Sumitomo Dainippon Pharma

News Release

December 15, 2021

Sumitomo Dainippon Pharma Co., Ltd.

Sumitomo Dainippon Pharma Announces Phase 3 Study of Investigational Cancer Vaccine DSP-7888 in Patients with Glioblastoma Terminates

Sumitomo Dainippon Pharma Co., Ltd. (Head Office: Osaka, Japan; Representative Director, President, and CEO: Hiroshi Nomura) and Sumitomo Dainippon Pharma Oncology, Inc. announce today that the Phase 3 WIZARD 201G study of investigational cancer vaccine DSP-7888 (development code; generic name, adegramotide/nelatimotide; hereafter, "DSP-7888") in patients with recurrent or progressive glioblastoma (GBM) will terminate following its second interim analysis after determining there is a low probability of meeting the primary endpoint of overall survival (OS) at the final analysis.

This study evaluated the safety and efficacy of DSP-7888, an investigational WT1 immunotherapeutic cancer vaccine, in combination with bevacizumab versus bevacizumab alone in patients with recurrent or progressive GBM following initial therapy. Patients were randomized 1:1 in the study with an enrollment planned for 338 patients. The second interim analysis was done at 185 events for evaluating OS and no new safety concerns were identified by the Independent Data Monitoring Committee (IDMC).

The phase 1/2 study of DSP-7888 in combination with checkpoint inhibitors in solid tumors will continue as planned.

The impact of this matter on our consolidated earnings results for the year ending March 31, 2022 will be minimal.

References

About DSP-7888

DSP-7888 is an investigational WT1 immunotherapeutic cancer vaccine containing two peptides that induce WT1-specific cytotoxic T-lymphocytes (WT1-CTL) and helper T-cells to attack WT1-expressing cancerous cells found in various types of hematologic and solid tumors. Researchers have identified that adding a peptide to induce helper T-cells may improve outcomes compared to a treatment regimen based on a killer peptide alone.

The Phase 3 WIZARD 201G study is a global, multicenter, randomized, adaptive study (estimated enrollment number of patients: 338; NCT03149003) being conducted in the United States, Japan and other countries in patients with recurrent or progressive glioblastoma (GBM). In addition, DSP-7888 is in a Phase 1/2 study (estimated enrollment number of patients: 84; NCT03311334) in the United States in combination with nivolumab or pembrolizumab in patients with advanced solid tumors with a Phase 2 expansion arm in platinum-resistant ovarian cancer in combination with

pembrolizumab. In 2017, the FDA granted Orphan Drug Designations for DSP-7888 in brain cancer and in myelodysplastic syndrome (MDS).

Contact:
Corporate Communications
Sumitomo Dainippon Pharma Co., Ltd.
TEL: +81-6-6203-1407 (Osaka); +81-3-5159-3300 (Tokyo)