



AMGEN HIGHLIGHTS HEMATOLOGY PORTFOLIO AT ASH 2023

December 8, 2023

Multiple Investigator Sponsored Studies Support the Potential of BLINCYTO® (blinatumomab) Across Acute Lymphoblastic Leukemia Treatment Paradigm

New Data Reinforce KYPROLIS® (carfilzomib) as an Important Treatment Option for Relapsed or Refractory Multiple Myeloma

Additional Analyses Support Eculizumab (a biosimilar candidate to SOLIRIS®) as a Potential Option in Paroxysmal Nocturnal Hemoglobinuria

THOUSAND OAKS, Calif., Dec. 8, 2023 /PRNewswire/ -- Amgen (NASDAQ:AMGN) today announced the presentation of new data from its blood cancer portfolio and pipeline at the 65th American Society of Hematology (ASH) Annual Meeting and Exposition, taking place from Dec. 9-12 in San Diego.

"Data at this year's ASH meeting illustrate the expanding potential of our innovative hematology medicines, BLINCYTO and KYPROLIS, as well as our commitment to providing additional treatment options with our biosimilar eculizumab," said David M. Reese, M.D., executive vice president of Research and Development at Amgen. "As the pioneer of T-cell engager technology and building on nearly a decade of real-world experience, we continue to advance our first-in-class BITE® molecule, BLINCYTO, into earlier lines of treatment where we have seen encouraging data in patients living with acute lymphoblastic leukemia."

Abstracts are available on the [ASH website](#).

Key Abstracts and Presentation Times:

Amgen Sponsored Abstracts

KYPROLIS® (carfilzomib)

- **Real-World Outcomes for Relapsed or Refractory Multiple Myeloma Patients Treated with Lenalidomide and Daratumumab Sparing Triplet Regimens: A United States Retrospective Cohort Study**
Abstract #[4705](#), Session #652, Monday, December 11 from 6:00 - 8:00 p.m. PT

Eculizumab (investigational biosimilar ABP 959 candidate to SOLIRIS®)

- **Efficacy of Parallel and Crossover Analysis As Well As Pharmacokinetic Similarity Were Confirmed between ABP 959 and Eculizumab Reference Product in Patients with PNH**
Abstract #[4092](#), Session #508, Monday, December 11 from 6:00 - 8:00 p.m. PT

Investigator Sponsored Studies

BLINCYTO® (blinatumomab)

- **Chemotherapy-Free Combination of Blinatumomab and Ponatinib in Adults With Newly Diagnosed Philadelphia Chromosome-Positive Acute Lymphoblastic Leukemia: Updates From a Phase II Trial**
Abstract #[2827](#), Session #612, Sunday, December 10 from 6:00 - 8:00 p.m. PT
- **Phase II Study of Low-Intensity Chemotherapy (Mini-Hyper-CVD) and Ponatinib Followed by Blinatumomab and Ponatinib in Patients With Philadelphia Chromosome-Positive Acute Lymphoblastic Leukemia**
Abstract #[2868](#), Session #614, Sunday, December 10 from 6:00 - 8:00 p.m. PT
- **Assessment of Outcomes of Consolidation Therapy By Number of Cycles of Blinatumomab Received in Newly Diagnosed Measurable Residual Disease Negative Patients with B-Lineage Acute Lymphoblastic Leukemia: In the ECOG-ACRIN E1910 Randomized Phase III National Clinical Trials Network Trial***
Abstract #[2877](#), Session #614, Sunday, December 10 from 6:00 - 8:00 p.m. PT
- **Phase 2 Trial of Mini-Hyper-CVD Plus Inotuzumab Ozogamicin, With or Without Blinatumomab, in Older Patients With Newly Diagnosed Philadelphia Chromosome-Negative B-Cell Acute Lymphoblastic Leukemia**
Abstract #[2878](#), Session #614, Sunday, December 10 from 6:00 - 8:00 p.m. PT
- **Pediatric Patients with High-Risk B-Cell ALL in First Complete Remission May Benefit from Less Toxic Immunotherapy with Blinatumomab – Results from Randomized Controlled Phase 3 Trial AIEOP-BFM ALL 2017**
Abstract #[825](#), Session #614, Monday, December 11 from 2:45 - 4:15 p.m. PT
- **Dose Reduced Chemotherapy in Sequence with Blinatumomab for Newly Diagnosed Older Patients with Ph/BCR::ABL Negative B-Precursor Adult Lymphoblastic Leukemia (ALL): Preliminary Results of the GMALL Bold Trial**
Abstract #[964](#), Session #614, Monday, December 11 from 4:30 - 6:00 p.m. PT

