



June 15, 2022

To whom it may concern:

Company Name TOHO HOLDINGS CO., LTD.
Corporate Atsushi Udoh, President and
Representative Representative Director

(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 Imatinib Tablets 100mg "KMP" for KYOSOMIRAI PHARMA

TOHO HOLDINGS CO., LTD. (Headquarters: Tokyo; President and Representative Director: Atsushi Udoh) is pleased to announce that KYOSOMIRAI PHARMA CO., LTD. (Headquarters: Tokyo; President and Representative Director: Nobuaki Hosaka), the wholly-owned subsidiary involved in pharmaceuticals manufacture and sales business, received an approval of partial amendments to indications, dosage and administration of Imatinib Tablets 100mg "KMP" on October 15, 2022 as below.

Outline of Imatinib Tablets 100mg "KMP"

Classes	Product Name	Original Brand Name
Antineoplastic agent (Tyrosine kinase inhibitor)	Imatinib Tablets 100mg "KMP"	Glivec® Tablets 100mg

## Outline of Amendments to Indications, Dosage and Administration of Imatinib Tablets 100mg "KMP"

Indications and Usage	oChronic myelogenous leukemia oKIT (CD117) positive gastrointestinal stromal tumor oPhiladelphia chromosomepositive acute lymphocytic leukemia oFIP1L1-PDGFRα-positive hypereosinophilic syndrome and/or chronic eosinophilic leukemia
Dosage and Administration	oChronic myelogenous leukemia Chronic phase: the imatinib tablet should generally be administered to adult patients orally once daily at 400 mg after a meal. The dose should be adjusted according to the patient's hematological condition and depending on the age or symptom. The dosage may be increased up to 600 mg once daily.  Transition or acute phase: the imatinib tablet should generally be administered to adult patients orally once daily at 600 mg after a meal. The dose should be adjusted according to the patient's hematological condition and depending on the age or symptom. The dosage may be increased up to 800 mg daily (400 mg twice a day).  oKIT (CD117) positive gastrointestinal stromal tumor The imatinib tablet should generally be administered to adult patients orally once daily at 400 mg after a meal. The dose should be reduced depending on the patient's age or symptom.  oPhiladelphia chromosomepositive acute lymphocytic leukemia The imatinib tablet should generally be administered to adult patients orally once daily at 600 mg after a meal. The dose should be reduced according to the patient's hematological condition and depending on the age or symptom.  oFIP1L1-PDGFRα-positive hypereosinophilic syndrome and/or chronic eosinophilic leukemia The imatinib tablet should generally be administered to adult patients orally once daily at 100 mg after a meal. The dose should be adjusted according to the patient's condition. The dosage may be increased up to 400 mg once daily.

(Underlined parts are revised parts.)