



## Amgen Highlights New Data From KYPROLIS® (carfilzomib) And Oncology Pipeline At IMW 2019

September 12, 2019

### Data Presented From Anti-BCMA BiTE® and MCL-1 Programs

#### KYPROLIS Data Examine More Convenient Once-Weekly Dosing Regimen and Include Additional Phase 3 Results

THOUSAND OAKS, Calif., Sept. 12, 2019 /PRNewswire/ -- Amgen (NASDAQ:AMGN) today announced that new data from its oncology portfolio and pipeline will be presented at the 17<sup>th</sup> International Myeloma Workshop (IMW) 2019 in Boston, Sept. 12-15, 2019.

Data featured from Amgen's hematology franchise will include oral presentations from Phase 1 studies of AMG 420, the anti-B-cell maturation antigen (BCMA) bispecific T cell engager (BiTE®) and AMG 176, the MCL-1 inhibitor in patients with relapsed or refractory multiple myeloma. Other data being presented will include safety and efficacy results of once-weekly dosing of KYPROLIS® (carfilzomib) in different regimens across several patient populations, and Phase 3 results from the first KYPROLIS trial to be conducted in China.

"We are proud to build on the success of KYPROLIS and look to advance the next generation of multiple myeloma therapies through our evolving pipeline," said David M. Reese, M.D., executive vice president of Research and Development at Amgen. "We are excited by the initial results we have seen in our ongoing BCMA BiTE program and are focusing our efforts on the investigation of intermittent dosing paradigms that don't involve continuous infusion. Our goal is to bring forward effective molecules that have the greatest potential to provide patient-friendly, convenient treatment options and support the healthcare professionals who fight these difficult-to-treat diseases."

A complete listing of abstracts can be found on the [IMW website](#). Notable abstracts of interest include:

#### Oncology Pipeline

- **The Anti-BCMA Bispecific T-Cell Engager (BiTE) Molecule AMG 420 Induced MRD-Negative Complete Responses in R/R Multiple Myeloma in a FIH Study**

Abstract #OAB-025, Oral Presentation, Friday, Sept. 13, at 2:30 p.m. ET in Veterans Auditorium

The Phase 1b study examining AMG 420 in patients with relapsed and/or refractory multiple myeloma is ongoing. The Company is also exploring intermittent dosing options with AMG 420 that could be evaluated following the Phase 1b study.

A Phase 1 dose escalation study of AMG 701, a half-life extended anti-BCMA BiTE molecule that can be dosed intermittently is underway with data expected for presentation in 2020.

- **A Phase 1, First-in-Human Study of AMG 176, a Selective MCL-1 Inhibitor, in Patients With Relapsed or Refractory Multiple Myeloma**

Abstract #OAB-080, Oral Presentation, Saturday, Sept. 14, at 4 p.m. ET in Hynes Ballroom

The Phase 1 dose escalation clinical trial for AMG 397 ([NCT03465540](#)) is on a clinical hold to evaluate a safety signal for cardiac toxicity. In keeping with Amgen's commitment to patient safety, the AMG 176 Phase 1 trial ([NCT02675452](#)) has been placed on a voluntary hold for new enrollment.

