Amgen Showcases Oncology Pipeline At ASCO 2019

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Data From Largest Oncology Pipeline in Company's History
First-in-Human Data Evaluating Investigational AMG 510, the First KRASG12C Inhibitor to Reach Clinical Stage, in Solid Tumors
Potential Versatility of BiTE® Immuno-oncology Platform Reinforced With Phase 1 Asset Updates

THOUSAND OAKS, Calif., May 15, 2019 /PRNewswire/ -- Amgen (NASDAQ: AMGN) today announced that data from its oncology pipeline will be presented at the 55th Annual Meeting of the American Society of Clinical Oncology (ASCO) in Chicago, May 31-June 4, 2019. Seven investigational assets will be featured across a range of hematologic malignancies and solid tumors.

"Biology and human genetics have been the foundation of Amgen's innovation for the last four decades," said David M. Reese, M.D., executive vice president of Research and Development at Amgen. "Based on the fundamentals of our science and the speed at which we are moving, I believe Amgen will have a profound effect on how certain cancers are treated in the future. We are committed to bringing novel cancer therapies more quickly than ever before to the patients who need them."

Notable data from the Company's oncology pipeline include first-in-human data for investigational AMG 510, the first $KRAS^{G12C}$ inhibitor to reach the clinical stage in patients with locally-advanced or metastatic $KRAS^{G12C}$ mutant solid tumors. Additional early-stage pipeline data will showcase Amgen's bispecific T cell engager (BiTE®) platform across hematologic malignancies and solid tumors, including for the first time, in prostate cancer. BiTE molecules are designed to engage patients' T cells to tumor-specific antigens, activating the cytotoxic potential of T cells with the goal of eliminating detectable cancer. Updated results will also be presented from a Phase 1 dose escalation study evaluating investigational AMG 420, a B-cell maturation antigen (BCMA) targeting BiTE molecule, in patients with relapsed or refractory multiple myeloma.

A complete listing of Amgen's abstracts is available on the ASCO website. Notable abstracts include:

Clinical Data Abstracts

- **Phase 1 Study of Pasotuxizumab (BAY 2010112), a PSMA-Targeting Bispecific T cell Engager (BiTE) Immunotherapy for Metastatic Castration-Resistant Prostate Cancer (mCRPC)**
  Abstract #5034, Poster Presentation, Saturday, June 1 from 1:15-4:15 p.m. CT in McCormick Place, Hall A
- **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**
  Abstract #8007, Oral Presentation, Sunday, June 2 from 11:57 a.m.–12:09 p.m. CT in McCormick Place, Room E451
- **Phase 1 Study Evaluating the Safety, Tolerability, Pharmacokinetics (PK), and Efficacy of AMG 510, a Novel Small Molecule $KRAS^{G12C}$ Inhibitor, in Advanced Solid Tumors**
  Abstract #3003, Oral Presentation, Monday, June 3 from 9–9:12 a.m. CT in McCormick Place, Room S406

Trials-in-Progress Abstracts

- **Phase 1 Study of AMG 757, a Half-Life Extended Bi-Specific T Cell Engager (BiTE) Antibody Construct Targeting DLL3, in Patients with Small Cell Lung Cancer (SCLC)**
  Abstract #TPS8577, Poster Presentation, Sunday, June 2 from 8–11 a.m. CT in McCormick Place, Hall A
- **Phase 1 Study of AMG 119, a Chimeric Antigen Receptor (CAR) T Cell Therapy Targeting DLL3, in Patients with Relapsed/Refractory Small Cell Lung Cancer (SCLC)**
  Abstract #TPS8576, Poster Presentation, Sunday, June 2 from 8–11 a.m. CT in McCormick Place, Hall A
- **Novel anti-EGFRvIII Bispecific T Cell Engager (BiTE) Antibody Construct in Glioblastoma (GBM): Trial in Progress of AMG 596 in Patients with Recurrent or Newly Diagnosed Disease**
  Abstract #TPS2071, Poster Presentation, Sunday, June 2 from 8–11 a.m. CT in McCormick Place, Hall A

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 KRAS
The subject of more than three decades of research, *RAS* proteins make up the most frequently mutated gene family in human cancers.[1,2] Within this

family, *KRAS* is the most prevalent variant and is particularly common in solid tumors.[2] A specific mutation known as $KRAS^{G12C}$ accounts for approximately 12 percent of all *KRAS* mutations across tumor types.[3] Amgen is exploring the potential of $KRAS^{G12C}$ inhibition across a broad variety of tumor types.

About BiTE® Technology

Bispecific T cell engager (BiTE®) 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 to eliminate detectable cancer. The BiTE immuno-oncology platform has the potential to treat different tumor types through tumor-specific antigens. The BiTE platform leads 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.

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 patients' 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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2. Fernandez-Medarde A, Santos E. Ras in Cancer and Developmental Diseases. *Genes Cancer.* 2011;2(3):344-358.
3. Hobbs G, Wittinghofer A, Der C. Selective Targeting of the KRAS G12C Mutant: Kicking KRAS When It's Down. *Cancer Cell.* 2016;29(3):251-253.

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