Sumitomo Dainippon Pharma

News Release

January 26, 2017

Sumitomo Dainippon Pharma Co., Ltd.

Sumitomo Dainippon Pharma Completes Acquisition of Tolero Pharmaceuticals, Inc. (US Biotechnology Company)

Sumitomo Dainippon Pharma Co., Ltd. (Head office: Osaka, Japan; President: Masayo Tada; Securities Code: 4506, First Section of TSE, "Sumitomo Dainippon Pharma") announced today that it has completed the acquisition of Tolero Pharmaceuticals, Inc. (Head office: Lehi, UT, U.S., CEO: David J. Bearss, "Tolero") as of January 25, 2017 (U.S. Pacific Standard Time).

Through this transaction, Sumitomo Dainippon Pharma has acquired six compounds, including a cyclin-dependent kinase 9 (CDK9) inhibitor alvocidib, which is under clinical development by Tolero for the treatment of hematologic malignancies, and has strengthened its development pipeline in oncology, one of its focus therapeutic areas. Alvocidib is currently being investigated in a Phase 2 study for biomarker-positive patients with acute myeloid leukemia (AML) in the U.S., and a New Drug Application (NDA) is expected to be submitted to the U.S. Food and Drug Administration (FDA) in fiscal 2018 at the earliest.

Going forward, Sumitomo Dainippon Pharma, Boston Biomedical and Tolero will collaborate in drug discovery activities and we, as part of the Sumitomo Dainippon Pharma group, will aim to create a continuous flow of innovative products in the oncology area. David J. Bearss will continue to serve as the CEO of Tolero, as he did prior to the acquisition.

A description of this acquisition was disclosed in the announcement "Sumitomo Dainippon Pharma to Acquire Tolero Pharmaceuticals, Inc. (US Biotechnology Company)" made on December 21, 2016.

(Reference)

About Cyclin-dependent kinase (CDK) 9 inhibitor; alvocidib

Alvocidib targets CDK9, a member of the cyclin-dependent kinase family, which activates the transcription of cancer-related genes. The subsequent down-regulation of MCL-1, an anti-apoptotic gene, may be responsible for the potential clinical anti-cancer activity observed with alvocidib.
Alvocidib is an investigational intravenous small-molecule agent and has received Orphan Drug Designation from the U.S. Food and Drug Administration (FDA) and European Medicines Agency (EMA) for the treatment of acute myeloid leukemia (AML). The National Cancer Institute (NCI) conducted alvocidib's Phase 2 study（J-1101/NCI-8972, Haematologica 2015;100(9)）comparing the ACM regimen (alvocidib, cytarabine and mitoxantrone) to the standard-of-care (cytarabine and

daunorubicin) in frontline AML patients who had one or more poor-risk features. In this study, the ACM regimen (alvocidib combination therapy) demonstrated a statistically significant improvement in the complete remission (CR) rate, one of primary endpoints for AML therapy, compared to the standard-of-care, 70% and 46%, respectively. Moreover, the tolerability of both regimens was similar.

Alvocidib is licensed from Sanofi S.A. (Head office: France) to Tolero for exclusive worldwide rights to develop and commercialize. Torelo will make payments to Sanofi on the successful achievement of milestones related to the commercialization and pay tiered royalties on sales of alvocidib.

Disclaimer Regarding Forward-looking Statements

The statements made in this press release are forward-looking statements based on management's assumptions and beliefs in light of the information available up until the day of the announcement, and involve both known and unknown risks and uncertainties.

Actual financial results may differ materially from those presented in this document; as such results are dependent on a number of factors. Information concerning pharmaceuticals (including compounds under development) contained within this press release is not intended as advertising or medical advice.

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