#### KYPROLIS

- **Safety and Efficacy of Once-Weekly Carfilzomib (K) Dosing in Frail Patients (pts): A Subgroup Analysis from the Phase 3 A.R.R.O.W. Study**  
Abstract #OAB-046, Oral Presentation, Saturday, Sept. 14, at 10:15 a.m. ET in Veterans Auditorium
- **Efficacy and Safety of Carfilzomib-Pomalidomide-Dexamethasone in Relapsed and/or Refractory Multiple Myeloma: Pooled Analysis of 2 Single Arm Studies**  
Abstract #OAB-049, Oral Presentation, Saturday, Sept. 14, at 11 a.m. ET in Veterans Auditorium
- **A Phase 1b Study of Once-Weekly Carfilzomib Combined with Lenalidomide and Dexamethasone (wKRd) in Patients (pts) with Newly Diagnosed Multiple Myeloma (NDMM)**  
Abstract #OAB-078, Oral Presentation, Saturday, Sept. 14, at 3:30 p.m. ET in Hynes Ballroom
- **Trial in Progress: Once-Weekly vs. Twice-Weekly Dosing of Carfilzomib-Lenalidomide-Dexamethasone in Patients w/ Relapsed or Refractory Multiple Myeloma**  
Abstract #SP-114, Poster Session II, Saturday, Sept. 14, from 12:30-2 p.m. ET in Hynes Auditorium
- **A Phase 3 Study of Carfilzomib and Dexamethasone (Kd) in Patients with Relapsed and Refractory Multiple Myeloma (MM) in China**  
Abstract #SP-115, Poster Session II, Saturday, Sept. 14, from 12:30-2 p.m. ET in Hynes Auditorium
- **A Patient-Physician Tool to Improve CoMMunication in Relapsed Refractory Multiple Myeloma (RRMM)**  
Abstract #SP-071, Poster Session II, Saturday, Sept. 14, from 12:30-2 p.m. ET in Hynes Auditorium
- **Carfilzomib (K) in Relapsed and Refractory Multiple Myeloma (RRMM): Frailty Subgroup Analysis from Phase 3 ASPIRE and ENDEAVOR**  
Abstract #SP-113, Poster Session II, Saturday, Sept. 14, from 12:30-2 p.m. ET in Hynes Auditorium

- **Real-World Use of Carfilzomib Therapy Among Patients with Existing Cardiovascular Medical History: An Analysis of a Prospective Observational Study**  
Abstract #SP-138, Poster Session II, Saturday, Sept. 14, from 12:30-2 p.m. ET in Hynes Auditorium
- **Depth of Response and Outcomes by Initial Therapy Prior to Autologous Hematopoietic Stem Cell Transplantation for Multiple Myeloma**  
Abstract #SP-164, Poster Session II, Saturday, Sept. 14, from 12:30-2 p.m. ET in Hynes Auditorium
- **Real-World Evidence of the Use of Carfilzomib and Dexamethasone According to Age Subgroup: An Interim Analysis from a Prospective Observational Study**  
Abstract #SP-139, Poster Session II, Saturday, Sept. 14, from 12:30-2 p.m. ET in Hynes Auditorium

Completion of the Phase 3 CANDOR study evaluating KYPROLIS in combination with dexamethasone and DARZALEX<sup>®</sup> (daratumumab) (KdD) compared to KYPROLIS and dexamethasone alone in patients with relapsed or refractory multiple myeloma is expected in the second half of 2019.

#### **About BiTE<sup>®</sup> Technology**

Bispecific T cell engager (BiTE<sup>®</sup>) 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 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](https://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](http://www.amgen.com) and follow us on [www.twitter.com/amgen](https://www.twitter.com/amgen).

#### **About KYPROLIS<sup>®</sup> (carfilzomib)**

Proteasomes play an important role in cell function and growth by breaking down proteins that are damaged or no longer needed. KYPROLIS has been shown to block proteasomes, leading to an excessive build-up of proteins within cells. In some cells, KYPROLIS can cause cell death, especially in myeloma cells because they are more likely to contain a higher amount of abnormal proteins.

Since its first approval in 2012, approximately 130,000 patients worldwide have received KYPROLIS. KYPROLIS is approved in the U.S. for the following:

- In combination with dexamethasone or with lenalidomide plus dexamethasone for the treatment of patients with relapsed or refractory multiple myeloma who have received one to three lines of therapy.
- As a single agent for the treatment of patients with relapsed or refractory multiple myeloma who have received one or more lines of therapy.

