Sumitomo Dainippon Pharma Oncology Announces First Patient Dosed in Phase 1 Dose Expansion Study of TP-1287 in Patients with Sarcoma

CAMBRIDGE, Mass., November 3, 2021 – Sumitomo Dainippon Pharma Oncology, Inc., a clinical-stage company focused on research and development for novel cancer therapeutics, today announced that the first patient has been dosed in the Phase 1 dose expansion portion of the study evaluating the investigational agent TP-1287, an oral cyclin-dependent kinase 9 (CDK9) inhibitor, in patients with sarcoma.

The Phase 1 open-label study consists of two parts, dose escalation and dose expansion. The dose escalation portion of the study established the maximum tolerated dose (MTD) and recommended Phase 2 Dose (RP2D) of TP-1287 in patients with advanced metastatic or progressive solid tumors. The dose expansion portion of the study will evaluate the potential antitumor activity and safety of TP-1287 in patients with Ewing sarcoma (EWS), dedifferentiated liposarcoma (DDLPS) and synovial sarcoma (SS).

“Patients with sarcoma currently face a significant unmet need and have limited treatment options. The dose expansion of TP-1287 provides an opportunity for us to evaluate this treatment and its potential benefits for this patient population,” said Patricia S. Andrews, Chief Executive Officer, Global Head of Oncology, Sumitomo Dainippon Pharma Oncology, Inc (SDP Oncology). “Furthermore, this is an important step forward for our Phase 1 trial as we continue to evaluate TP-1287’s safety and efficacy.”

The primary objective of the Phase 1 dose expansion portion of the study is to evaluate the preliminary antitumor activity of TP-1287 in terms of objective response rate (ORR) when administered at the RP2D in patients with sarcoma subtypes. The secondary objectives are to determine the progression-free survival (PFS), PFS rate at 16 weeks and PFS rate at 24 weeks following first administration of TP-1287 in patients with the defined sarcoma subtypes and evaluate the safety of TP-1287 when administered at the RP2D in patients with the defined sarcoma subtypes.

The study is being conducted at sites in the United States. Additional information on this trial, including comprehensive inclusion and exclusion criteria, can be accessed at www.ClinicalTrials.gov (NCT03604783).

About TP-1287

TP-1287 is an investigational oral CDK9 inhibitor that has shown favorable oral bioavailability in preclinical models. TP-1287 is enzymatically cleaved, yielding the active moiety, a potent inhibitor of CDK9.[1] Inhibiting CDK9 is thought to downregulate the transcription of target genes, including MCL-1, reducing leukemic blast viability in MCL-1–dependent hematologic malignancies, and c-MYC, an important oncogene across multiple tumor types.[2,3,4] TP-1287 is currently being evaluated in a Phase 1 study in patients with advanced solid tumors (NCT03604783).

About Sumitomo Dainippon Pharma Oncology

Sumitomo Dainippon Pharma Oncology, Inc., is a wholly owned subsidiary of Sumitomo Dainippon Pharma Co., Ltd. As a global oncology organization with teams in the U.S. and Japan, SDP Oncology is relentlessly committed to advancing purposeful science by transforming new discoveries into meaningful treatments for patients with cancer. SDP

Oncology's robust and diverse pipeline of preclinical and advanced-stage assets spans multiple areas, including oncogenic pathways, survival mechanisms and novel protein interactions, which aim to address unmet clinical needs in oncology.

For more information, visit www.sdponcology.com.

About Sumitomo Dainippon Pharma

Sumitomo Dainippon Pharma is among the top-10 listed pharmaceutical companies in Japan, operating globally in major pharmaceutical markets, including Japan, the U.S., China and other Asian countries. Sumitomo Dainippon Pharma aims to create innovative pharmaceutical products in the Psychiatry & Neurology area, the Oncology area and Regenerative medicine/Cell therapy field, which have been designated as the focus therapeutic areas. Sumitomo Dainippon Pharma is based on the merger in 2005 between Dainippon Pharmaceutical Co., Ltd., and Sumitomo Pharmaceuticals Co., Ltd. Today, Sumitomo Dainippon Pharma has more than 7,000 employees worldwide. Additional information about Sumitomo Dainippon Pharma is available through its corporate website at www.ds-pharma.com.

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This press release contains "forward-looking statements," as that term is defined in the Private Securities Litigation Reform Act of 1995 regarding the research, development and commercialization of pharmaceutical products. The forward-looking statements in this press release are based on management's assumptions and beliefs in light of information presently available and involve both known and unknown risks and uncertainties. Any forward-looking statements set forth in this press release speak only as of the date of this press release. We do not undertake to update any of these forward-looking statements to reflect events or circumstances that occur after the date hereof. Information concerning pharmaceuticals (including compounds under development) contained within this material is not intended as advertising or medical advice.

References

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