



Chugai Files for Additional Indications of Tecentriq and Avastin for the Treatment of Unresectable Hepatocellular Carcinoma

- First cancer immunotherapy-based combination which showed efficacy for the treatment of hepatocellular carcinoma (HCC)
- The filing is based on the results from the global phase III IMbrave150 study in patients with unresectable HCC who have not received prior systemic therapy

TOKYO, February 14, 2020 -- [Chugai Pharmaceutical Co., Ltd.](#) (TOKYO: 4519) announced that it filed regulatory applications with the Ministry of Health, Labour and Welfare for the anti-cancer agent/humanized anti-PD-L1 monoclonal antibody Tecentriq® Intravenous Infusion 1200 mg [generic name: atezolizumab (genetical recombination)] and the anti-cancer agent/humanized anti-VEGF monoclonal antibody Avastin® Intravenous Infusion 100 mg/4 mL and 400 mg/16 mL [generic name: bevacizumab (genetical recombination)] for the treatment of unresectable, advanced or metastatic hepatocellular carcinoma (HCC).

“The combination of Tecentriq and Avastin is the first immunotherapy-based treatment regimen that showed efficacy in HCC, and may improve outcome for patients,” said Dr. Yasushi Ito, Chugai’s Executive Vice President, Co-Head of Project & Lifecycle Management Unit. “We are committed to obtain regulatory approval to provide the new treatment as soon as possible for patients with this devastating disease who currently have limited treatment options.”

This filing is based on the phase III IMbrave150 study in patients with unresectable HCC who have not received prior systemic therapy. Roche filed an application for Tecentriq in combination with Avastin for the treatment of HCC both in the US and EU. In the US, FDA accepted the filing in January 2020, and is reviewing the application under the Real-Time Oncology Review pilot program, which aims to explore a more efficient review process to ensure treatments are available to patients as early as possible.

<Reference>

- Roche presents pivotal data demonstrating Tecentriq in combination with Avastin improves overall survival in people with the most common form of liver cancer (A press release issued by Roche in November 22, 2019)

<https://www.roche.com/media/releases/med-cor-2019-11-22b.htm>

- Tecentriq in Combination with Avastin Increases Overall Survival and Progression-free Survival as an Initial Treatment in People with Unresectable Hepatocellular Carcinoma (A press release issued by Chugai in October 21, 2019)

https://www.chugai-pharm.co.jp/english/news/detail/20191021171500_657.html

As a leading company in the field of oncology, Chugai is committed to contribute to patients and medical professionals by offering Tecentriq as a new treatment option.

About IMbrave150 study

IMbrave150 is a global Phase III, multicenter, open-label study of 501 people with unresectable HCC who have not received prior systemic therapy. People are randomized 2:1 to receive the combination of Tecentriq and Avastin or sorafenib. People receive the combination or the control arm treatment until unacceptable toxicity or loss of clinical benefit as determined by the investigator. Co-primary endpoints were overall survival (OS) and progression free survival (PFS) by independent-review facility (IRF) per RECIST v1.1. Secondary efficacy endpoints included objective response rate (ORR), time to progression (TTP) and duration of response (DOR) as well as patient-reported outcomes (PROs), safety and pharmacokinetics.

About hepatocellular carcinoma (HCC)

HCC accounts for over 90% of liver cancer and is an aggressive type of cancer with limited treatment options hence it is a major cause of cancer deaths worldwide.^{1, 2)} In Japan, about 40,000 people are diagnosed with liver cancer every year and the number of deaths accounts for about 28,000 per year.³⁾ HCC develops predominantly in people with cirrhosis due to chronic hepatitis (B or C) or alcohol consumption, and typically presents at an advanced stage.¹⁾ The prognosis for unresectable HCC remains limited, with few systemic therapeutic options and a 1-year survival rate of less than 50%.⁴⁾

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[References]

- 1: Llovet J et al. Hepatocellular carcinoma. Nat Rev Dis Primers. 2016;2:16018.
- 2: Liver Cancer Study Group of Japan. The 20th follow-up survey of nation-wide research for primary liver cancer 2008-2009. Kanzo. 60(8): 258-293 (2019)
- 3: Cancer Registry and Statistics. Cancer Information Service, National Cancer Center Japan [Internet; cited October 2019] Available from: https://ganjoho.jp/reg_stat/index.html
- 4: Giannini G et al. Prognosis of untreated hepatocellular carcinoma. Hepatology. 2015;61(1):184-190.

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