KYPROLIS is also approved in Algeria, Argentina, Australia, Bahrain, Belarus, Brazil, Canada, Chile, Colombia, Ecuador, Egypt, European Union, Hong Kong, India, Israel, Japan, Jordan, Kuwait, Lebanon, Macao, Malaysia, Mexico, Morocco, New Zealand, Oman, Philippines, Qatar, Russia, Saudi Arabia, Singapore, S. Korea, Switzerland, Taiwan, Thailand, Turkey, United Arab Emirates and additional U.S. regulatory applications for KYPROLIS are underway and have been submitted to health authorities worldwide.

#### **Important U.S. KYPROLIS<sup>®</sup> (carfilzomib) Safety Information**

##### **Cardiac Toxicities**

- New onset or worsening of pre-existing cardiac failure (e.g., congestive heart failure, pulmonary edema, decreased ejection fraction), restrictive cardiomyopathy, myocardial ischemia, and myocardial infarction including fatalities have occurred following administration of KYPROLIS. Some events occurred in patients with normal baseline ventricular function. Death due to cardiac arrest has occurred within one day of administration.

- Monitor patients for signs or symptoms of cardiac failure or ischemia. Evaluate promptly if cardiac toxicity is suspected. Withhold KYPROLIS for Grade 3 or 4 cardiac adverse events until recovery, and consider whether to restart at 1 dose level reduction based on a benefit/risk assessment.
- While adequate hydration is required prior to each dose in Cycle 1, monitor all patients for evidence of volume overload, especially patients at risk for cardiac failure. Adjust total fluid intake as clinically appropriate.
- For patients  $\geq 75$  years, the risk of cardiac failure is increased. Patients with New York Heart Association Class III and IV heart failure, recent myocardial infarction, conduction abnormalities, angina, or arrhythmias may be at greater risk for cardiac complications and should have a comprehensive medical assessment prior to starting treatment with KYPROLIS and remain under close follow-up with fluid management.

#### **Acute Renal Failure**

- Cases of acute renal failure, including some fatal renal failure events, and renal insufficiency adverse events (including renal failure) have occurred. Acute renal failure was reported more frequently in patients with advanced relapsed and refractory multiple myeloma who received KYPROLIS monotherapy. Monitor renal function with regular measurement of the serum creatinine and/or estimated creatinine clearance. Reduce or withhold dose as appropriate.

#### **Tumor Lysis Syndrome**

- Cases of Tumor Lysis Syndrome (TLS), including fatal outcomes, have occurred. Patients with a high tumor burden should be considered at greater risk for TLS. Adequate hydration is required prior to each dose in Cycle 1, and in subsequent cycles as needed. Consider uric acid lowering drugs in patients at risk for TLS. Monitor for evidence of TLS during treatment and manage promptly, and withhold until resolved.

#### **Pulmonary Toxicity**

- Acute Respiratory Distress Syndrome (ARDS), acute respiratory failure, and acute diffuse infiltrative pulmonary disease such as pneumonitis and interstitial lung disease have occurred. Some events have been fatal. In the event of drug-induced pulmonary toxicity, discontinue KYPROLIS.

#### **Pulmonary Hypertension**

- Pulmonary arterial hypertension (PAH) was reported. Evaluate with cardiac imaging and/or other tests as indicated. Withhold KYPROLIS for PAH until resolved or returned to baseline and consider whether to restart based on a benefit/risk assessment.

#### **Dyspnea**

- Dyspnea was reported in patients treated with KYPROLIS. Evaluate dyspnea to exclude cardiopulmonary conditions including cardiac failure and pulmonary syndromes. Stop KYPROLIS for Grade 3 or 4 dyspnea until resolved or returned to baseline. Consider whether to restart based on a benefit/risk assessment.

#### **Hypertension**

- Hypertension, including hypertensive crisis and hypertensive emergency, has been observed, some fatal. Control hypertension prior to starting KYPROLIS. Monitor blood pressure regularly in all patients. If hypertension cannot be adequately controlled, withhold KYPROLIS and evaluate. Consider whether to restart based on a benefit/risk assessment.

