

November 27, 2018

Sumitomo Dainippon Pharma Co., Ltd.

## Sumitomo Dainippon Pharma Announces Resolution of Disputes under Consolidated Patent Infringement Lawsuit Regarding ANDAs for LATUDA® in the U.S.

Sumitomo Dainippon Pharma Co., Ltd. (Head Office: Osaka, Japan; Representative Director, President and CEO: Hiroshi Nomura) announced today that, as a result of settlements (the "Settlements") with remaining defendants of the consolidated patent infringement lawsuit (the "Lawsuit"), jointly filed with its U.S. subsidiary, Sunovion Pharmaceuticals Inc. ("Sunovion"), before the U.S. District Court for the District of New Jersey (the "Court") in February 2018 against a total of 16 generic companies seeking to market a generic version of their proprietary atypical antipsychotic agent, LATUDA® (lurasidone HCI), based on U.S. Patent No. 9,815,827 (the "827 Patent") and U.S. Patent No. 9,907,794 (the "794 Patent"), all disputes underlying the Lawsuit have been resolved.

After filing the Lawsuit, Sumitomo Dainippon Pharma and Sunovion had, while pursuing the Lawsuit, engaged in negotiation with defendants for settlements, following the Court's order, and the number of defendants of the Lawsuit had reduced through withdrawal and settlement agreements. As a result of the Settlements, all disputes underlying the Lawsuit have been resolved and the Lawsuit will conclude with respect to all the defendants thereof, following confirmatory procedure of the Court.

Pursuant to the Settlements and other settlement agreements entered with some of the defendants of this Lawsuit, certain number of generic companies that were parties to the Lawsuit will be permitted to distribute their generic versions of lurasidone HCL starting on February 21, 2023. Other terms and conditions of the settlement agreements will not be disclosed.

The impact of resolving the Lawsuit on Sumitomo Dainippon Pharma's consolidated financial results of the fiscal year ending March 31, 2019 is not expected to be material. We are currently evaluating the potential impact on Sumitomo Dainippon Pharma's consolidated financial results of the fiscal year ending March 31, 2020 and thereafter.

Separately, three patent infringement lawsuits remain pending in the U.S. District Court for the District of New Jersey against three generic companies, also based on the 827 Patent and the 794 Patent, which also submitted Abbreviated New Drug Applications seeking approval of a generic lurasidone HCL.



## **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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