September 27, 2021
Nobelpharma Co., Ltd.

mTOR inhibitor“RAPALIMUS® Tablets 1mg”

Approved for Additional Indication

Nobelpharma Co., Ltd. (Headquarters: Chuo-ku, Tokyo, Managing Director & CEO: Jin Shiomura), announced today, that the mTOR inhibitor RAPALIMUS® Tablets 1mg (generic name: sirolimus) has been approved for the following additional “indications” and “dosage and administration” on September 27, 2021.

RAPALIMUS® Tablets Raparimus Tablets® 1mg is the world's first drug for the treatment of refractory lymphatic diseases, which is expected to improve clinical manifestations and QOL by reducing mass lesions with its mTOR activity inhibition.

We are pleased additional “indications” and “dosage and administration”can offer a new treatment option for refractory lymphatic diseases .

We will continue to contribute to society by providing critical but neglected pharmaceuticals and medical devices.

Extract of the Additional “Indication” “Dosage and Administration”*

“Indication”

○Following refractory lymphatic disease

Lymphangioma (lymphatic malformation); Lymphangiomatosis; Gorham's disease; Lymphangiectasia

“Dosage and Administration”(For refractory lymphatic diseases)

In general, start taking 2 mg of sirolimus if the body surface area is 1.0m^2 or more or 1 mg if less than 1.0 m^2 orally once daily. Thereafter, the dosage will be adjusted according to the blood trough concentration and/or the patient's condition, but must not exceed 4 mg once daily.

*See "RAPALIMUS® Tablets 1mg" package insert in the revised post-approval version.

[Contact for inquiries regarding this matter]
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