

Sumitomo Dainippon Pharma Oncology Announces First Patient Dosed in Phase 1 Study of DSP-0390 in Patients with Recurrent High-Grade Glioma

CAMBRIDGE, Mass., October 21, 2021 – Sumitomo Dainippon Pharma Oncology, Inc., a clinical-stage company focused on research and development for novel cancer therapeutics, today announced the first patient has been dosed in a Phase 1 study evaluating its investigational agent DSP-0390, an emopamil-binding protein (EBP) inhibitor, for the treatment of patients with recurrent high-grade glioma.

High grade gliomas are the most common type of malignant brain tumor and cause significant morbidity and mortality.¹ Preclinical studies have shown DSP-0390 may have anti-tumor activity that may help address this persistent unmet medical need.

"Dosing the first patient in this study represents another important milestone for SDP Oncology and broadens our fight against brain tumors along with our investigational agent WT1 immunotherapeutic cancer vaccine," said Patricia S. Andrews, Chief Executive Officer and Global Head of Oncology, Sumitomo Dainippon Pharma Oncology (SDP Oncology). "We look forward to generating data to guide the development of DSP-0390 with the goal of developing meaningful treatments for patients with brain cancer."

The primary objective of the first-in-human, open-label, dose-escalation study is to assess the safety and tolerability of DSP-0390 in patients with recurrent high-grade glioma. The trial will also determine the maximum tolerated dose (MTD) and/or recommended dose for expansion (RDE). The secondary objective is to characterize the pharmacokinetic (PK) profile of DSP-0390.

Following the completion of the dose-escalation portion of the trial, the study will move into a Part 2 expansion to evaluate whether there is preliminary antitumor activity of DSP-0390 and establish the recommended Phase 2 dose (RP2D) in recurrent World Health Organization (WHO) Grade III or IV malignant glioma.

The trial is being conducted in the United States and Japan. Additional information, including comprehensive inclusion and exclusion criteria, can be accessed at www.ClinicalTrials.gov ([NCT05023551](https://clinicaltrials.gov/ct2/show/study/NCT05023551)).

About DSP-0390

DSP-0390 is an emopamil-binding protein (EBP) inhibitor, that is currently being investigated in a Phase 1 study in patients with recurrent high-grade glioma ([NCT05023551](https://clinicaltrials.gov/ct2/show/study/NCT05023551)). EBP is an endoplasmic reticulum membrane protein involved in cholesterol biosynthesis.² Since most cancer cells are characterized by an upregulation of the various pathways responsible for their biosynthesis and the demand for cholesterol to support cell proliferation is high,^{3,4,5} the inhibition of EBP by DSP-0390 therefore is expected to lead to disruption of cholesterol homeostasis and induce cell death in cancer cells.^{6,7} Moreover, as EBP is reported to be highly expressed in several types of cancer and correlates with an aggressive phenotype of certain types of cancers, DSP-0390 has the potential to have anti-tumor activity in these cancers.^{8,9}

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.

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