Sumitomo Pharma

News Release

September 27, 2022

Sumitomo Pharma Co., Ltd.

Appeal of Inter Partes Review (IPR) USPTO Decision on the Method of Use Patent for LATUDA®

Sumitomo Pharma Co., Ltd. (Head Office: Osaka, Japan; Representative Director, President and CEO: Hiroshi Nomura; Securities Code: 4506, Prime Market of TSE) announced today that the Company has filed an appeal with the United States Court of Appeals for the Federal Circuit (CAFC) seeking revocation of the decision of the United States Patent and Trademark Office (USPTO) that the claims in the method of use patent (U.S. patent number: 9,815,827, the '827 Patent) related to the proprietary atypical antipsychotic agent LATUDA® (lurasidone HCl tablets) are unpatentable based on the Inter Partes Review (IPR) proceeding whose petition was filed with the USPTO by Slayback Pharma LLC, New Jersey, U.S.

The USPTO decision was previously reported in the press release dated December 9, 2021 available here.

The Company continues to believe the '827 Patent is valid and will continue to vigorously protect the patent rights for LATUDA®.

Because the entire process could take at least one year or more before the matter is resolved, the Company believes that the appeal will not affect its consolidated earnings for the fiscal year ending March 31, 2023.

About Inter Partes Review (IPR)

Inter Partes Review (IPR) is a proceeding before the United States Patent and Trademark Office (USPTO) where a third-party, a petitioner, filing a petition with the USPTO, challenges the validity of a U.S. patent, against the patent owner. The party who disagrees with the IPR final decision may file an appeal with the United States Court of Appeals for the Federal Circuit (CAFC) seeking revocation of the decision.

About LATUDA®

LATUDA® is an atypical antipsychotic agent with a unique chemical structure created by Sumitomo Pharma, which its U.S. subsidiary, Sunovion Pharmaceuticals Inc. has been marketing in the U.S. since February 2011. As announced by press release in November 2018, Sumitomo Pharma resolved disputes under a consolidated patent infringement lawsuit regarding Abbreviated New Drug Applications (ANDAs) for LATUDA® in the U.S. Pursuant to the settlement agreements between Sumitomo

Pharma, Sunovion and certain number of generic companies in the U.S., those companies will be permitted to distribute their generic versions of lurasidone HCl in the U.S. starting on February 20, 2023.

Disclaimer Regarding Forward-looking Statements

The statements made in this press release contain forward-looking statements based on management's assumptions and beliefs in light of information available as of the day of this release, which involve both known and unknown risks and uncertainties. Actual results of those matters covered in the forward-looking statements including financial forecast may differ materially from those contained in this release, due to a number of factors.

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