News Release

Nov 27, 2018

BLINCYTO® for drip infusion 35 μg launched in Japan for the treatment of relapsed or refractory B-cell acute lymphoblastic leukemia

Amgen Astellas BioPharma K.K. (Headquarters, Tokyo; President and Representative Director: Steve Sugino, “Amgen Astellas”) and Astellas Pharma Inc. (Headquarters, Tokyo; President and CEO: Kenji Yasukawa, Ph.D., “Astellas”) announced the launch of antineoplastic drug / bispecific antibody product BLINCYTO® Drip Infusion 35 μg (generic name: blinatumomab (Genetical Recombination)) for the treatment of relapsed or refractory B-cell acute lymphoblastic leukemia (ALL) today.

BLINCYTO is the first-and-only bispecific T cell engager (BiTE®) immunotherapy construct approved globally. It is also the first approved immunotherapy from Amgen's BiTE® platform, an innovative approach that helps the body's immune system target cancer cells.

Yukio Kobayashi, M.D., Ph.D, professor of hematology, International University of Health and Welfare Mita Hospital said, “With advances in medicine to date, about 80 percent of patients with ALL have achieved complete remission after a first-line treatment, however, the estimated 5-year disease-free survival rate remains approximately 50 percent.[1] In this way, treatment of relapsed or refractory ALL has room for improvement. I believe that the impact of adding BLYNCYTO, a new immunotherapeutic agent into the options is large.”

Yasushi Yamazaki, Oncology Business Unit Head at Amgen Astellas, said, “We are very delighted to bring a new therapeutic option to Japanese ALL patients who, up to now, had been fighting against the intractable illness with limited choices outside chemotherapy. We remain committed to delivering new innovative therapy to Japanese patients with serious illnesses like cancer.”

Nobuaki Tanaka, Senior Vice President, Sales & Marketing Japan of Astellas said, “We expect the launch of BLINCYTO as the first-and-only bispecific BiTE® immunotherapy construct approved globally will contribute unmet medical needs of ALL patients in Japan.”

BLINCYTO will be jointly promoted by Amgen Astellas and Astellas.

Important Japan Product Information

Indication:
Relapsed or refractory B-cell acute lymphoblastic leukemia

Dosage and Administration:
In general, BLINCYTO® is administered as continuous intravenous infusion with the following dosing regimen for 28 days followed by a 14-day treatment-free interval. This constitutes one cycle and is repeated up to 5 cycles. After that, BLINCYTO® is administered with the following dosing regimen for 28 days followed by a 56-day treatment-free interval. This constitutes one cycle and is repeated up to 4 cycles. Of note, dose of BLINCYTO® can be reduced as appropriate depending on patient's condition.

- Patients with a body weight of ≥45 kg: 9 μg/day on Days 1 to 7 of Cycle 1, then 28 μg/day.
- Patients with a body weight of < 45 kg: 5 μg/m^2 (body surface area [BSA])/day on Days 1 to 7 of Cycle 1, then 15 μg/m^2 (BSA)/day. The dose should not exceed the dose for patients with a body weight of ≥45 kg.

For more information, see the latest Japan Package Inserts.

NHI drug price
BLINCYTO® for drip infusion 35 μg: JPY281,345

NHI price listing date
November 20, 2018

Launch date
November 27, 2018

Product image

About Amgen Astellas BioPharma
Amgen Astellas BioPharma K.K.（http://www.aabp.co.jp/jp/） is a Japanese company that began operations on October 1, 2013, to provide breakthrough-science-based medicines to help address unmet medical needs of patients in Japan. The company is a joint venture between Amgen, one of the world's leading independent biotechnology companies, and Astellas Pharma Inc., a leading Tokyo-based R&D oriented global pharmaceutical company. AABP has grown into an organization with over 400 employees and comprehensive functions to be fully operational as a marketing authorization holder in Japan. The joint venture will become a wholly-owned Amgen affiliate as soon as 2020.

About Astellas
Astellas Pharma Inc., based in Tokyo, Japan, is a company dedicated to improving the health of people around the world through the provision of innovative and reliable pharmaceutical products. For more information, please visit our website at https://www.astellas.com/en.

About Amgen
Amgen is committed to unlocking the potential of biology for patients suffering from serious illnesses by discovering, developing, manufacturing and delivering innovative human therapeutics. This approach begins by using tools like advanced human genetics to unravel the complexities of disease and understand the fundamentals of human biology.

Amgen focuses on areas of high unmet medical need and leverages its expertise to strive for solutions that improve health outcomes and dramatically improve people's lives. A biotechnology pioneer since 1980, Amgen has grown to be one of the world's leading independent biotechnology companies, has reached millions of patients around the world and is developing a pipeline of medicines with breakaway potential.

For more information, visit www.amgen.com and follow us on www.twitter.com/amgen.

About Amgen's Commitment to Oncology
Amgen Oncology is committed to helping patients take on some of the toughest cancers, such as those that have been resistant to drugs, those that progress rapidly through the body and those where limited treatment options exist. Amgen's supportive care treatments help patients combat certain side effects of strong chemotherapy, and our targeted medicines and immunotherapies focus on more than a dozen different malignancies, ranging from blood cancers to solid tumors. With decades of experience providing therapies for cancer patients, Amgen continues to grow its portfolio of innovative and biosimilar oncology medicines.

For more information, follow us on www.twitter.com/amgenoncology.

Cautionary Notes (Astellas)
In this news release, statements made with respect to current plans, estimates, strategies and beliefs and other statements that are not historical facts are forward-looking statements about the future performance of Astellas. These statements are based on management's current assumptions and beliefs in light of the information currently available to it and involve known and unknown risks and uncertainties. A number of factors could cause actual results to differ materially from those discussed in the forward-looking statements. Such factors include, but are not limited to: (i) changes in general economic conditions and in laws and regulations, relating to pharmaceutical markets, (ii) currency exchange rate fluctuations, (iii) delays in new product launches, (iv) the inability of Astellas to market existing and new products effectively, (v) the inability of Astellas to continue to effectively research and develop products accepted by customers in highly competitive markets, and (vi) infringements of Astellas' intellectual property rights by third parties. Information about pharmaceutical products (including products currently in

development) which is included in this news release is not intended to constitute an advertisement or medical advice.

Cautionary Notes (Amgen Astellas)
Information about pharmaceutical products (including products currently in development) which is included in this news release is not intended to constitute an advertisement or medical advice.

###

CONTACT:

Amgen Astellas BioPharma K.K.
Corporate Affairs (TEL +81-3-5293-9694)

Astellas Pharma Inc.
Corporate Communications (TEL +81-3-3244-3201)

Reference

1. Sakura, T., et al. "High-dose methotrexate therapy significantly improved survival of adult acute lymphoblastic leukemia: a phase III study by JALSG." Leukemia 32.3 (2018): 626.