



BLINCYTO® (blinatumomab) Approved In Japan For The Treatment Of Relapsed Or Refractory B-cell Acute Lymphoblastic Leukemia

September 25, 2018

First Approved Oncology Treatment From Amgen Astellas Joint Venture

BLINCYTO is the First-and-Only Approved CD19-Directed CD3 Bispecific T Cell Engager (BiTE®) Immunotherapy

THOUSAND OAKS, Calif., Sept. 24, 2018 /PRNewswire/ -- Amgen (NASDAQ:AMGN) today announced that the Japanese Ministry of Health, Labour and Welfare has granted marketing approval for BLINCYTO® (blinatumomab) for the treatment of relapsed or refractory B-cell acute lymphoblastic leukemia (ALL). BLINCYTO was developed in Japan by Amgen Astellas BioPharma K.K. (AABP), a joint venture between Amgen and Astellas Pharma Inc., a pharmaceutical company headquartered in Tokyo.

"As proof-of-concept for our bispecific T cell engager technology, BLINCYTO has laid the groundwork for Amgen to deliver on our passion of addressing cancer by exploring numerous biologic pathways and therapeutic modalities," said David M. Reese, M.D., executive vice president of Research and Development at Amgen. "This innovation is a good example of how we provide new options to patients with serious illnesses like cancer. In bringing BLINCYTO to Japanese patients, we reinforce our commitment to deliver novel cancer therapies on behalf of patients worldwide."

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.

"Today's approval of BLINCYTO marks a significant milestone that reinforces our commitment to addressing unmet medical needs of patients in Japan," said Steve Sugino, president and representative director, AABP. "As our first oncology treatment approved in the region, we are proud to provide a much-needed innovative treatment option for adults and children with relapsed or refractory B-cell ALL, one of the most aggressive B-cell malignancies."

Hitoshi Kiyoi, M.D., Ph.D., professor of internal medicine, Hematology and Oncology, Nagoya University Graduate School of Medicine said, "The standard therapy for relapsed or refractory B-cell ALL has not been established in Japan and therefore different chemotherapy regimens have been selected, depending on the condition and background of each patient. BLINCYTO is a much-needed and important new treatment option for patients with relapsed or refractory B-cell ALL, as demonstrated by the efficacy and survival benefit seen in the TOWER study."

The approval is based on data from multiple global studies, including the Phase 3 TOWER study and Japan Phase 1b/2 Horai study. In the TOWER study, BLINCYTO demonstrated a superior improvement in median overall survival (OS) versus standard of care (SOC) chemotherapy. Median OS was 7.7 months (95 percent CI: 5.6, 9.6) for BLINCYTO versus 4.0 months (95 percent CI: 2.9, 5.3) for SOC (HR for death=0.71; $p=0.012$). Safety results among subjects who received BLINCYTO were comparable to those seen in the previous Phase 2 studies of BLINCYTO in adult patients with Philadelphia chromosome-negative (Ph-) relapsed or refractory B-cell precursor ALL. In the TOWER study, major adverse reactions were pyrexia (39.0 percent), decrease in white blood cell count (14.6 percent), cytokine release syndrome (13.5 percent), febrile neutropenia (10.9 percent), headache (10.1 percent), elevated liver enzyme (10.1 percent) and decrease in platelet count (10.1 percent). In the Phase 1b/2 Horai study, BLINCYTO was administered to 35 Japanese adult and pediatric patients with relapsed or refractory B-cell precursor ALL. The safety results from the Horai study were comparable to those seen in the global studies, including TOWER. In the Horai study, major adverse reactions in adult patients were cytokine release syndrome (46.2 percent), pyrexia (46.2 percent), decrease in white blood cell count (38.5 percent) and decrease in platelet count (34.6 percent), and major adverse reactions in pediatric patients were elevated liver enzyme (66.7 percent), pyrexia (66.7 percent), cytokine release syndrome (55.6 percent) and abdominal pain (44.4 percent).

BLINCYTO is now approved in 57 countries, including the United States (U.S.), all member countries in the European Union (EU) and the European Economic Area, Canada and Australia.

