December 21, 2016

Sumitomo Dainippon Pharma Co., Ltd.

Sumitomo Dainippon Pharma to Acquire 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 the company and Tolero Pharmaceuticals, Inc. (Head office: Lehi, UT, U.S., CEO: David J. Bearss., "Tolero") have reached an agreement on December 21, 2016 on the acquisition of Tolero through U.S. Holding company wholly owned by Sumitomo Dainippon Pharma.

According to the terms of the agreement, Sumitomo Dainippon Pharma will make an upfront payment of US$ 200 million to the shareholders of Tolero on closing of the acquisition, and thereafter it will make development milestone payments up to US$ 430 million related to the compounds being developed by Tolero based on its progress. Furthermore, after the launch, Sumitomo Dainippon Pharma will also make commercial milestone payments up to US$ 150 million, based on the net sales of the compounds.

1. Objectives of acquisition

Tolero is a biotechnology company in the U.S. specializing in research and development of therapeutic agents in the areas of oncology and hematological disorders. Tolero possesses excellent drug discovery capabilities for kinase inhibitors and other drug targets, and is developing the six compounds below, including cyclin-dependent kinase 9 (CDK9) inhibitor alvocidib, which is under clinical development for hematologic malignancies.

Compound	Mechanism	Stage
alvocidib	CDK9 inhibitor	Phase 2 study completed / Acute myeloid leukemia
		Phase 2 study ongoing / Acute myeloid leukemia with biomarker
		Preclinical Myelodysplastic syndromes with biomarker
TP-0903	AXL Kinase inhibitor	Phase 1 study ongoing / Solid tumors
TP-1287	Oral CDK9 inhibitor	Preclinical
TP-0184	ALK2 inhibitor	Preclinical

In addition to the above list, Tolero possesses two compounds in the preclinical stage.

Torelo has demonstrated POC (Proof of Concept) of alvocidib in a randomized Phase 2 study for acute myeloid leukemia (AML). Tolero is also currently conducting a Phase 2 study for

biomarker-positive patients of the disease in the U.S. Tolero aims for a New Drug Application to the FDA in fiscal 2018 at the earliest.

Masayo Tada, Representative Director, President and CEO of Sumitomo Dainippon Pharma, stated that “Oncology, which is one of our focus therapeutic areas, has extremely high unmet medical needs, and we believe that it is the vital mission of any R&D-oriented pharmaceutical company to deliver innovative treatment options to patients and their families. As Tolero possesses a group of attractive development compounds, including alvocidib, we expect that this acquisition will help us to reinforce our oncology pipeline and achieve sustained growth of the Sumitomo Dainippon Pharma Group after the expiry of the exclusivity period of our mainstay atypical antipsychotic LATUDA®. Now that Tolero’s high drug discovery abilities are on our side, we also expect to create a continuous flow of development compounds going forward.”

2. Outline of the acquisition

After the acquisition, Tolero will become a wholly-owned subsidiary of Dainippon Sumitomo Pharma America Holdings, Inc. (Head office: MA, U.S., “Holding company”), a holding company wholly-owned by Sumitomo Dainippon Pharma, and continue its research and development in Lehi, Utah. The boards of directors of Sumitomo Dainippon Pharma and Tolero have each approved this acquisition. However, fulfillment of the terms and conditions of the U.S. Antitrust Law and completion of statutory procedures (including approval from Tolero’s shareholders) are required to complete the acquisition. After completion of these procedures, the acquisition is expected to be deemed closed in February 2017. In this transaction, Lazard Frères K.K. serves as Sumitomo Dainippon Pharma’s financial advisor and Jones Day’s Tokyo Office serves as its legal advisor.

The acquisition will be implemented by way of a merger between Tolero and a special purpose company which has been established under the Holding company for facilitating this deal. Tolero will be the surviving company. The existing shareholders of Tolero will receive cash in compensation for the merger.

