October 28, 2015

"Sirolimus (NPC-12G)," an external preparation for treatment of angiofibroma in tuberous sclerosis, received SAKIGAKE fast-track designation from MHLW

Yesterday, the Ministry of Health, Labour and Welfare announced six drugs designated under its SAKIGAKE fast-track review system; one of which was "Sirolimus (NPC-12G)" for external use to treat angiofibroma in tuberous sclerosis currently under development by Nobelpharma.

Angiofibroma in tuberous sclerosis is autosomal dominant disorder-specific skin lesion characterized by systemic hamartoma, the aggravation of which induces rhinostenosis and hemorrhage, having a significant adverse impact on patients' quality of life (QOL). Laser treatment and surgical excision are the only treatments available today, leaving risks of frequent relapses, pigmentary change, scars, and infections.

[SAKIGAKE Fast-track Review System]

A system, with the intention to provide state-of-the-art drug in Japan ahead of other countries, to grant SAKIGAKE fast-track review designation at an early development stage to innovative pharmaceuticals, medical devices, and regenerative medicines fulfilling certain criteria such as [1] innovativeness with new functional mechanism, [2] seriousness of target diseases, [3] extremely high efficacy for target diseases, and [4] inclination to early development and application in Japan ahead of other countries.

A designated product will be prioritized for consultation and reviews in the approval process and also adequately supported for the preparation of a manufacturing scheme and of smooth product supply to clinical settings in line with review schedule, further accelerating prompt practical application.

For the review period, reduction by half to 6 months from normal 12 months is targeted by employing the expedited review processes.

Visit MHLW website for more information on “SAKIGAKE System.”