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News Release

June 22, 2020

Sumitomo Dainippon Pharma Co., Ltd.

Notice of the Filing of a Petition for Inter Partes Review (IPR) to USPTO 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 a petition for an Inter Partes Review (IPR) was filed with the United States Patent and Trademark Office (USPTO, Petitioner: Slayback Pharma LLC, New Jersey, U.S.) regarding 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).

Sumitomo Dainippon Pharma believes the '827 Patent is valid and the IPR administrative process will not materially affect our consolidated financial forecast of the fiscal year ending March 2021 and our consolidated revenues estimate of the fiscal years ending March 2022 and beyond. If there is any material development that need to be reported, Sumitomo Dainippon Pharma will make announcement on such information in a timely manner.

References

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 USPTO decides within 6 months from the accorded petition filing date, and based on the contents of the petition and a preliminary response to the petition that the patent owner may file, as to whether the Patent Trial and Appeal Board (PTAB) should commence the proceeding to hear the case. If the proceeding is instituted and not dismissed, a final written decision by the PTAB will be issued in general within a period of 1 year from the institution. During the proceeding, submission by each party of documentary response and reply, discovery and oral hearing are made and conducted for the PTAB to issue the final written decision. The party who disagrees with the PTAB's final decision may file the appeal with the United States Court of Appeals for the Federal Circuit (CAFC) for revocation of the decision, and the process could take years 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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