

February 1, 2021

ONO Announces Transfer of the Manufacturing and Marketing Approval Authorization for Kinedak Tablets to Alfresa Pharma Corporation

Ono Pharmaceutical Co., Ltd. (Osaka, Japan; President, Representative Director, Gyo Sagara; “ONO”) announced today that it has agreed to transfer the manufacturing and marketing approval authorization (MMAA) for Kinedak tablets which ONO has retained, as from April 1st, 2021 to Alfresa Pharma Corporation (Osaka, Japan; President, Koichi Shimada; “Alfresa Pharma”).

Kinedak tablets, for which the MMAA will be transferred this time, is a first-in-class ethical drug created by ONO and has been used for the treatment of many patients with diabetic peripheral neuropathy.

From now on, ONO and Alfresa Pharma will work together toward the transfer, to ensure a stable supply of Kinedak tablets and to contribute the activities for proper use of the product through the provision and collection of product information.

Product to be transferred:

Product name	Therapeutic category
Kinedak [®] tablets 50 mg	Aldose reductase inhibitor

1. Kinedak[®] tablets

Product name	Kinedak [®] Tablets
Generic name	Epalrestat
Therapeutic category	Aldose reductase inhibitor
Content	50 mg
Dosage form	Film-coated tablet
Indication	Improvement of subjective symptoms (numbness and pain), abnormality of vibration sense and abnormal changes in heart beat associated with diabetic peripheral neuropathy (in case of high levels of glycosylated hemoglobin)

2. Outline of the relevant companies

2.1 Ono Pharmaceutical Co., Ltd. (As of September 30, 2020)

1	Company	Ono Pharmaceutical Co., Ltd.
2	Location	8-2, Kyutaromachi 1-chome, Chuo-ku, Osaka
3	Representative	Gyo Sagara, President, Representative Director
4	Business operation	Research, development, manufacture, purchase and sales of various pharmaceutical products, mainly ethical drugs
5	Capital	JPY 17.358 billion
6	Founded	1947
7	Net assets	JPY 610.598 billion
8	Gross assets	JPY 706.795 billion

2.2 Alfresa Pharma Corporation (As of September 30, 2020)

1	Company	Alfresa Pharma Corporation
2	Location	2-2-9 Kokumachi, Chuo-ku, Osaka
3	Representative	Koichi Shimada, President and CEO
4	Business operation	Manufacture, import, export and sales of pharmaceutical products, diagnostics, medical devices, raw materials for pharmaceutical products, etc.
5	Capital	JPY 3 billion
6	Founded	1939
7	Net assets	JPY 38.493 billion
8	Gross assets	JPY 51.971 billion

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