



July 19, 2023

To whom it may concern:

Company Name TOHO HOLDINGS CO., LTD.

Corporate Atsushi Udoh, Representative Director,

Representative CEO

(Prime Market of Tokyo Stock

Exchange Securities Code: 8129)

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Notice Regarding Approval of Partial Amendments to Indications, Dosage and Administration of ROSUVASTATIN TABLETS 2.5mg/5mg "KYOSOMIRAI", ROSUVASTATIN OD TABLETS 2.5mg/5mg "KYOSOMIRAI", ROSUVASTATIN TABLETS 2.5mg/5mg "KMP", ROSUVASTATIN OD TABLETS 2.5mg/5mg "KMP" for KYOSOMIRAI PHARMA

TOHO HOLDINGS CO., LTD. (Headquarters: Tokyo; Representative Director, CEO: Atsushi Udoh) is pleased to announce that KYOSOMIRAI PHARMA CO., LTD. (Headquarters: Tokyo; President and Representative Director: Yasuyuki Kumada), the wholly-owned subsidiary involved in pharmaceuticals manufacture and sales business, received an approval of partial amendments to indications, dosage and administration of ROSUVASTATIN TABLETS 2.5mg/5mg "KYOSOMIRAI", ROSUVASTATIN OD TABLETS 2.5mg/5mg "KYOSOMIRAI", ROSUVASTATIN TABLETS 2.5mg/5mg "KMP", ROSUVASTATIN OD TABLETS 2.5mg/5mg "KMP" on July 19, 2023 as below.

## Outline of ROSUVASTATIN TABLETS 2.5mg/5mg "KYOSOMIRAI", ROSUVASTATIN OD TABLETS 2.5mg/5mg "KYOSOMIRAI",

ROSUVASTATIN TABLETS 2.5mg/5mg "KMP", ROSUVASTATIN OD TABLETS 2.5mg/5mg "KMP"

Classes	Product Name	Original Brand Name
HMG-CoA Reductase Inhibitor	ROSUVASTATIN TABLETS 2.5mg"KYOSOMIRAI" ROSUVASTATIN TABLETS 5mg"KYOSOMIRAI" ROSUVASTATIN OD TABLETS 2.5mg"KYOSOMIRAI" ROSUVASTATIN OD TABLETS 5mg"KYOSOMIRAI" ROSUVASTATIN TABLETS 2.5mg"KMP" ROSUVASTATIN TABLETS 5mg"KMP" ROSUVASTATIN OD TABLETS 2.5mg"KMP" ROSUVASTATIN OD TABLETS 5mg"KMP"	CRESTOR® Tablets 2.5mg CRESTOR® Tablets 5mg CRESTOR®OD Tablets 2.5mg CRESTOR®OD Tablets 5mg

## Outline of Amendments to Indications, Dosage and Administration of ROSUVASTATIN TABLETS 2.5mg/5mg "KYOSOMIRAI", ROSUVASTATIN OD TABLETS 2.5mg/5mg "KYOSOMIRAI",

## ROSUVASTATIN TABLETS 2.5mg/5mg "KMP", ROSUVASTATIN OD TABLETS 2.5mg/5mg "KMP"

Indications and Usage	Hypercholesterolemia, <u>Familial hypercholesterolemia</u>	
Dosage and Administration	The usual initial dose of rosuvastatin for adult patients is 2.5 mg once daily. The initial dose can be increased to 5 mg if expedited lowering of LDL cholesterol is required. The dose can be adjusted according to the patient's age and symptoms. The dose can be increased up to 10 mg if a patient's LDL-cholesterol level has not been sufficiently lowered by 4 weeks after the start of treatment or dose increase. The dose can be further increased only in severe patients such as those with familial hypercholesterolemia in whom the LDL-cholesterol level is not sufficiently lowered with rosuvastatin 10 mg, but the maximum daily dose is 20 mg.	

(Underlined parts are revised parts.)