3. Outline of Tolero

(1)	Company Name	Tolero Pharmaceuticals, Inc.
(2)	Address of Headquarters	2975 Executive Parkway　Suite # 320　Lehi, UT 84043, U.S.
(3)	Representative	CEO：David J. Bearss
(4)	Business Description	Research and Development of pharmaceuticals in the areas of oncology and hematological disorders.
(5)	Share Capital	US$ 866 (As of December 14,2016)
(6)	Date Established	June 2011
(7)	Major shareholders and shareholding ratio	David J. Bearss (22.1%), Orelot LLC (15.2%), Alger Health Sciences Fund（8.9%）and others (As of December 14, 2016) ※

(8) Relationship with Sumitomo Dainippon Pharma	Nothing particular in terms of capital tie, personal connection. In November 2016, Sumitomo Dainippon Pharma and Tolero entered into a loan agreement (where Sumitomo Dainippon Pharma is a creditor) with the upper limit being set at US$ 6 million.

(9) Financial status for recent business years (consolidated)

Fiscal Year (US$)	FY2013	FY2014	FY2015
Shareholder's equity	△7,691thousand	△14,461 thousand	△25,473 thousand
Total assets	844 thousand	13,172 thousand	3,546 thousand
Shareholder's equity per share	△0.9	△1.7	△2.9
Revenue	142 thousand	―	―
Operating profit	△2,958 thousand	△4,557 thousand	△9,742 thousand
Net income	△4,473 thousand	△6,328 thousand	△9,340 thousand
Earnings per share	△0.5	△0.7	△1.1
Dividend per share	―	―	―

※ Shown the name of the representative investor and shareholding ratio of aggregate amount of shares jointly held by the joint holders where applicable

4. Number of owned shares and percentage of ownership before and after acquisition

(1) Number of shares already acquired	0 shares Percentage of voting rights: 0%
(2) Number of shares to be acquired	100 shares ※Note 1 Percentage of voting rights: 100% (Planned)
(3) Total value for the acquisition	Approximately up to US$ 780 million ※Note 2 Details: Upfront payment: US$ 200 million Development and commercial milestone: up to US$ 580 million

Note 1: This acquisition will be made through a cash merger. Sumitomo Dainippon Pharma will not acquire Tolero' shares because all outstanding shares of Tolero will be extinguished in exchange for cash payment to existing shareholders as consideration for the merger.

Note 2: Total value for the acquisition does not include advisory fees and so forth (approximately ￥700 million).

5. Schedule

(1) Sumitomo Dainippon Pharma's Board Meeting Resolution	December 21, 2016
(2) Signing Date	December 21, 2016
(3) Completion of Acquisition	February, 2017 (will be completed) ※

※ As stated in (2) above, fulfillment of the terms and conditions of the U.S. Antitrust Law and

the completion of statutory procedures (including approval from Tolero's shareholders) are required to complete the acquisition.

6. Financial impact on group performance

Financial impact on the Sumitomo Dainippon Pharma's consolidated financial results for fiscal year ending March 31, 2017 and beyond is currently under review. We will make an announcement if any other disclosure is required.

(Reference)

Cyclin-dependent kinase (CDK) 9 inhibitor; alvocidib

Alvocidib targets CDK9, a member of cyclin-dependent kinase family, which activates 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 it received Orphan Drug Designation from the U.S. Food and Drug Administration (FDA) and European Medicines Agency (EMA) in the treatment of acute myeloid leukemia (AML). National Cancer Institute (NCI) conducted alvocidib's Phase 2 study（J-1101/NCI-8972, Haematologica 2015;100(9)） comparing ACM regimen (alvocidib, cytarabine and mitoxantrone) to the standard-of-care (cytarabine and daunorubicin), in front line AML patients who had one or more poor-risk features. In this study, 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.

Torelo is also developing TP-1287 (oral delivery), a prodrug of alvocidib.

AXL receptor tyrosine kinase inhibitor; TP-0903

AXL is known to be involved in acquiring resistance to conventional agents and developing metastatic capacity in cancer cells. TP-0903 targeting AXL is a potential anti-cancer agent for a variety of cancer types.

ALK2 inhibitor; TP-0184

TP-0184 inhibits enzymatic activity of activin receptor-like kinase-2(ALK2）, a member of bone morphogenetic protein (BMP) receptor family, leading to decreased expression of hepcidin, which is a circulating peptide overexpressed in hepatic cells in response to chronic inflammation related to cancer and auto immune diseases. TP-0184 has a potential to ameliorate anemia of

chronic disease.

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 information available up to the day of announcement, and involve both known and unknown risks and uncertainties.
Actual financial results may differ materially from those presented in this document, being 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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