

August 8, 2022

Name of listed company: Chugai Pharmaceutical Co., Ltd.
Code number: 4519 (Prime Market of Tokyo Stock Exchange)
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Notice of the Settlement of Patent Infringement Litigation in the U.S.

[Chugai Pharmaceutical Co., Ltd.](#) (Headquarters: Tokyo, Japan, hereafter Chugai) announced that Chugai, Roche and Genentech (collectively “the Companies”) have entered into a settlement agreement with Fresenius Kabi USA, LLC (hereafter, Fresenius) on August 5, 2022 relating to the patent lawsuit filed by the Companies on March 19, 2020. In the lawsuit, the Companies alleged that the submission of an Abbreviated New Drug Application (“ANDA”) by Fresenius for a generic version of Alecensa[®] (generic name: alectinib, an ALK inhibitor, anti-cancer agent) to the U.S. Food and Drug Administration infringed Chugai’s patents in the U.S. (Nos. 9,126,931; 9,440,922; 9,365,514 and 10,350,214) under the framework of the Drug Price Competition and Patent Term Restoration Act (known as Hatch-Waxman Act). In accordance with the settlement agreement, the Companies and Fresenius will take steps to withdraw the lawsuit.

<Patent Infringement Lawsuit to be withdrawn>

Lawsuit filed at the United States District Court for the District of Delaware

Dates of Complaint: March 19, 2020 (U.S. Eastern Standard Time)

Defendant: Fresenius Kabi USA, LLC

Patents in suit: U.S. Patent Nos. 9,126,931; 9,440,922; 9,365,514 and 10,350,214

The impact on the consolidated financial results for the fiscal year ending December 2022 of Chugai is expected to be negligible.

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