

April 24, 2015

Sumitomo Dainippon Pharma Co., Ltd.

Sumitomo Dainippon Pharma Makes a Follow-up Announcement on the Preliminary Findings from a Phase III Clinical Study (PASTEL Study) of Lurasidone, an Atypical Antipsychotic Agent, in the Treatment of Patients with Schizophrenia

Sumitomo Dainippon Pharma Co., Ltd. (Head Office: Osaka, Japan; President: Masayo Tada; Securities Code: 4506, First Section of TSE) today made a follow-up announcement on the preliminary findings from a Phase III clinical study (PASTEL study) conducted for application for approval in Japan of lurasidone hydrochloride (generic name, "lurasidone"), an atypical antipsychotic in the treatment of patients with schizophrenia. A close analysis has shown some differences, as detailed below, from the preliminary findings that were announced in the December 25, 2014 press release.

Sumitomo Dainippon Pharma does not believe the test results would warrant approval of production and distribution of lurasidone for the treatment of patients with schizophrenia in Japan, and is now reviewing its lurasidone development policy for Japan, which will be announced as soon as decided. A Phase III clinical study conducted for application for approval of production and distribution of lurasidone for the treatment of patients with bipolar disorder in Japan will be continued as planned.

Financial impact of this development on the consolidated performance of the Company's fiscal year ending on March 31, 2016 is minor.

Differences from the preliminary findings (Changes are underlined)

By pre-specified analysis in modified ITT population* (n=439), improvements were demonstrated both for lurasidone 40 mg/day group (-17.9) and 80 mg/day group (-17.3) compared to the placebo group (-13.1) in the primary endpoint, namely, the change from baseline of the PANSS total score after 6 weeks of administration. In neither group, however, the difference was statistically significant.

At the same time, by additional analysis in the ITT population (n=450), statistically significant improvements were demonstrated for lurasidone 40 mg/day (-17.7) and lurasidone 80 mg/day (-16.8) groups compared to the placebo group (-11.9) in the primary endpoint, namely, the change from baseline of the PANSS total score after 6 weeks of administration.

For your quick reference, the corresponding portion of the December 25, 2014 announcement is shown below.

By pre-specified analysis in modified ITT population* (n=430), statistically significant improvement was demonstrated for lurasidone 40 mg/day group (-18.1) compared to the

placebo group (-13.0) in the primary endpoint, namely, the change from baseline of the PANSS total score after 6 weeks of administration. The lurasidone 80 mg/day group (-17.5) also demonstrated improvement compared to placebo but the difference was not statistically significant.

At the same time, by additional analysis in the ITT population (n=446), statistically significant improvements were demonstrated for lurasidone 40 mg/day (-17.8) and lurasidone 80 mg/day (-17.3) groups compared to the placebo group (-12.1) in the primary endpoint, namely, the change from baseline of the PANSS total score after 6 weeks of administration.

* Any scores that were evaluated within 12 hours after the use of lorazepam or hypnotic drugs were excluded.

Contact:

Corporate Communications

Sumitomo Dainippon Pharma

TEL: +81-6-6203-1407 (Osaka)

+81-3-5159-3300 (Tokyo)