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Chugai Obtains Regulatory Approval for Perjeta and Herceptin for Additional Indication of HER2-Positive Colorectal Cancer

- Combination therapy of Perjeta and Herceptin obtained regulatory approval for advanced or recurrent HER2-positive colon cancer or rectal cancer not amenable to curative resection that has progressed after cancer chemotherapy
- HER2 targeted antibody drugs have been approved as a new treatment approach, based on personalized medicine, for colorectal cancer
- The approval is based on a Japanese investigator-initiated phase II clinical trial (TRIUMPH study) in HER2-positive curatively unresectable advanced or recurrent colorectal cancer with prior chemotherapy

TOKYO, March 28, 2022 -- Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) announced that it obtained regulatory approval from the Ministry of Health, Labour and Welfare (MHLW) for the anti-HER2 humanized monoclonal antibodies, Perjeta® for intravenous infusion 420mg/14 mL [generic name: pertuzumab] (hereafter, Perjeta) and Herceptin® for intravenous infusion 60 and 150 [generic name: trastuzumab] (hereafter, Herceptin), for the additional indication of advanced or recurrent HER2-positive colon cancer or rectal cancer not amenable to curative resection that has progressed after cancer chemotherapy.

“There are many effective treatments available for colorectal cancer, however, recent genetic studies have revealed that some patients do not respond adequately to standard treatment. We are very pleased that now we have the opportunity to offer the combination therapy of Perjeta and Herceptin to these patients, as a new treatment option based on personalized medicine,” said Chugai’s President and CEO, Dr. Osamu Okuda. “HER2-positive colorectal cancer is a rare subtype that accounts for 1~5% of all colorectal cancers. This approval opens the way for personalized medicine for this subtype for the first time in Japan and overseas. I would like to thank everyone who supported us for this approval, especially those who participated in the investigator-initiated study which formed the basis of this trial, including patients, their families and medical professionals. We are committed to providing information on the proper use of this combination therapy so that it may contribute to the treatment of colorectal cancer.”

The approval is based on the results of an investigator-initiated phase II clinical trial (TRIUMPH study) conducted in Japan that evaluated the efficacy and safety of the combination of Perjeta and Herceptin in 30 patients with HER2-positive, curatively unresectable advanced or recurrent colorectal cancer who had previously undergone chemotherapy. The primary endpoint was the objective response rate as determined by the investigator's judgment. Objective response was observed in 29.6% of patients confirmed HER2 expression in tumor tissue and 28.0% of patients diagnosed with HER2-positive and RAS wild-type by liquid biopsy. Major adverse events included infusion-related reactions, diarrhea, decreased appetite, nausea, stomatitis and nasopharyngitis.

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HER2 protein overexpression and gene amplification should be determined with the pathological testing kit VENTANA ultraView Pathway HER2 (4B5) provided by Roche Diagnostics K.K. and Pathvision HER-2 DNA Probe Kit provided by Abbott Japan Joint company. Both tests obtained regulatory approval on March 17, 2022 and March 10, 2022, respectively, as companion diagnostics for Perjeta and Herceptin to identify patients with HER2 positive colorectal cancer who may benefit from the combination therapy.

[Approval Information (Perjeta)] * This additional section only

Indications

- Advanced or recurrent HER2-positive colon cancer or rectal cancer not amenable to curative resection that has progressed after cancer chemotherapy

Dosage and administration

- For cases of advanced or recurrent HER2-positive colon cancer or rectal cancer not amenable to curative resection that has progressed after cancer chemotherapy, the usual adult dosage is a loading dose of 840 mg pertuzumab (genetical recombination) and subsequent doses of 420 mg every 3 weeks, each administered by intravenous infusion over 60 minutes, in combination with trastuzumab (genetical recombination). If the first infusion is well tolerated, subsequent infusions may be administered over a shorter time of at least 30 minutes.

[Approval Information (Herceptin)] * This additional section only

Indications

- Advanced or recurrent HER2-positive colon cancer or rectal cancer not amenable to curative resection that has progressed after cancer chemotherapy

Dosage and administration

- Use Regimen B for advanced or recurrent HER2-positive colon cancer or rectal cancer not amenable to curative resection that has progressed after cancer chemotherapy, in combination with pertuzumab (genetical recombination).

  Regimen B: The usual adult dosage is a loading dose of 8 mg/kg (body weight) trastuzumab (genetical recombination) and subsequent doses of 6 mg/kg every 3 weeks, each administered by intravenous infusion over at least 90 minutes.

  If the first infusion is well tolerated, subsequent infusions may be administered over a shorter time of at least 30 minutes.

About Perjeta

Perjeta is a humanized monoclonal antibody that targets human epidermal growth factor receptor type 2 (HER2), which is involved in the growth of tumor cells. Perjeta in combination with Herceptin blocks the HER-signaling system more extensively. The drug was launched in 2013 for “inoperable or recurrent HER2-positive breast cancer.” The indication was amended as “HER-2 positive breast cancer,” after obtaining regulatory approval for the additional indication of “neoadjuvant and adjuvant therapy in HER2-positive breast cancer” in 2018.

About Herceptin

Herceptin, like Perjeta, is a humanized monoclonal antibody that targets human epidermal growth factor receptor type 2 (HER2), which is involved in the growth of tumor cells. Herceptin was launched in 2001

for “metastatic breast cancer overexpressing HER2.” In 2011, it was approved for the treatment of patients with “advanced or recurrent gastric cancer overexpressing HER2 not amenable to curative resection,” and in 2021 for “advanced or recurrent HER2-positive salivary gland cancer not amenable to curative resection.”

The product names listed above are protected by law.

[Reference]

1. Nat Med. 2021 Nov;27(11):1899-1903. https://pubmed.ncbi.nlm.nih.gov/34764486/ (accessed in March 2022)
2. Kato T, et al. J Clin Oncol 2016; 34（15s）: Abstr#3591

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