Innovation all for the patients

CHUGAI

Roche A member of the Roche group

Chugai Obtains Approval for Anti-PD-L1 Antibody, "TECENTRIQ®" for Additional Dosing of the Treatment of Unresectable, Advanced or Recurrent Non-small Cell Lung Cancer

TOKYO, December 21, 2018 -- Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) announced today that it has obtained regulatory approval for its humanized anti-PD-L1 monoclonal antibody, "TECENTRIQ® Intravenous Infusion 1200 mg" (generic name: atezolizumab [genetical recombination]) from the Ministry of Health, Labour and Welfare (MHLW) for additional dosing for the treatment of "previously untreated unresectable advanced or recurrent non-squamous non-small cell lung cancer (NSCLC)."

"Following the approval for previously treated NSCLC obtained in January, 2018, we are pleased to gain another approval which enables us to provide a new treatment option as an initial treatment for patients with advanced or recurrent non-squamous NSCLC," said Dr. Yasushi Ito, Chugai's Executive Vice President, Co-Head of Project & Lifecycle Management unit. "Chugai has been conducting five clinical studies in NSCLC in Japan to evaluate TECENTRIQ alone or in combination with other drugs. We are committed to work closely with Roche to provide patients with as many new treatment options as possible to meet their needs."

This approval is based on results from the Phase III IMpower150 study, which showed that TECENTRIQ in combination with AVASTIN® and chemotherapy helped people live significantly longer, compared to AVASTIN and chemotherapy. The safety profile of the TECENTRIQ combination was consistent with the safety profiles of the individual medicines, and no new safety signals were identified with the combination.

[Reference]

Press release issued by Roche on May 17, 2018

Phase III IMpower150 study showed Roche's Tecentriq and Avastin plus carboplatin and paclitaxel helped people with a specific type of metastatic lung cancer live significantly longer compared to Avastin plus carboplatin and paclitaxel

https://www.roche.com/media/releases/med-cor-2018-05-17.htm

In Japan, the annual prevalence of lung cancer is estimated to be approximately 134,000 in 2015 (male: 91,000, female: 43,000). The annual mortality of lung cancer, the leading cause of cancer death in Japan, is approximately 77,000 (male: 55,000, female: 22,000; predicted figure for 2015).*

As a top pharmaceutical company in oncology in Japan, Chugai is committed to contribute to patients and medical professionals by offering TECENTRIQ as a new treatment option.

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

Prescribing Information

The underlined part has been newly added and changed.

Product name	TECENTRIQ® Intravenous Infusion 1200 mg
Generic name	atezolizumab (genetical recombination)
Indications	Unresectable, advanced or recurrent non-small cell lung cancer
Dosage and administration	In case of patients with untreated unresectable, advanced or recurrent non squamous non-small cell lung cancer. The usual adult is 1200 mg atezolizumab (genetical recombination) in combination with carboplatin, paclitaxel and bevacizumab (genetical recombination) by intravenous infusion over 60 minutes once every 3 weeks. If the initial infusion is well tolerated, subsequent infusions can be delivered over 30 minutes. In case of patients with unresectable, advanced or recurrent non squamous non-small cell lung cancer who has undergone chemotherapy. The usual adult dosage is 1200 mg atezolizumab (genetical recombination) administered by intravenous infusion over 60 minutes once every 3 weeks. If the initial infusion is well tolerated, subsequent infusions can be delivered over 30 minutes.
Drug price	TECENTRIQ® Intravenous Infusion 1200 mg JPY 625,567/per vial
Conditions for approval	1. A risk management plan should be created and appropriately implemented. 2. Because the number of participants in Japanese clinical trials was very limited, post-marketing drug use surveillance of all patients receiving TECENTRIQ treatment should be conducted until data for a certain number of patients have been accumulated, in order to understand background information on people using TECENTRIQ as well as to collect safety and efficacy data on TECENTRIQ promptly, and take necessary measures for the appropriate use of TECENTRIQ.

About TECENTRIQ

In Japan, TECENTRIQ was approved for the indications on "unresectable advanced or recurrent NSCLC" in January, 2018 and was launched in April. In addition, a supplementary application for the first-line treatment of small cell lung cancer was filed in December 7, 2018.

[References]

* Center for Cancer Control and Information Services. Projected Cancer Statistics, 2015: http://ganjoho.jp/en/ (as of December 10, 2018.)

###