Passion for Innovation.
Compassion for Patients.™

Daiichi-Sankyo

Press Release

DS-7300 Phase 2 Trial Initiated in Patients with Pretreated Extensive-Stage Small Cell Lung Cancer

Tokyo and Basking Ridge, NJ – (July 20, 2022) – Daiichi Sankyo (TSE: 4568) announced today that the first patient has been dosed in a global phase 2 trial evaluating the efficacy and safety of DS-7300 in patients with pretreated extensive-stage small cell lung cancer (SCLC). DS-7300 is a specifically designed potential first-in-class B7-H3 directed antibody drug conjugate (ADC) discovered and being developed by Daiichi Sankyo.

Lung cancer is the second most common cancer and the leading cause of cancer-related deaths worldwide, with up to 14% being classified as SCLC in the U.S.[1,2] Most patients with SCLC are diagnosed with extensive-stage disease and have a 5-year survival rate as low as 3%, highlighting the significant unmet need for more effective treatment options.[3,4,5,6,7] B7-H3 is overexpressed in a wide range of cancer types, including SCLC, and its overexpression has been shown to correlate with poor prognosis in some cancers, making B7-H3 a promising therapeutic target.[8,9,10,11,12,13]

"Patients with pretreated extensive-stage small cell lung cancer have limited treatment options following disease progression," said Gilles Gallant, BPharm, PhD, FOPQ, Senior Vice President, Global Head, Oncology Clinical Development, Oncology R&D, Daiichi Sankyo. "Based on the encouraging results seen in the ongoing phase 1/2 trial, we have initiated this phase 2 trial of DS-7300 to further evaluate whether targeting B7-H3 with our DXd antibody drug conjugate technology may become a potential treatment option for patients with extensive-stage small cell lung cancer."

About the Phase 2 Trial

This global phase 2 trial is evaluating the efficacy and safety of two doses (8 mg/kg or 12 mg/kg) of DS-7300 in patients with histologically or cytologically confirmed extensive-stage SCLC that received at least one prior line of platinum-based chemotherapy.

Patients will be randomized 1:1 to receive either 8 mg/kg or 12 mg/kg of DS-7300. The primary endpoint of the trial is objective response rate (ORR) as assessed by blinded independent central review. Secondary endpoints include progression-free survival, duration of response, overall survival, time to response, disease

control rate, investigator-assessed ORR, pharmacokinetics, immunogenicity and safety. The trial will enroll approximately 80 patients across Asia, Europe and North America. For more information about this trial, please visit ClinicalTrials.gov.

About B7-H3

B7-H3 is a transmembrane protein that belongs to the B7 family, which also includes PD-L1. B7-H3 is overexpressed in a wide range of cancer types, including SCLC, squamous non-small cell lung cancer, and prostate cancer. B7-H3 overexpression has been shown to correlate with poor prognosis in some cancers, making B7-H3 a promising therapeutic target.[8,9,10,11,12,13] Currently, no B7-H3 directed medicines are approved for the treatment of any cancer.

About Small Cell Lung Cancer

Lung cancer is the second most common cancer and the leading cause of cancer-related deaths worldwide with up to 14% being classified as SCLC in the U.S.[1,2] Extent of disease at initial diagnosis of SCLC is an important prognostic factor, as the 5-year survival rate is approximately 30% for patients with localized disease compared with only 3% of patients with extensive-stage disease.[14]

First-line standard of care for patients with extensive-stage SCLC consists of platinum-based chemotherapy with or without immunotherapy, depending on local availability.[15] Treatment options beyond first-line have limited efficacy and are associated with rapid disease progression and high rates of hematologic toxicity, highlighting the unmet need for novel therapies.[16]

About DS-7300

DS-7300 is an investigational B7-H3 directed ADC and is one of five ADCs currently in clinical development in the oncology pipeline of Daiichi Sankyo. Designed using Daiichi Sankyo's proprietary DXd ADC technology, DS-7300 is comprised of a humanized anti-B7-H3 IgG1 monoclonal antibody attached to a number of topoisomerase I inhibitor payloads (an exatecan derivative, DXd) via tetrapeptide-based cleavable linkers.

In addition to the phase 2 trial in extensive-stage SCLC, DS-7300 is being evaluated in a phase 1/2 trial in collaboration with the Sarah Cannon Research Institute in three cohorts of patients with metastatic squamous non-small cell lung cancer, esophageal squamous cell carcinoma and castration-resistant prostate cancer.

DS-7300 is an investigational medicine that has not been approved for any indication in any country. Safety and efficacy have not been established.

About Daiichi Sankyo

Daiichi Sankyo is dedicated to creating new modalities and innovative medicines by leveraging our world-class science and technology for our purpose "to contribute to the enrichment of quality of life around the world." In addition to our current portfolio of medicines for cancer and cardiovascular disease, Daiichi Sankyo is primarily focused on developing novel therapies for people with cancer as well as other diseases with high unmet medical needs. With more than 100 years of scientific expertise and a presence in more than 20 countries, Daiichi Sankyo and its 16,000 employees around the world draw upon a rich legacy of innovation to realize our 2030 Vision to become an "Innovative Global Healthcare Company Contributing to the Sustainable Development of Society." For more information, please visit: www.daiichisankyo.com.

Media Contacts:

Global/US:
Sarah McGovern
Daiichi Sankyo, Inc.
smcgovern@dsi.com
+1 908 821 7376 (mobile)

Japan:
Masashi Kawase
Daiichi Sankyo Co., Ltd.
kawase.masashi.a2@daiichisankyo.co.jp
+81 3 6225 1126 (office)

Investor Relations Contact:
DaiichiSankyoIR@daiichisankyo.co.jp

References:

[1] World Health Organization. International Agency for Research on Cancer. *Lung Fact Sheet.* Accessed July 2022.
[2] American Cancer Society. *Cancer Facts & Figures 2022*. Accessed July 2022.
[3] Früh M, et al. *Ann Oncol*. 2013;24(suppl 6):vi99-vi105.
[4] Chen P, et al. *Transl Lung Cancer Res*. 2020;9(3):768-786.
[5] Hiddinga BI, et al. *Eur Respir Rev.* 2021;30(161):210079.
[6] Saltos A, et al. *Front. Oncol*. 2020;10:1074.
[7] Karachaliou N, et al. *Transl Lung Cancer Res*. 2016;5(1):2-15.
[8] Yamato M, et al. *Mol Cancer Ther.* 2022;21:635–46.
[9] Dong P, et al. *Front Oncol*. 2018;8:264.
[10] Picarda E, et al. *Clin Cancer Res*. 2016;22(14):3425-3431.
[11] Bendell JC, et al. *J Clin Oncol*. 2020;39(15 suppl 1). Abstract TPS3646.
[12] Kontos F, et al. *Clin Cancer Res*. 2021;27(5):1227-1235.
[13] Qiu M-j, et al. *Front. Oncol*. 2021;11:600238.
[14] SEER Small Cell Carcinoma of the Lung and Bronchus SEER 5-Year Relative Survival Rates. Data from SEER 2012-2018.
[15] Horn L, et al. *N Engl J Med*. 2018; 379:2220-2229.
[16] Patel S, et al. *Ther Adv Med Oncol*. 2021;13:17588359211020529.