Amgen To Present First Clinical Data For BCMA-Targeted Half-Life Extended BiTE® Therapy AMG 701 At ASH 2020

December 5, 2020

83% Overall Response Rate in Most Recent Evaluable Cohort of Heavily Pre-Treated Multiple Myeloma Patients
Data Show Encouraging Activity With Responses Lasting up to 26 Months

THOUSAND OAKS, Calif., Dec. 5, 2020 /PRNewswire/ -- Amgen (NASDAQ:AMGN) today announced the first presentation of clinical safety and efficacy data from the Phase 1 study of AMG 701 in heavily pre-treated patients with relapsed/refractory multiple myeloma (R/R MM). AMG 701 is an investigational half-life extended (HLE) bispecific T cell engager (BiTE®) immuno-oncology therapy targeting B-cell maturation antigen (BCMA). The data will be presented during a live oral presentation on Dec. 5 at the virtual 62nd American Society of Hematology (ASH) Annual Meeting & Exposition.

"The emerging data from the BiTE platform in hematological malignancies are encouraging. Previously, Amgen provided important evidence for BCMA-directed BiTE molecules as a therapeutic approach in multiple myeloma. AMG 701 continues to show the potential of that strategy in patients who are heavily pre-treated," said David M. Reese, M.D., executive vice president of Research and Development at Amgen.

"These data are the latest in a series that reinforce both the potential versatility of the BiTE platform and Amgen's commitment to developing innovative medicines for novel targets in difficult-to-treat cancers," Reese continued. "This year alone, Amgen has presented proof-of-concept data for four BiTE® molecules in hematological malignancies and solid tumors, and we are proud to end the year with these data in multiple myeloma at ASH."

This interim analysis of the Phase 1 dose escalation study evaluated AMG 701 in 85 R/R MM patients who had received at least three prior lines of therapy, and a median of six lines. The response rate was 36% at doses of 3-18 mg with responses lasting up to 26 months in one patient. Six of seven patients, who were tested for minimal residual disease (MRD), were MRD-negative. In the most recent evaluable cohort, there was an 83% ORR, with 4/5 responders being triple refractory.

"Despite advances in the treatment of multiple myeloma, there remains an unmet need for patients with this difficult-to-treat disease who have relapsed or refractory disease following current standard therapies," said Professor Simon J. Harrison, director of the Centre of Excellence in Cellular Immunotherapy, Peter MacCallum Cancer Centre and Royal Melbourne Hospital, Melbourne, Australia. "These first-in-human data show that AMG 701, a half-life extended BiTE therapy targeting BCMA, has encouraging signs of activity as a single agent in this heavily pre-treated patient population."

The most common hematological adverse events (AEs) were anemia (42%), neutropenia (25%) and thrombocytopenia (21%). The most common non-hematological AEs were cytokine release syndrome (CRS, 65%), diarrhea (31%) and hypophosphatemia (31%). CRS was mostly grade 1 (27%) or 2 (28%) based on Lee Blood 2014 criteria. All Grade 3 CRS events (9%) were reversible with mitigation procedures outlined in the study protocol, with a median duration of two days.

Learn more about Amgen's development of innovative medicines for novel targets in difficult-to-treat tumors at AmgenOncology.com/medical, and follow Amgen Oncology on Twitter and LinkedIn.

About BiTE® Technology

BiTE® (bispecific T cell engager) technology is a targeted immuno-oncology platform that is designed to engage patient's own T cells to any tumor-specific antigen, activating the cytotoxic potential of T cells to eliminate detectable cancer. The BiTE immuno-oncology platform has the potential to treat different tumor types through tumor-specific antigens. The BiTE platform has a goal of leading to 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 hematologic malignancies and solid tumors, further investigating BiTE technology with the goal of enhancing patient experience and therapeutic potential. To learn more about BiTE technology, visit www.AmgenBiTETechnology.com.

About Multiple Myeloma

Multiple myeloma is an incurable blood cancer, characterized by a recurring pattern of remission and relapse.[1] It is a rare and life-threatening disease that accounts for approximately one percent of all cancers.[2,3] Worldwide, approximately 160,000 people are diagnosed with multiple myeloma each year, and 106,000 patient deaths are reported on an annual basis.[2]

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 any statements on the outcome, benefits and synergies of collaborations, or potential collaborations, with any other company, including BeiGene, Ltd. or any collaboration or potential collaboration in pursuit of therapeutic antibodies against COVID-19 (including statements regarding such collaboration's, or our own, ability to discover and develop fully-human neutralizing antibodies targeting SARS-CoV-2 or antibodies against targets other than the SARS-CoV-2 receptor binding domain, and/or to produce any such antibodies to potentially prevent or treat COVID-19), or the Otezla® (apremilast) acquisition (including anticipated Otezla sales growth and the timing of non-GAAP EPS accretion), as well as 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, effects of pandemics or other widespread health problems such as the ongoing COVID-19 pandemic on our business, outcomes, progress, or effects relating to studies of Otezla as a potential treatment for COVID-19, 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. An outbreak of disease or similar public health threat, such as COVID-19, and the public and governmental effort to mitigate against the spread of such disease, could have a significant adverse effect on the supply of materials for our manufacturing activities, the distribution of our products, the commercialization of our product candidates, and our clinical trial operations, and any such events may have a material adverse effect on our product development, product sales, business and results of operations. 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 collaborate with or acquire other companies, products or technology, and to integrate the operations of companies or to support the products or technology 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 related to our product candidates is preliminary and investigative. Such product candidates are not approved by the U.S. Food and Drug Administration, and no conclusions can or should be drawn regarding the safety or effectiveness of the product candidates. Further, any 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 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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