Sumitomo Dainippon Pharma

News Release

December 9, 2021

Sumitomo Dainippon Pharma Co., Ltd.

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

Sumitomo Dainippon Pharma Co., Ltd. (Head Office: Osaka, Japan; Representative Director, President and CEO: Hiroshi Nomura) announced today that the United States Patent and Trademark Office (USPTO) has decided that all of 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 (hereinafter referred to as the "decision") in the Inter Partes Review (IPR) proceeding whose petition was filed with the USPTO by Slayback Pharma LLC, New Jersey, U.S.

Sumitomo Dainippon Pharma is currently analyzing the decision and plans to seek revocation of the decision via a petition to the USPTO Director and/or appeal to the United States Court of Appeals for the Federal Circuit (CAFC) in the future.

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

Sumitomo Dainippon Pharma believes that the decision will not affect our consolidated earnings because the entire process could take more than 1.5 years in the future before it is finally resolved.

*The petition for the IPR which was filed with the USPTO was announced in a press release dated June 22, 2020.

Reference

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 seek further review of the decision by the USPTO Director and/or file an appeal with the United States Court of Appeals for the Federal Circuit (CAFC) seeking revocation of the decision. This entire process could take more than 1.5 years in the future before it is fully resolved.

About LATUDA®

LATUDA® is an atypical antipsychotic agent with a unique chemical structure created by Sumitomo Dainippon 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

Dainippon Pharma resolved disputes under a consolidated patent infringement lawsuit regarding ANDAs for LATUDA® in the U.S. Pursuant to the settlement agreements between Sumitomo Dainippon 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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