About the TOWER Study

The TOWER study was a Phase 3, randomized, active-controlled, open-label study investigating the efficacy of BLINCYTO versus SOC chemotherapy in 405 adult patients with Ph- relapsed or refractory B-cell precursor ALL. The study enrolled a difficult-to-treat patient population which included patients with one or more relapses or refractory disease. In the BLINCYTO arm, this included 35 percent of patients that had relapsed post-allogeneic hematopoietic stem cell transplant (alloHSCT) and excluded those with late first relapse (≥ 12 months after initial remission). Patients were randomized in a 2:1 ratio to receive BLINCYTO (n=271) or treatment with investigator choice of SOC chemotherapy (n=134). The determination of efficacy was based on OS. These results were published in *The New England Journal of Medicine*.¹

About the Horai Study

The Horai study is a Phase 1b/2, single-arm, open-label study evaluating the safety and efficacy of BLINCYTO in Japanese adult and pediatric patients with relapsed or refractory B-cell precursor ALL. The primary endpoint for the Phase 1b portion was incidence of dose-limiting toxicities; the primary endpoint for the Phase 2 portion was complete remission or complete remission with partial hematologic recovery within 12 weeks of treatment with BLINCYTO. Secondary endpoints include duration of response, OS and relapse-free survival. An extension of the study is ongoing. For more information about this trial, please visit www.clinicaltrials.gov under trial identification number NCT02412306.

About ALL in Japan

ALL is a rapidly progressing cancer of the blood and bone marrow that occurs in both adults and children.^{2,3} Japan is reported to have approximately 5,000 ALL patients, and it is estimated that of these, there are around 520 patients with relapsed or refractory ALL annually.⁴⁻⁷ Adults with relapsed or refractory ALL typically have a very poor prognosis, with a median OS of three to five months.⁸ Prognosis for children with ALL who are refractory or experience a relapse is extremely poor, and post-relapse survival is only achieved in 40-50 percent of patients.⁹⁻¹¹

About BiTE® Technology

Bispecific T cell engager (BiTE[®]) antibody constructs are a novel immune-oncology technology that can be engineered to target any tumor antigen expressed by any type of cancer. The modified antibodies are designed to kill malignant cells using the patient's own immune system by bridging T cells to tumor cells. BiTE[®] antibody constructs help connect the T cells to the targeted cell, with the intent of causing T cells to inject toxins which trigger cancer cell death (apoptosis). Amgen is developing BiTE[®] antibody constructs to uniquely (or specifically) target numerous hematologic malignancies and solid tumors.

About BLINCYTO[®] (blinatumomab)

BLINCYTO is a bispecific CD19-directed CD3 T cell engager (BiTE[®]) immunotherapy that binds to CD19 expressed on the surface of cells of B-lineage origin and CD3 expressed on the surface of effector T cells. BLINCYTO was granted breakthrough therapy and priority review designations by the U.S. Food and Drug Administration (FDA) in 2014, and now carries full approval in the U.S. for the treatment of relapsed or refractory B-cell precursor ALL in adults and children. In the U.S., BLINCYTO is also approved under accelerated approval for the treatment of adults and children with B-cell precursor ALL in first or second complete remission with minimal residual disease (MRD) greater than or equal to 0.1 percent.

BLINCYTO is approved in the EU for the treatment of Ph- relapsed or refractory B-cell precursor ALL in adults and children.

Important Japan Product Information

Indication:

Relapsed or refractory B-cell acute lymphoblastic leukemia

Dosage and Administration:

In general, blinatumomab (Genetical Recombination) 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, blinatumomab (Genetical Recombination) 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 $\mu\text{g}/\text{day}$ on Days 1 to 7 of Cycle 1, then 28 $\mu\text{g}/\text{day}$.
- Patients with a body weight of < 45 kg: 5 $\mu\text{g}/\text{m}^2$ (body surface area [BSA])/day on Days 1 to 7 of Cycle 1, then 15 $\mu\text{g}/\text{m}^2$ (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.

Important Safety Information Regarding BLINCYTO[®] (blinatumomab) U.S. Indication

BLINCYTO is indicated for the treatment of B-cell precursor acute lymphoblastic leukemia (ALL) in first or second complete remission with minimal residual disease (MRD) greater than or equal to 0.1% in adults and children. This indication is approved under accelerated approval based on MRD response rate and hematological relapse-free survival. Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trials.

