Innovation all for the patients

CHUGAI

Roche A member of the Roche group

Phase III IPATential150 Study Evaluating Ipatasertib in Combination with Abiraterone and Prednisone/Prednisolone in Patients with Metastatic Castration-Resistant Prostate Cancer Meets One of Its Co-Primary Endpoint

- Ipatasertib in combination with abiraterone and prednisone/prednisolone showed an improvement in radiographic progression-free survival as an initial treatment for patients with metastatic castration-resistant prostate cancer whose tumor had PTEN loss compared with abiraterone and prednisone/prednisolone in the phase III IPATential150 study
- Safety of the combination of ipatasertib, abiraterone and prednisone/prednisolone was consistent with previous analyses and known risks

TOKYO, June 19, 2020 -- Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) announced that the phase III IPATential 150 study, evaluating ipatasertib in combination with abiraterone and prednisone/prednisolone as an initial treatment for metastatic castration-resistant prostate cancer (mCRPC) met one of its co-primary endpoints of radiographic progression-free survival (rPFS) in patients whose tumor had PTEN loss.

Ipatasertib in combination with abiraterone and prednisone/prednisolone showed a statistically meaningful improvement in rPFS in patients with mCPRC whose tumor had PTEN loss which was defined as a co-primary endpoint of the study compared with the current standard of care, abiraterone and prednisone/prednisolone. The other co-primary endpoint of rPFS in the intent-to-treat (ITT) population was not met. Safety of the combination therapy of ipatasertib, abiraterone and prednisone/prednisolone was consistent with previous analyses and known risks. Data from the IPATential 150 study will be presented at an upcoming medical meeting. While the overall survival benefit and additional secondary endpoints are not yet mature, the study will continue until the next planned analysis.

“We are very pleased that ipatasertib in combination with abiraterone and prednisone/prednisolone showed positive results in a pivotal study with mCRPC patients,” said Dr. Osamu Okuda, Chugai’s President, COO. “Treatments with new mode of action are awaited for mCRPC which is resistant to or recurrent after the standard of care hormonal therapy. We will be working together with Roche to provide patients with this new treatment option as early as possible.”

About IPATential150 study[1]

IPATential150 is a multi-center, double-blind, placebo-controlled randomized phase III study in adult male patients with asymptomatic or mildly symptomatic, previously untreated mCRPC investigating the efficacy and safety of ipatasertib in combination with abiraterone and prednisone/prednisolone. Patients were randomized in a 1:1 ratio to receive either ipatasertib in combination with abiraterone

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

and prednisone/prednisolone or abiraterone and prednisone/prednisolone. Co-primary endpoints were investigator-assessed rPFS in the ITT population and a subpopulation whose tumors have PTEN loss, as assessed by immunohistochemistry (Ventana assay). PFS in the study is defined as the time from date of randomization to the first occurrence of disease progression or death from any cause, whichever occurs earlier. Secondary endpoints include overall survival (OS), safety, time to pain progression (TPP), time to initiation of cytotoxic chemotherapy and time to function deterioration.

[Reference]

1: ClinicalTrials.gov. Ipatasertib plus abiraterone plus prednisone/prednisolone, relative to placebo plus abiraterone plus prednisone/prednisolone in adult male patients with metastatic castrate-resistant prostate cancer (IPATential150). [Internet; cited June 2020]. Available from: https://clinicaltrials.gov/ct2/show/record/NCT03072238?term=ipatential150&draw=2&rank=1

###