Amgen Highlights The Versatility Of The BiTE® Immuno-Oncology Platform In Multiple Tumor Types At ASCO 2019

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Updated Phase 1 Data of Investigational AMG 420 in Relapsed and/or Refractory Multiple Myeloma Highlighted in Oral Presentation and Accepted for Best of ASCO®

Investigational AMG 212 (Pasotuxizumab) Phase 1 Study Explores Use of BiTE Platform in a Solid Tumor

THOUSAND OAKS, Calif., June 2, 2019 /PRNewswire/ -- Amgen (NASDAQ: AMGN) today announced new data from Phase 1 studies evaluating investigational bispecific T cell engager (BiTE®) molecules were presented at the 55th Annual Meeting of the American Society of Clinical Oncology (ASCO) in Chicago. Data presented included updated investigational AMG 420 safety and efficacy results in patients with relapsed and/or refractory multiple myeloma (R/R MM), as well as initial results from the investigational AMG 212 (pasotuxizumab) first-in-human trial in patients with metastatic castration-resistant prostate cancer (mCRPC). BiTE technology is a targeted immuno-oncology platform that is designed to engage patients' own T cells to a tumor-specific antigen, activating the cytotoxic potential of T cells.

"Our BiTE immuno-oncology platform offers unique versatility, with the potential to treat various tumors through targeting tumor-associated antigens," said David M. Reese, M.D., executive vice president of Research and Development at Amgen. "As a leader in the development of targeted immuno-oncology therapies, we continue to investigate and advance more than a dozen BiTE molecules across a broad range of hematologic malignancies and solid tumors. These data at the ASCO Annual Meeting reinforce the potential of BiTE technology for patients with difficult-to-treat cancers like multiple myeloma and prostate cancer."

ASCO Annual Meeting Abstract #8007: Evaluation of AMG 420, An Anti-BCMA Bispecific T Cell Engager (BiTE) Immunotherapy, In R/R Multiple Myeloma (MM) Patients: Updated Results of a First-in-Human (FIH) Phase 1 Dose-Escalation Study

Updated results from a Phase 1, first-in-human dose-escalation trial of investigational AMG 420, a B-cell maturation antigen (BCMA)-targeting BiTE molecule, in patients with R/R MM were shared during an oral presentation at the ASCO Annual Meeting. This abstract was also selected for inclusion in the Best of ASCO® educational program. The objectives of the study included assessment of the safety, tolerability and anti-tumor activity of AMG 420 per International Myeloma Working Group 2006 Uniform Response Criteria for Multiple Myeloma. In the study, 42 patients with R/R MM who had progression after at least two prior lines of treatment (including a proteasome inhibitor and an immunomodulatory imide drug) received AMG 420 at varying doses [0.2 to 800 µg/day (d)]. Of the doses tested in this study, 400 µg/d was the maximum tolerated dose (MTD).

As of the latest readout, AMG 420 induced clinical responses in 13 of 42 patients across the dosing cohorts. Of the six patients that achieved a minimal residual disease (MRD)-negative complete response (CR), five were treated at the 400 µg/d dose. In addition, at the 400 µg/d dose, one patient achieved a very good partial response, and one achieved a partial response. The overall response rate at 400 µg/d was 70 percent (7/10). The median duration of response was nine months (range 5.8-13.6 months). Median time to response was one month, with 11 of 13 patients responding in the first cycle.

Serious adverse events (AEs) were reported in 19 patients (45 percent). Sixteen required hospitalization and four had prolonged hospitalization. No grade 3 or 4 central nervous system toxicities were observed. Serious AEs occurring in more than one patient included infections (n=13) and peripheral polyneuropathy (n=2). Treatment-related serious AEs included polyneuropathy (n=2, both grade 3) and edema (n=1, grade 3). Grade 3 cytokine release syndrome (CRS) was seen in one patient. Two patients died during the study from AEs not considered treatment-related: one patient died from acute respiratory distress due to concurrent flu and aspergillosis, and the second patient died from liver failure secondary to a viral infection during the course of treatment.

"These updated results presented at the ASCO Annual Meeting showed that AMG 420 at the 400 µg/d dose was efficacious with no new safety concerns in heavily pre-treated patients with relapsed and/or refractory multiple myeloma," said Max S. Topp, M.D., professor, University Hospital of Wuerzburg, Germany, and AMG 420 clinical study investigator. "Based on these results, we recommend AMG 420 at the 400 µg/d dose for further investigation."

