Innovation all for the patients

CHUGAI

Roche A member of the Roche group

Results from the Investigator-Initiated Phase I Study of RAF/MEK Inhibitor, CKI27 Published in the Lancet Oncology Online

TOKYO, October 29, 2020 -- Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519; hereinafter "Chugai") announced that results from the investigator-initiated phase I study of RAK/MEK inhibitor, CKI27 (VS-6766) conducted in the U.K. was published on October 28, 2020 (local time) in the online version of the Lancet Oncology. CKI27 is out-licensed from Chugai to Verastem Oncology, a U.S.-based company.

"Intermittent schedules of the oral RAF–MEK inhibitor CH5126766/VS-6766 in patients with RAS/RAF-mutant solid tumours and multiple myeloma: a single-centre, open-label, phase 1 dose-escalation and basket dose-expansion study"
https://www.thelancet.com/journals/lanonc/article/PIIS1470-2045(20)30464-2/fulltext

The study was an investigator-initiated study in patients with RAS/RAF-mutated solid tumors and multiple myeloma, conducted at The Institute of Cancer Research, London, and The Royal Marsden NHS Foundation Trust in the U.K. It consisted of two parts; 1) dose escalation part to determine the recommended dosage (29 patients) and 2) basket expansion part to investigate efficacy and safety of the recommended dosage determined in the dose escalation part (29 patients).

The recommended dosage were determined to be 4 mg/day twice weekly in the dose escalation part. In the subsequent basket expansion part, 7 of 26 evaluable patients (26.9%) achieved objective responses. All patients with KRAS-mutation had non-G12C mutations. The most common treatment-related adverse events occurred as grade 3 or higher based on CTCAE v4.0 (the Common Terminology Criteria for Adverse Events provided by the U.S. National Cancer Institute) was skin rash, which developed in 11 of 57 evaluable patients (19.3%). No treatment-related death occurred. The results of the study were announced in the 53rd American Society of Clinical Oncology Annual Meeting (June, 2017).

CKI27 (VS-6766) is a new oral RAF/MEK inhibitor. Under the global licensing agreement concluded in January, 2020, clinical development of CKI27 is being conducted by Verastem Oncology under the name of VS-6766.

Chugai, which aims at becoming a top innovator in the healthcare industry, continues to pursue science and proprietary technology and promote open innovation including collaboration with academia, to contribute for patients across the world through innovative drugs.

CHUGAI PHARMACEUTICAL CO., LTD. Corporate Communications Dept.
1-1, Nihonbashi-Muromachi 2-chome, Chuo-ku Tokyo, 103-8324 Japan
Media Relations Group TEL:+81-(0)3-3273-0881 E-mail:pr@chugai-pharm.co.jp
Investor Relations Group TEL:+81-(0)3-3273-0554 E-mail:ir@chugai-pharm.co.jp

[Reference]
Chugai Announces Global Licensing Agreement with Verastem Oncology for RAF/MEK Inhibitor CKI27 (VS-6766) (Press release issued on January 9, 2020)
https://www.chugai-pharm.co.jp/english/news/detail/20200109100000_680.html

###