BLINCYTO is indicated for the treatment of relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL) in adults and children.

WARNING: CYTOKINE RELEASE SYNDROME and NEUROLOGICAL TOXICITIES

- **Cytokine Release Syndrome (CRS), which may be life-threatening or fatal, occurred in patients receiving BLINCYTO[®]. Interrupt or discontinue BLINCYTO[®] as recommended.**
- **Neurological toxicities, which may be severe, life-threatening or fatal, occurred in patients receiving BLINCYTO[®]. Interrupt or discontinue BLINCYTO[®] as recommended.**

Contraindications

BLINCYTO[®] is contraindicated in patients with a known hypersensitivity to blinatumomab or to any component of the product formulation.

Warnings and Precautions

- **Cytokine Release Syndrome (CRS):** CRS, which may be life-threatening or fatal, occurred in patients receiving BLINCYTO[®]. The median time to onset of CRS is 2 days after the start of infusion. Closely monitor patients for signs and symptoms of serious adverse events such as fever, headache, nausea, asthenia, hypotension, increased alanine aminotransferase (ALT), increased aspartate aminotransferase (AST), increased total bilirubin (TBILI), and disseminated intravascular coagulation (DIC). The manifestations of CRS after treatment with BLINCYTO overlap with those of infusion reactions, capillary leak syndrome (CLS), and hemophagocytic histiocytosis/macrophage activation syndrome (MAS). In clinical trials of BLINCYTO, CRS was reported in 15% of patients with relapsed or refractory ALL and in 7% of patients with MRD-positive ALL. Interrupt or discontinue BLINCYTO[®] as outlined in the PI.
- **Neurological Toxicities:** Approximately 65% of patients receiving BLINCYTO[®] in clinical trials experienced neurological toxicities. The median time to the first event was within the first 2 weeks of BLINCYTO[®] treatment and the majority of events resolved. The most common ($\geq 10\%$) manifestations of neurological toxicity were headache and tremor. Severe, life-threatening, or fatal neurological toxicities occurred in approximately 13% of patients, including encephalopathy, convulsions, speech disorders, disturbances in consciousness, confusion and disorientation, and coordination and balance disorders. Manifestations of neurological toxicity included cranial nerve disorders. Monitor patients for signs or symptoms and interrupt or discontinue BLINCYTO[®] as outlined in the PI.