ASCO 2019 Abstract #5034: Phase 1 Study of Pasotuxizumab (BAY 2010112), a PSMA-targeting BiTE (Bispecific T Cell Engager) Immunotherapy for Metastatic Castration-Resistant Prostate Cancer (mCRPC)

Initial results from a Phase 1 dose-escalation study of investigational AMG 212 (pasotuxizumab, formerly known as BAY 2010112), in patients with mCRPC who are refractory to standard therapy were presented in a poster at the ASCO Annual Meeting. AMG 212 is an investigational BiTE molecule which is designed to target prostate-specific membrane antigen (PSMA), a promising target in mCRPC. In the trial, 16 patients with mCRPC were enrolled into five dosing cohorts, with a target dose range of 5 to 80 µg/d delivered by continuous intravenous infusion. The primary objective was to determine safety and MTD and secondary objectives included pharmacokinetics (PK), biomarkers and tumor response. Antitumor activity as indicated by decline in serum level of prostate-specific antigen (PSA) was dose dependent. PSA decreases of ≥ 50 percent occurred in three patients (n=1 each in 20 µg/d, 40 µg/d and 80 µg/d cohorts). One long-term responder was treated for 14 months (40 µg/d) and one for 19.4 months (80 µg/d). The latter patient showed a complete regression of soft-tissue metastases and marked regression of bone metastases, as well as a significant and durable improvement in disease-related symptoms. Recruitment in the trial was stopped before MTD was reached to facilitate initiation of a new study sponsored by Amgen.

"Metastatic castrate-resistant prostate cancer is considered a heterogenous disease and despite advances made over the last few years, the majority of patients face a poor outlook[1]," said Horst-Dieter Hummel, M.D., University Hospital of Wuerzburg, Germany, and AMG 212 clinical study investigator. "In the first clinical study investigating the potential of a BiTE molecule in solid tumors, AMG 212 showed clinical activity, including two long-term responders. We look forward to studying AMG 212 further in this patient population."

The most common drug-related AEs were fever (94 percent, n=15) and chills (69 percent, n=11). A drug-related serious AE (fatigue) was reported in

one patient. CRS was reported for three patients (19 percent); two were grade 2 and one was grade 3. No grade 5 AEs occurred.

Additional Updates on Amgen's BiTE Immuno-Oncology Platform at ASCO 2019
Amgen continues to investigate the BiTE immuno-oncology platform across a broad range of solid and hematologic malignancies with the goal of enhancing patient experience and therapeutic potential. Amgen is investigating more than a dozen BiTE molecules across a range of solid and hematologic malignancies, with an additional two trials-in-progress being presented at the ASCO Annual Meeting.

During poster sessions, researchers shared information on the studies of AMG 596, an investigational BiTE molecule targeting epidermal growth factor receptor variant III (EGFRvIII) in glioblastoma (GBM), and AMG 757, an investigational BiTE molecule targeting delta-like ligand 3 (DLL3) in small-cell lung cancer (SCLC). GBM and SCLC are both aggressive and difficult-to-treat forms of cancer where there is a significant unmet medical need for patients.

Forty-three percent of GBM tumors test positive for amplification or mutation of the EGFR, the most common of which is the EGFRvIII gain-of-function mutation.[2] A Phase 1, first-in-human, open-label, sequential dose-escalation and dose-expansion study is ongoing for investigational AMG 596, evaluating its safety, tolerability, and PK and pharmacodynamics in patients with EGFRvIII-postive glioblastoma. The study is expected to enroll 82 patients in two groups: one with recurrent GBM and a second in newly diagnosed patients in the maintenance treatment phase following standard of care treatment.

DLL3 is an inhibitory ligand of notch receptors that is expressed in most SCLC tumors but minimally expressed in normal tissues.[3] An ongoing open-label, ascending, multiple-dose, Phase 1 study is evaluating investigational AMG 757 in adult patients with SCLC which has progressed or recurred after at least one platinum-based chemotherapy regimen. Primary objectives are to evaluate safety and tolerability and to determine the MTD or recommended Phase 2 dose. Secondary objectives are to characterize PK and evaluate preliminary anti-tumor activity.

For more information on these and other ongoing clinical trials, visit www.AmgenTrials.com.

Amgen Webcast Investor Meeting
Amgen will host a webcast investor meeting at ASCO 2019 on Monday, June 3 at 6:30 p.m. CT. David M. Reese, M.D., executive vice president of Research and Development at Amgen, along with members of Amgen's clinical development team and clinical investigators, will participate at the investor meeting to discuss Amgen's oncology program and data presented at ASCO 2019.

Live audio of the conference call will be broadcast over the internet simultaneously and will be available to members of the news media, investors and the general public.

The webcast, as with other selected presentations regarding developments in Amgen's business given at certain investor and medical conferences, can be accessed on Amgen's website, www.amgen.com, under Investors. Information regarding presentation times, webcast availability and webcast links are noted on Amgen's Investor Relations Events Calendar. The webcast will be archived and available for replay for at least 90 days after the event.

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 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. 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 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.

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