#### **Venous Thrombosis**

- Venous thromboembolic events (including deep venous thrombosis and pulmonary embolism) have been observed. Thromboprophylaxis is recommended for patients being treated with the combination of KYPROLIS with dexamethasone or with lenalidomide plus dexamethasone. The thromboprophylaxis regimen should be based on an assessment of the patient's underlying risks.
- Patients using hormonal contraception associated with a risk of thrombosis should consider an alternative method of effective contraception during treatment.

#### **Infusion Reactions**

- Infusion reactions, including life-threatening reactions, have occurred. Symptoms include fever, chills, arthralgia, myalgia, facial flushing, facial edema, vomiting, weakness, shortness of breath, hypotension, syncope, chest tightness, or angina. These reactions can occur immediately following or up to 24 hours after administration. Premedicate with dexamethasone to reduce the incidence and severity of infusion reactions. Inform patients of the risk and of symptoms and seek immediate medical attention if they occur.

## Hemorrhage

- Fatal or serious cases of hemorrhage have been reported. Hemorrhagic events have included gastrointestinal, pulmonary, and intracranial hemorrhage and epistaxis. Promptly evaluate signs and symptoms of blood loss. Reduce or withhold dose as appropriate.

## Thrombocytopenia

- KYPROLIS causes thrombocytopenia with recovery to baseline platelet count usually by the start of the next cycle. Monitor platelet counts frequently during treatment. Reduce or withhold dose as appropriate.

## Hepatic Toxicity and Hepatic Failure

- Cases of hepatic failure, including fatal cases, have occurred. KYPROLIS can cause increased serum transaminases. Monitor liver enzymes regularly regardless of baseline values. Reduce or withhold dose as appropriate.

## Thrombotic Microangiopathy

- Cases of thrombotic microangiopathy, including thrombotic thrombocytopenic purpura/hemolytic uremic syndrome (TTP/HUS), including fatal outcome have occurred. Monitor for signs and symptoms of TTP/HUS. Discontinue if diagnosis is suspected. If the diagnosis of TTP/HUS is excluded, KYPROLIS may be restarted. The safety of reinitiating KYPROLIS is not known.

## Posterior Reversible Encephalopathy Syndrome (PRES)

- Cases of PRES have occurred in patients receiving KYPROLIS. If PRES is suspected, discontinue and evaluate with appropriate imaging. The safety of reinitiating KYPROLIS is not known.

## Increased Fatal and Serious Toxicities in Combination with Melphalan and Prednisone in Newly Diagnosed Transplant-ineligible Patients

- In a clinical trial of transplant-ineligible patients with newly diagnosed multiple myeloma comparing KYPROLIS, melphalan, and prednisone (KMP) vs bortezomib, melphalan, and prednisone (VMP), a higher incidence of serious and fatal adverse events was observed in patients in the KMP arm. KMP is not indicated for transplant-ineligible patients with newly diagnosed multiple myeloma.

## Embryo-fetal Toxicity

- KYPROLIS can cause fetal harm when administered to a pregnant woman.
- Females of reproductive potential should be advised to avoid becoming pregnant while being treated with KYPROLIS and for 6 months following the final dose. Males of reproductive potential should be advised to avoid fathering a child while being treated with KYPROLIS and for 3 months following the final dose. If this drug is used during pregnancy, or if pregnancy occurs while taking this drug, the patient should be apprised of the potential hazard to the fetus.

## ADVERSE REACTIONS

- The most common adverse reactions in the combination therapy trials: anemia, neutropenia, diarrhea, dyspnea, fatigue, thrombocytopenia, pyrexia, insomnia, muscle spasm, cough, upper respiratory tract infection, hypokalemia.
- The most common adverse reactions in monotherapy trials: anemia, fatigue, thrombocytopenia, nausea, pyrexia, dyspnea, diarrhea, headache, cough, edema peripheral

Please see full Prescribing Information at [www.kyprolis.com](http://www.kyprolis.com).

## 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.

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 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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