- Infections: Approximately 25% of patients receiving BLINCYTO® in clinical trials experienced serious infections such as sepsis, pneumonia, bacteremia, opportunistic infections, and catheter-site infections, some of which were life-threatening or fatal. Administer prophylactic antibiotics and employ surveillance testing as appropriate during treatment. Monitor patients for signs or symptoms of infection and treat appropriately, including interruption or discontinuation of BLINCYTO® as needed.
- Tumor Lysis Syndrome (TLS), which may be life-threatening or fatal, has been observed. Preventive measures, including pretreatment nontoxic cytoreduction and on-treatment hydration, should be used during BLINCYTO® treatment. Monitor patients for signs and symptoms of TLS and interrupt or discontinue BLINCYTO® as needed to manage these events.
- Neutropenia and Febrile Neutropenia, including life-threatening cases, have been observed. Monitor appropriate laboratory parameters (including, but not limited to, white blood cell count and absolute neutrophil count) during BLINCYTO® infusion and interrupt BLINCYTO® if prolonged neutropenia occurs.
- Effects on Ability to Drive and Use Machines: Due to the possibility of neurological events, including seizures, patients receiving BLINCYTO® are at risk for loss of consciousness, and should be advised against driving and engaging in hazardous occupations or activities such as operating heavy or potentially dangerous machinery while BLINCYTO® is being administered.
- Elevated Liver Enzymes: Transient elevations in liver enzymes have been associated with BLINCYTO® treatment with a median time to onset of 3 days. In patients receiving BLINCYTO®, although the majority of these events were observed in the setting of CRS, some cases of elevated liver enzymes were observed outside the setting of CRS, with a median time to onset of 19 days. Grade 3 or greater elevations in liver enzymes occurred in approximately 7% of patients outside the setting of CRS and resulted in treatment discontinuation in less than 1% of patients. Monitor ALT, AST, gamma-glutamyl transferase (GGT), and TBIL prior to the start of and during BLINCYTO® treatment. BLINCYTO® treatment should be interrupted if transaminases rise to > 5 times the upper limit of normal (ULN) or if TBIL rises to > 3 times ULN.
- Pancreatitis: Fatal pancreatitis has been reported in patients receiving BLINCYTO® in combination with dexamethasone in clinical trials and the post-marketing setting. Evaluate patients who develop signs and symptoms of pancreatitis and interrupt or discontinue BLINCYTO® and dexamethasone as needed.
- Leukoencephalopathy: Although the clinical significance is unknown, cranial magnetic resonance imaging (MRI) changes showing leukoencephalopathy have been observed in patients receiving BLINCYTO®, especially in patients previously treated with cranial irradiation and antileukemic chemotherapy.
- Preparation and administration errors have occurred with BLINCYTO® treatment. Follow instructions for preparation (including admixing) and administration in the PI strictly to minimize medication errors (including underdose and overdose).
- Immunization: Vaccination with live virus vaccines is not recommended for at least 2 weeks prior to the start of BLINCYTO® treatment, during treatment, and until immune recovery following last cycle of BLINCYTO®.
- Risk of Serious Adverse Reactions in Pediatric Patients due to Benzyl Alcohol Preservative: Serious and fatal adverse reactions including "gasping syndrome," which is characterized by central nervous system depression, metabolic acidosis, and gasping respirations, can occur in neonates and infants treated with benzyl alcohol-preserved drugs including BLINCYTO® (with preservative). When prescribing BLINCYTO® (with preservative) for pediatric patients, consider the combined daily metabolic load of benzyl alcohol from all sources including BLINCYTO® (with preservative) and other drugs containing benzyl alcohol. The minimum amount of benzyl alcohol at which serious adverse reactions may occur is not known. Due to the addition of bacteriostatic saline, 7-day bags of BLINCYTO® solution for infusion with preservative contain benzyl alcohol and are not recommended for use in any patients weighing < 22 kg.

Adverse Reactions

- The most common adverse reactions (≥ 20%) in clinical trial experience of patients with MRD-positive B-cell precursor ALL (BLAST Study) treated with BLINCYTO® were pyrexia, infusion related reactions, headache, infections (pathogen unspecified), tremor, and chills. Serious adverse reactions were reported in 61% of patients. The most common serious adverse reactions (≥2%) included pyrexia, tremor, encephalopathy, aphasia, lymphopenia, neutropenia, overdose, device related infection, seizure, and staphylococcal infection.
- The most common adverse reactions (≥ 20%) in clinical trial experience of patients with Philadelphia chromosome-negative relapsed or refractory B-cell precursor ALL (TOWER Study) treated with BLINCYTO® were infections (bacterial and pathogen unspecified), pyrexia, headache, infusion-related reactions, anemia, febrile neutropenia, thrombocytopenia, and neutropenia. Serious adverse reactions were reported in 62% of patients. The most common serious adverse reactions (≥ 2%) included febrile neutropenia, pyrexia, sepsis, pneumonia, overdose, septic shock, CRS, bacterial sepsis, device related infection, and bacteremia.
- Adverse reactions that were observed more frequently (≥ 10%) in the pediatric population compared to the adult population were pyrexia (80% vs. 61%), hypertension (26% vs. 8%), anemia (41% vs. 24%), infusion-related reaction (49% vs. 34%), thrombocytopenia (34% vs. 21%), leukopenia (24% vs. 11%), and weight increased (17% vs. 6%).
- In pediatric patients less than 2 years old (infants), the incidence of neurologic toxicities was not significantly different than

for the other age groups, but its manifestations were different; the only event terms reported were agitation, headache, insomnia, somnolence, and irritability. Infants also had an increased incidence of hypokalemia (50%) compared to other pediatric age cohorts (15-20%) or adults (17%).

Dosage and Administration Guidelines

- BLINCYTO® is administered as a continuous intravenous infusion at a constant flow rate using an infusion pump which should be programmable, lockable, non-elastomeric, and have an alarm.
- It is very important that the instructions for preparation (including admixing) and administration provided in the full Prescribing Information are strictly followed to minimize medication errors (including underdose and overdose).

