

July 18, 2019

To whom it may concern:

Company Name Corporate Representative	TOHO HOLDINGS CO., LTD. Norio Hamada, Chairman of the Board and Chief Executive Officer (CEO), Representative Director (First Section of Tokyo Stock Exchange Securities Code:8129)
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Notice Regarding Approval of Partial Amendments to Indications, Dosage and Administration of
Donepezil Hydrochloride Tablets 3mg / 5mg / 10mg “FFP” and Donepezil Hydrochloride OD
Tablets 3mg / 5mg / 10mg “FFP” for KYOSOMIRAI PHARMA

TOHO HOLDINGS CO., LTD. (Headquarters: Tokyo; Chairman of the Board and Chief Executive Officer (CEO), Representative Director,: Norio Hamada) is pleased to announce that KYOSOMIRAI PHARMA CO., LTD. (Headquarters:Tokyo; President and Representative Director: Atsushi Udoh), the wholly-owned subsidiary involved in pharmaceuticals manufacture and sales business, received an approval of partial amendments to indications, dosage and administration of Donepezil Hydrochloride Tablets 3mg / 5mg / 10mg “FFP” and Donepezil Hydrochloride OD Tablets 3mg / 5mg / 10mg “FFP” on July 17, 2019 as below.

Outline of Donepezil Hydrochloride Tablets 3mg / 5mg / 10mg “FFP” and Donepezil Hydrochloride OD
Tablets 3mg / 5mg / 10mg “FFP”

Class	Product Name	Original Brand Name
Therapeutic agent for Alzheimer's disease	Donepezil Hydrochloride Tablets 3mg / 5mg / 10mg “FFP”	Aricept Tablets 3mg / 5mg / 10mg
Therapeutic agent for dementia with Lewy bodies	Donepezil Hydrochloride OD Tablets 3mg / 5mg / 10mg “FFP”	Aricept D Tablets 3mg / 5mg / 10mg

Outline of Amendments to Indications, Dosage and Administration of Donepezil Hydrochloride Tablets 3mg / 5mg / 10mg “FFP” and Donepezil Hydrochloride OD Tablets 3mg / 5mg / 10mg “FFP”

Indications and Usage	Suppression of progression of dementia symptoms in Alzheimer's disease and <u>dementia with Lewy bodies</u>
Dosage and Administration	<p><u>Suppression of progression of dementia symptoms in Alzheimer's disease</u></p> <p>The usual initial adult dose for oral use is 3mg of donepezil hydrochloride once daily. After 1 to 2weeks the dose is increased to 5mg. The dosage for patients with severe Alzheimer's disease is increased to 10mg after dosing at 5mg for 4 or more weeks. The dose can be reduced appropriately according to patients' symptoms.</p> <p><u>Suppression of progression of dementia with Lewy bodies</u></p> <p><u>The usual initial adult dose for oral use is 3mg of donepezil hydrochloride once daily. After 1 to 2weeks the dose is increased to 5mg. The dosage for patients with severe Alzheimer's disease is increased to 10mg after dosing at 5mg for 4 or more weeks. The dose can be reduced to 5mg according to patients' symptoms.</u></p>

(Underlined parts are revised parts.)