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Chugai Obtains Partial Change Approval for Neutrogin and Avastin Based on Public Knowledge-based Applications

TOKYO, June 20, 2022 -- Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) announced that it obtained regulatory approval from the Ministry of Health, Labour and Welfare (MHLW) for partial changes in approved matters of a recombinant human G-CSF Neutrogin® [generic name: lenograstim (genetical recombination)] and an anti-cancer agent/anti-VEGF humanized monoclonal antibody Avastin® [generic name: bevacizumab (genetical recombination)]. These approvals are based on public knowledge-based applications.

The Review Committee on Unapproved Drugs and Indications with High Medical Needs concluded on December 20, 2021, that the following indications of Neutrogin and Avastin are public knowledge in the medical and pharmaceutical fields: Neutrogin as a treatment for relapsed or refractory acute myeloid leukemia (AML) in combination with anticancer agents, and Avastin 10 mg/kg every 2 weeks as a treatment for ovarian cancer. The First Committee on New Drugs, Pharmaceutical Affairs and Food Sanitation Council also decided that public knowledge-based application was reasonable for each drug on February 4, 2022. In response to these decisions, Chugai submitted regulatory applications for the two drugs on February 10, 2022, and obtained approval. The Japanese Society of Hematology and the Japanese Society of Pediatric Hematology/Oncology had requested the development of the additional indication for Neutrogin. The Japan Society of Gynecologic Oncology and the Japan Society of Obstetrics and Gynecology had requested the development of an additional dosage and administration for Avastin.

AML is a type of blood cancer in which immature blood cells become cancerous and inhibit normal hematopoietic function, causing various symptoms such as infection and anemia.[1] The medical needs for relapsed or refractory AML are high, and more treatment options are needed. FLAG plus IDA therapy with Neutrogin in combination with anticancer agents such as fludarabine and cytarabine is recommended in overseas clinical guidelines and is positioned as one of the treatment options.[2]

Ovarian cancer is an epithelial and stromal malignant tumor originating from the ovary. The 5-year survival rates for stage III and stage IV advanced ovarian cancer are reported to be 49.6% and 31.8%[3], respectively, and the disease often becomes recurrent.[4] The medical needs for both initial treatment and the treatment for advanced stages are high, and more treatment options are needed. Chemotherapy plus Avastin (10 mg/kg for every 2 weeks) combination is recommended in domestic and overseas clinical guidelines and approved overseas for the treatment of platinum-resistant advanced ovarian cancer.[5] Chugai obtained regulatory approval from the MHLW in November 2013 for Avastin 15 mg/kg every 3 weeks for the treatment of ovarian cancer.

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Approval Information *Newly added description

- Neutrogin

Indications: Treatment of relapse or refractory acute myeloid leukemia in combination with other anticancer agents

- Avastin *Changes underlined

Dosage and administration: [Ovarian cancer] The usual adult dose is 10 mg/kg (body weight) bevacizumab (genetical recombination) every 2 weeks or 15 mg/kg (body weight) bevacizumab (genetical recombination) every 3 weeks, administered by intravenous infusion in combination with other anticancer agents.

[Reference]

1. Revised edition of Practical Guidelines for Hematological Malignancies 2018
2. Report of the evaluation for acceptability of a public knowledge-based application for lenograstim for treatment of relapse or refractory acute myeloid leukemia in combination with anticancer agents. The Review Committee on Unapproved Drugs and Indications with High Medical Needs https://www.pmda.go.jp/files/000245194.pdf (Cited from Internet: Accessed June 2022. Japanese only)
3. The 60th Annual Report of the Gynecologic Oncology Committee of the Japanese Society of Obstetrics and Gynecology (Patients' case initiating treatment in 2012) http://fa.kyorin.co.jp/jsog/readPDF.php?file=71/5/071050725.pdf (Cited from Internet: Accessed June 2022. Japanese only)
4. FIGO cancer report 2021 update https://obgyn.onlinelibrary.wiley.com/doi/epdf/10.1002/ijgo.13878 (Cited from Internet: Accessed June 2022)
5. Report of the evaluation for acceptability of a public knowledge-based application for bevacizumab (genetical recombination) for the treatment of ovarian cancer at the dosage of 10 mg/kg for every 2 weeks, the Review Committee on Unapproved Drugs and Indications with High Medical Needs https://www.mhlw.go.jp/content/11120000/000885289.pdf (Cited from Internet: Accessed June 2022. Japanese only)

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