Please see full Prescribing Information, including Boxed WARNINGS and Medication Guide, for BLINCYTO®.

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.

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.

Forward-Looking Statements

This news release contains forward-looking statements that are based on the current expectations and beliefs of Amgen. All statements, other than statements of historical fact, are statements that could be deemed forward-looking statements, including estimates of revenues, operating margins, capital expenditures, cash, other financial metrics, expected legal, arbitration, political, regulatory or clinical results or practices, customer and prescriber patterns or practices, reimbursement activities and outcomes and other such estimates and results. Forward-looking statements involve significant risks and uncertainties, including those discussed below and more fully described in the Securities and Exchange Commission reports filed by Amgen, including our most recent annual report on Form 10-K and any subsequent periodic reports on Form 10-Q and current reports on Form 8-K. Unless otherwise noted, Amgen is providing this information as of the date of this news release and does not undertake any obligation to update any forward-looking statements contained in this document as a result of new information, future events or otherwise.

No forward-looking statement can be guaranteed and actual results may differ materially from those we project. Discovery or identification of new product candidates or development of new indications for existing products cannot be guaranteed and movement from concept to product is uncertain; consequently, there can be no guarantee that any particular product candidate or development of a new indication for an existing product will be successful and become a commercial product. Further, preclinical results do not guarantee safe and effective performance of product candidates in humans. The complexity of the human body cannot be perfectly, or sometimes, even adequately modeled by computer or cell culture systems or animal models. The length of time that it takes for us to complete clinical trials and obtain regulatory approval for product marketing has in the past varied and we expect similar variability in the future. Even when clinical trials are successful, regulatory authorities may question the sufficiency for approval of the trial endpoints we have selected. We develop product candidates internally and through licensing collaborations, partnerships and joint ventures. Product candidates that are derived from relationships may be subject to disputes between the parties or may prove to be not as effective or as safe as we may have believed at the time of entering into such relationship. Also, we or others could identify safety, side effects or manufacturing problems with our products, including our devices, after they are on the market.

Our results may be affected by our ability to successfully market both new and existing products domestically and internationally, clinical and regulatory developments involving current and future products, sales growth of recently launched products, competition from other products including biosimilars, difficulties or delays in manufacturing our products and global economic conditions. In addition, sales of our products are affected by pricing pressure, political and public scrutiny and reimbursement policies imposed by third-party payers, including governments, private insurance plans and managed care providers and may be affected by regulatory, clinical and guideline developments and domestic and international trends toward managed care and healthcare cost containment. Furthermore, our research, testing, pricing, marketing and other operations are subject to extensive regulation by domestic and foreign government regulatory authorities. Our business may be impacted by government investigations, litigation and product liability claims. In addition, our business may be impacted by the adoption of new tax legislation or exposure to additional tax liabilities. If we fail to meet the compliance obligations in the corporate integrity agreement between us and the U.S. government, we could become subject to significant sanctions. Further, while we routinely obtain patents for our products and technology, the protection offered by our patents and patent applications may be challenged, invalidated or circumvented by our competitors, or we may fail to prevail in present and future intellectual property litigation. We perform a substantial amount of our commercial manufacturing activities at a few key facilities, including in Puerto Rico, and also depend on third parties for a portion of our manufacturing activities, and limits on supply may constrain sales of certain of our current products and product candidate development. In addition, we compete with other companies with respect to many of our marketed products as well as for the discovery and development of new products. Further, some raw materials, medical devices and component parts for our products are supplied by sole third-party suppliers. Certain of our distributors, customers and payers have substantial purchasing leverage in their dealings with us. The discovery of significant problems with a product similar to one of our products that implicate an entire class of products could have a material adverse effect on


sales of the affected products and on our business and results of operations. Our efforts to acquire other companies or products and to integrate the operations of companies we have acquired may not be successful. A breakdown, cyberattack or information security breach could compromise the confidentiality, integrity and availability of our systems and our data. Our stock price is volatile and may be affected by a number of events. Our business performance could affect or limit the ability of our Board of Directors to declare a dividend or our ability to pay a dividend or repurchase our common stock. We may not be able to access the capital and credit markets on terms that are favorable to us, or at all.

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