

## Tecentriq in Combination with Avastin Increases Overall Survival and Progression-free Survival as an Initial Treatment in People with Unresectable Hepatocellular Carcinoma

• First phase III cancer immunotherapy study to show an improvement in overall survival and progression-free survival in hepatocellular carcinoma

TOKYO, October 21, 2019 -- <u>Chugai Pharmaceutical Co., Ltd.</u> (TOKYO: 4519) announced today the results of the Phase III IMbrave150 study, evaluating Tecentriq<sup>®</sup> (atezolizumab) in combination with Avastin<sup>®</sup> (bevacizumab) as a treatment for people with unresectable hepatocellular carcinoma (HCC) who have not received prior systemic therapy.

The combination of Tecentriq and Avastin improved overall survival (OS) and progression-free survival (PFS), the co-primary endpoints of the study, providing a statistically significant and clinically meaningful improvement compared with standard-of-care sorafenib. Safety for the combination of Tecentriq and Avastin was consistent with the known safety profiles of the individual medicines, with no new safety signals identified. Data from the IMbrave150 study will be presented at an upcoming medical meeting.

"We are very pleased that Tecentriq and Avastin in combination became the first treatment regimen containing immunotherapy to show positive results in a pivotal study with HCC patients," said Chugai's Executive Vice President, Co-Head of Project & Lifecycle Management Unit, Dr. Yasushi Ito. "Systemic therapy is the standard treatment for people with HCC who are not eligible for surgery or topical therapy. HCC is still a disease with poor prognosis, and new treatment options are awaited. We will be working together with Roche to provide patients with this new treatment option as early as possible."

## 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 OS and 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 measured by RECIST v1.1 (investigator-assessed [INV] and IRF) and HCC mRECIST (IRF), as well as patient-reported outcomes (PROs), safety and pharmacokinetics.

## About hepatocellular carcinoma (HCC)

HCC accounts for over 90% of liver cancer and an aggressive cancer with limited treatment options and is a major cause of cancer deaths worldwide. <sup>1, 2)</sup> In Japan, about 40 thousand people are diagnosed with a liver cancer every year and the number of deaths accounts for about 28 thousands per year. <sup>3)</sup> HCC

develops predominantly in people with cirrhosis due to chronic hepatitis (B or C) or alcohol consumption, and typically presents at an advanced stage. <sup>1)</sup> The prognosis for unresectable HCC remains limited, with few systemic therapeutic options and a 1-year survival rate of less than 50%. <sup>4)</sup>

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[References]

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3: Cancer Registry and Statistics. Cancer Information Service, National Cancer Center Japan [Internet; cited Ocotober 2019] Available from: <u>https://ganjoho.jp/reg\_stat/index.html</u>

4: Giannini G et al. Prognosis of untreated hepatocellular carcinoma. Hepatology. 2015;61(1):184-190.

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