Nippon Shinyaku Co., Ltd.
Chugai Pharmaceutical Co., Ltd.

Launch of the Anti-Cancer Agent / a Humanized Anti-CD20 Monoclonal Antibody “GAZYVA®"

TOKYO, August 29, 2018 -- Nippon Shinyaku Co., Ltd. (TOKYO: 4516) and Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) announced today that they launched obinutuzumab (genetical recombination), the glycoengineered type II anti-CD20 monoclonal antibody [brand name: GAZYVA® Intravenous Infusion 1000 mg (hereafter, "GAZYVA")], for the treatment of "CD20-positive follicular lymphoma" on August 29, 2018. Chugai obtained a manufacturing and marketing approval on July 2, 2018 and GAZYVA was listed on the National Health Insurance (NHI) reimbursement price list today.

Shouzou Sano, Nippon Shinyaku's Director, General Manager of Sales and Marketing Div. said " With the launch of GAZYVA, the new product is added to our lineup in the area of blood cancer, on which Nippon Shinyaku are focusing. By precisely responding the medical needs for CD20-positive follicular lymphoma, we believe that it can further contribute to the treatment of patients.

"GAZYVA, a new treatment option for CD20-positive follicular lymphoma, has been confirmed to provide more benefits compared to standard therapies in the global Phase III GALLIUM study," said Dr. Osamu Okuda, Chugai’s Executive Vice President, Co-Head of Project & Lifecycle Management Unit. "We aim to further advance the treatment of follicular lymphoma and focus on providing information of proper use of GAZYVA."

Currently, standard therapies for CD20-positive follicular lymphoma are a combination of RITUXAN® and bendamustine (BR therapy), a combination of RITUXAN and CHOP (cyclophosphamide, doxorubicin, vincristine and prednisolone) (R-CHOP therapy) and a combination of RITUXAN and CVP (cyclophosphamide, vincristine and prednisolone) (R-CVP therapy).

GAZYVA binds to CD20, a protein expressed on certain B cells, but not on stem cells or plasma cells, same as RITUXAN which is recommended as a treatment of non-Hodgkin’s lymphoma in treatment guidelines in Japan and overseas. The glycoengineered type II anti-CD20 monoclonal antibody is designed to attack and destroy targeted B cells both directly and by engaging the immune system.

Nippon Shinyaku and Chugai will work closely to make GAZYVA contribute to the treatment of patients with CD20-positive follicular lymphoma as one of the standard therapies.

Drug Information

Product name: GAZYVA® Intravenous Infusion 1000 mg

Generic name: obinutuzumab (genetical recombination)

Indication: CD20-positive follicular lymphoma

Dosage and administration:

The usual adult dose is 1000 mg obinutuzumab (recombinant) administered by intravenous infusion. In induction treatment, using the cycle durations and number of cycles shown as follows, GAZYVA is administered on Days 1, 8, and 15 of Cycle 1 and on Day 1 of Cycle 2 and beyond. In maintenance treatment, GAZYVA is administered as monotherapy once every 2 months, continuing treatment for up to 2 years

- If administering with cyclophosphamide hydrate, doxorubicin hydrochloride, vincristine sulfate, and prednisolone or methylprednisolone
  Eight 3-week cycles
- If administering with cyclophosphamide hydrate, vincristine sulfate, and prednisolone or methylprednisolone
  Eight 3-week cycles
- If administering with bendamustine hydrochloride
  Six 4-week cycles

Date of approval: July 2, 2018

Date of NHI reimbursement price listing: August 29, 2018

Date of launch: August 29, 2018

Shelf life: 3 years

Drug price: GAZYVA® Intravenous Infusion 1000 mg JPY 450,457 / Vial

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