Amgen Announces BLINCYTO® (blinatumomab) Five-Year Overall Survival Data At EHA 2019

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Phase 2 Single-Arm BLAST Study Shows Median Overall Survival of 36.5 Months in Patients With Minimal Residual Disease-Positive Acute Lymphoblastic Leukemia

More Than Half of Patients who Achieved an MRD-Negative Complete Response Still Alive at Five Years

Only CD19-Targeted Immuno-oncology Therapy With Five-Year Survival Data

THOUSAND OAKS, Calif., June 15, 2019 /PRNewswire/ -- Amgen (NASDAQ:AMGN) today announced the five-year overall survival (OS) analysis from the single-arm, Phase 2 BLAST study that evaluated BLINCYTO® (blinatumomab) in patients with minimal residual disease (MRD)-positive acute lymphoblastic leukemia (ALL). The study found that with a median follow-up of 59.8 months, the median OS for BLINCYTO-treated patients was 36.5 months (95 percent CI: 22 months - not estimable [NE]). More than half of patients who achieved a complete MRD response following the first cycle of BLINCYTO treatment were alive at five years. These results from the largest prospective trial ever conducted in MRD-positive ALL were presented today during an oral presentation at the 24th Annual Congress of the European Hematology Association (EHA) in Amsterdam.

"As the only CD19-targeted immuno-oncology therapy with five-year survival data, BLINCYTO continues to demonstrate compelling results for ALL patients," said David M. Reese, M.D., executive vice president of Research and Development at Amgen. "We are proud of the science behind our BiTE® technology. These data in an MRD-positive ALL patient population give us increased confidence in the clinical benefit of BLINCYTO, especially when these patients are treated earlier."

The Phase 2 open-label BLAST study enrolled 116 patients with MRD-positive Philadelphia chromosome-negative (Ph-) B-cell precursor ALL in first or subsequent complete hematologic remission after at least three intensive chemotherapy blocks of treatment. Of the 116 enrolled patients, OS was evaluated for 110 patients with less than five percent leukemic blasts, including 74 patients who received hematopoietic stem cell transplantation (HSCT) in continuous complete remission (CCR) after BLINCYTO treatment.

Results presented at EHA showed that in 84 patients who achieved a complete MRD response (had no measurable MRD), median OS was not reached (95 percent CI: 29.5 months - NE) compared to 14.4 months for those who had measurable MRD (n=23; 95 percent CI: 3.8 - 32.3 months). Among patients with MRD in first complete remission (CR1), median OS was not reached for those who achieved a complete MRD response (95 percent CI: 29.5 months - NE) versus 10.6 months (95 percent CI: 2.7 - 39.7 months) for those who did not achieve complete MRD response (n=13; *p*=0.008).

"The presence of MRD is a strong predictor of relapse in patients with B-cell precursor ALL," said Nicola Gökbuget, M.D., principal investigator for the BLAST study and head of the German Multicenter Study Group for Adult ALL in Frankfurt, Germany. "Results from the final follow-up of the BLAST trial at five years demonstrate that early achievement of complete molecular remission with BLINCYTO is associated with prolonged survival."

Safety results among MRD-positive patients were consistent with the known safety profile of BLINCYTO.

MRD refers to the presence of cancer cells that remain detectable, despite a patient having achieved complete remission by conventional assessment.[1] The presence of MRD is broadly considered the most important independent prognostic factor in ALL.[2-8] MRD is only measurable through the use of highly sensitive testing methods that detect cancer cells in the bone marrow with a sensitivity of at least one cancer cell in 10,000 cells – versus about one in 20 with a conventional microscope-based evaluation.[1,9,10]

BLINCYTO, a bispecific CD19-directed CD3 T cell BiTE® (bispecific T cell engager) molecule, is the first approved molecule from Amgen's BiTE immuno-oncology platform, and the first and only therapy to receive regulatory approval globally for the treatment of MRD.

About the BLAST Study

The BLAST study is the largest prospective trial in patients with MRD-positive ALL. It is an open-label, multicenter, single-arm, Phase 2 study that evaluated the efficacy, safety and tolerability of BLINCYTO in adult patients with MRD-positive B-cell precursor ALL in complete hematologic remission after three or more cycles of intensive chemotherapy. Patients received continuous intravenous infusion of BLINCYTO 15 µg/m^2/d for four weeks, followed by two weeks off. Patients received up to four cycles of treatment and could undergo HSCT at any time after the first cycle, if eligible. Efficacy was based on achievement of undetectable MRD within one cycle of BLINCYTO treatment and hematological relapse-free survival (RFS). Results from the primary analysis BLAST study were presented at the 57th American Society of Hematology (ASH) Annual Meeting & Exposition in 2015 and published in *Blood* in 2018. Additional secondary endpoints included incidence and severity of adverse events, OS, time to hematological remission and duration of complete MRD response. Survival follow-up visits for assessment of hematological RFS and OS took place every six months until completion of a five-year period after treatment start with BLINCYTO. Three-year OS data results from the BLAST study were also featured in an oral presentation during the 60th ASH Annual Meeting & Exposition on Dec. 3, 2018.

