HTU-520 is a drug product that contains terbinafine hydrochloride for the treatment of "tinea unguium," a mycosis of the nails as an infection site.

Taking advantage of the characteristics of a patch, our company is advancing the development of the drug in Japan, expecting the efficacy and safety by transferring the drug into the nails in high concentration.

The Phase II clinical study conducted this time was a double-blind comparative study in which repeated dose of HTU-520 or placebo was administered for 24 weeks to patients with tinea unguium. The efficacy of this drug was examined with improvement of symptoms as a primary endpoint.

As a result of the data analysis, an improvement tendency in the efficacy of HTU-520 was confirmed in the primary endpoint compared with the placebo group. Furthermore, no serious adverse reactions were noted for the safety.

Based on the above results, our company will carry on to a Phase III clinical study in the future.