

July 8, 2024 Nobelpharma Co., Ltd.

"RAPALIMUS[®] Granule 0.2%" Launched

Nobelpharma Co., Ltd. (Headquarters: Chuo-ku, Tokyo, Managing Director & CEO: Jin Shiomura) announced that the company has launched "RAPALIMUS® Granule 0.2%."

This product was approved on January 18, 2024 for the indications of intractable vascular anomalies.¹⁾

RAPALIMUS Tablets already on market had also been approved for the same indications.

<<Indications>>

OFollowing intractable vascular anomalies

lymphangioma (lymphatic malformation), lymphangiomatosis, Gorham's disease, lymphangiectasia

hemangioendothelioma, tufted angioma

arteriovenous malformation, blue rubber bleb nevus syndrome

combined vascular malformation, Klippel-Trenaunay-Weber syndrome

O"Vascular Anomalies"

"Vasculature" includes "blood vessels" and "lymphatic vessels." "Vascular tumors" typified by hemangioendothelioma and tufted angioma mainly means angioma that is made of quickly dividing cells of blood vessel walls, while the size of which tends to change in size within a short period as the tumor cells grow and involute. Comparatively, vascular malformation" including lymphatic malformation such as lymphangioma and arteriovenous malformation differs from tumors and does not change much in size but does not disappear either. In a longer term, it is said to enlarge as the patients grow and may become worse driven by certain events, including age of puberty, pregnancy, infection and trauma.

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Stubborn cases are called "refractory" and the treatment may become lengthy depending on the sites, size and symptoms. The symptoms of each case vary from continuing pain and hemorrhagic tendency to breathing trouble due to lesion sites. Some may interfere with certain aspects of life and cause aesthetic problems.¹⁾

We hope the RAPALIMUS Granule 0.2% and RAPALIMUS Tablets 1 mg become one of the treatment options and can be of any help for refractory vascular anomaly patients.

We have also created the web site for lymphatic disorder in Nobelpharma corporate site.

https://www.nobelpharma.co.jp/general/lymphangioma/

¹⁾ Corporate News: "mTOR inhibitor "RAPRLIMUS[®]" Approved for Additional Indication for Tablets 1 mg and Additional Formulation of Granule 0.2% mTOR" <u>https://www.nobelpharma.co.jp/_cms/wp-</u>

content/uploads/2024/01/59807d35a19212d4ccf0f0cb4e336971.pdf

Reference: Site for Information of Drug Therapy Working Group for Intractable Vascular Anomalies

https://cure-vas.jp/

We are determined to continue contributing to society by providing critical but neglected pharmaceuticals and medical devices.

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