About ALL and MRD

ALL is a rapidly progressing cancer of the blood and bone marrow that occurs in both adults and children.[11,12] Poor outcomes have been observed in patients who achieve first or second complete hematologic remission but are persistently MRD-positive, which currently remains detectable at the molecular level after treatment.[1,8] For more information about MRD, please visit AmgenOncology.com.

About BiTE Technology

BiTE (Bispecific T cell engager) technology is a targeted immuno-oncology platform that is designed to engage patients' own T cells to any tumor-specific antigen, activating the cytotoxic potential of T cells with the goal of eliminating detectable cancer. The BiTE immuno-oncology platform has the potential to treat different tumor types through tumor-specific antigens. The BiTE platform has the goal of off-the-shelf solutions, which have the potential to make innovative T cell treatment available to all providers when their patients need it. Amgen is advancing more than a dozen BiTE molecules across a broad range of solid and hematologic malignancies, further investigating BiTE technology with the goal of enhancing patient

experience and therapeutic potential.

About BLINCYTO® (blinatumomab)
BLINCYTO is a bispecific CD19-directed CD3 T cell BiTE (bispecific T cell engager), 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 in 2014, and 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 for the treatment of adults and children with B-cell precursor ALL in first or second complete remission with MRD greater than or equal to 0.1 percent. This indication is approved under accelerated approval based on MRD response rate and hematological RFS. Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trials. In the European Union (EU), BLINCYTO is indicated for the treatment of adults with Philadelphia chromosome-negative (Ph-) relapsed or refractory B-precursor ALL and for the treatment of Ph- CD19-positive B-cell precursor ALL in first or second complete remission with MRD greater than or equal to 0.1 percent.

BLINCYTO is now approved in 57 countries, including all member countries in the EU and European Economic Area, Canada, Japan and Australia.

Important EU BLINCYTO® (blinatumomab) Safety Information

This product is subject to additional monitoring in the EU. All suspected adverse reactions should be reported in accordance with the national reporting system.

The adverse reactions described in this section were identified in clinical studies of patients with B-precursor ALL (N = 843). The most serious adverse reactions that may occur during blinatumomab treatment include: infections (24.8%), neurologic events (13.8%), neutropenia/febrile neutropenia (10.1%), cytokine release syndrome (3.3%), and tumour lysis syndrome (0.7%). The most common adverse reactions were: pyrexia (69.2%), infusion-related reactions (43.4%), infections – pathogen unspecified (42.1%), headache (32.9%), anaemia (22.8%), thrombocytopenia (20.9%), febrile neutropenia (20.2%), oedema (20.0%), neutropenia (19.7%), rash (16.7%), increased liver hepatic enzymes (16.1%), bacterial infectious disorders (15.4%), tremor (15.2%), cough (15.1%), leukopenia (13.4%), back pain (13.3%), chills (13.0%), hypotension (12.8%), viral infectious disorders (12.7%), decreased immunoglobulins (12.5%), cytokine release syndrome (11.6%), tachycardia (11.3%), insomnia (10.7%), fungal infectious disorders (10.6%) and pain in extremity (10.2%).

Please refer to the Summary of Product Characteristics for full European prescribing information.

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

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® for evidence of CRS, 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 (≥ 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 of neurological toxicity 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 TBILI 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 TBILI 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 increase (17% vs. 6%).
- In pediatric patients less than 2 years old (infants), the incidence of neurologic toxicities was not significantly different than 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 Oncology
Amgen Oncology is searching for and finding answers to incredibly complex questions that will advance care and improve lives for cancer patients and their families. Our research drives us to understand the disease in the context of the patient's life – not just their cancer journey – so they can take control of their lives.

For the last four decades, we have been dedicated to discovering the firsts that matter in oncology and to finding ways to reduce the burden of cancer. Building on our heritage, Amgen continues to advance the largest pipeline in the Company's history, moving with great speed to advance those innovations for the patients who need them.

At Amgen, we are driven by our commitment to transform the lives of cancer patients and keep them at the center of everything we do.

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. We rely on collaborations with third parties for the development of some of our product candidates and for the commercialization and sales of some of our commercial products. 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.

The scientific information discussed in this news release relating to new indications for our products is preliminary and investigative and is not part of the labeling approved by the U.S. Food and Drug Administration or the European Medicines Agency for the products. The products are not approved for the investigational use(s) discussed in this news release, and no conclusions can or should be drawn regarding the safety or effectiveness of the products for these uses.

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