

FOR IMMEDIATE RELEASE

January 19, 2018

Sato Pharmaceutical Co., Ltd.
Eisai Co., Ltd.

ORAL ANTIFUNGAL AGENT NAILIN[®] CAPSULES 100MG APPROVED IN JAPAN

Sato Pharmaceutical Co., Ltd. (Headquarters: Tokyo, President and CEO: Seiichi Sato, “Sato Pharma”) obtained marketing and manufacturing approval for the oral antifungal agent NAILIN[®] Capsules 100mg containing the active ingredient fosravuconazole L-lysine ethanolate (“fosravuconazole”) for the treatment of onychomycosis in Japan on January 19, 2018.

Sato Pharma and Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, “Eisai”) are jointly providing information on its proper use.

Fosravuconazole, the active ingredient of NAILIN[®] Capsules 100mg, is a new triazole class oral antifungal component discovered by Eisai. Sato Pharma conducted a Phase III clinical study of the agent in patients with onychomycosis in Japan, and after confirming efficacy and safety of the agent in the study, Sato Pharma applied for marketing and manufacturing authorization in January 2017.

Onychomycosis affects 1 in every 10 Japanese people, and there are an estimated approximately 11 million sufferers in Japan. With Sato Pharma now having obtained marketing and manufacturing approval for NAILIN[®] Capsules 100mg, as an oral treatment for onychomycosis, this is the first new treatment for the disease in approximately 20 years.

By providing NAILIN[®] Capsules 100mg as a new option for the treatment of onychomycosis, Sato Pharma and Eisai will strive to fulfil the needs of onychomycosis patients and healthcare professionals.

(Outline of the marketing authorization)

[Product Name]

NAILIN® Capsules 100 mg

[Active Ingredient and Content (per capsule)]

Fosravuconazole L-lysine ethanolate 169.1 mg
(100 mg as ravuconazole)

[Indication]

<Indicated Type of Bacteria> Dermatophytosis (*Trichophyton* genus)

<Indicated Disease> Onychomycosis

[Dosage and Administration]

The usual adult dosage is 1 capsule (100 mg as ravuconazole) administered orally once daily for a period of 12 weeks

[Packaging]

84 capsules (PTP 14 capsules X 6)

Media Inquiries	
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