- **Updated Results from a Phase II Study of Hyper-CVAD, with or without Inotuzumab Ozogamicin, and Sequential Blinatumomab in Patients with Newly Diagnosed B-cell Acute Lymphoblastic Leukemia**
Abstract #[4245](#), Session #614, Monday, December 11 from 6:00 - 8:00 p.m. PT
- **Comparison between Dasatinib-Blinatumomab Vs Ponatinib-Blinatumomab Chemo-Free Strategy for Newly Diagnosed Ph+ Acute Lymphoblastic Leukemia Patients. Preliminary Results of the Gimema ALLL2820 Trial**
Abstract #[4249](#), Session #614, Monday, December 11 from 6:00 - 8:00 p.m. PT

**E1910 is sponsored by National Cancer Institute (NCI), part of the National Institutes of Health, and conducted by the NCI Funded National Clinical Trial Network.*

KYPROLIS® (carfilzomib)

- **Carfilzomib-Lenalidomide-Dexamethasone (KRd) Vs. Lenalidomide-Dexamethasone (Rd) in Newly Diagnosed Fit or Intermediate-Fit Multiple Myeloma Patients Not Eligible for Autologous Stem-Cell Transplantation (Phase III EMN20 Trial): Analysis of Sustained Undetectable Minimal Residual Disease (MRD)**
Abstract #[205](#), Session #653, Saturday, December 9 from 2:00 - 3:30 p.m. PT
- **Daratumumab, Carfilzomib, Lenalidomide, and Dexamethasone Induction and Consolidation with Tandem Transplant in High-Risk Newly Diagnosed Myeloma Patients: Final Results of the Phase 2 Study IFM 2018-04**
Abstract #[207](#), Session #653, Saturday, December 9 from 2:00 - 3:30 p.m. PT
- **GEM2017FIT Trial: Induction Therapy with Bortezomib-Melphalan and Prednisone (VMP) Followed By Lenalidomide and Dexamethasone (Rd) Versus Carfilzomib, Lenalidomide and Dexamethasone (KRd) Plus/Minus Daratumumab (D), 18 Cycles, Followed By Consolidation and Maintenance Therapy with Lenalidomide and Daratumumab: Phase III, Multicenter, Randomized Trial for Elderly Fit Newly Diagnosed Multiple Myeloma (NDMM) Patients Aged between 65 and 80 Years**
Abstract #[209](#), Session #653, Saturday, December 9 from 2:00 - 3:30 p.m. PT
- **Results of the Phase III Randomized Iskia Trial: Isatuximab-Carfilzomib-Lenalidomide-Dexamethasone Vs Carfilzomib-Lenalidomide-Dexamethasone As Pre-Transplant Induction and Post-Transplant Consolidation in Newly Diagnosed Multiple Myeloma Patients**
Abstract #[4](#), Plenary Scientific Session, Sunday, December 10 from 2:00 - 4:00 p.m. PT

About BLINCYTO® (blinatumomab)

BLINCYTO is a BiTE® (bispecific T-cell engager) immuno-oncology therapy that targets CD19 surface antigens on B cells. BiTE molecules fight cancer by helping the body's immune system detect and target malignant cells by engaging T cells (a type of white blood cell capable of killing other cells perceived as threats) to cancer cells. By bringing T cells near cancer cells, the T cells can inject toxins and trigger cancer cell death (apoptosis). BiTE immuno-oncology therapies are currently being investigated for their potential to treat a wide variety of cancers.

BLINCYTO was granted breakthrough therapy and priority review designations by the U.S. Food and Drug Administration and is approved in the U.S. for the treatment of:

- CD19-positive B-cell precursor ALL in first or second complete remission with minimal residual disease (MRD) greater than or equal to 0.1% in adults and pediatric patients.
- relapsed or refractory CD19-positive B-cell precursor ALL in adults and pediatric patients.

In the European Union (EU), BLINCYTO is indicated as monotherapy for the treatment of:

- adults with Philadelphia chromosome-negative CD19 positive relapsed or refractory B-precursor acute lymphoblastic leukemia (ALL). Patients with Philadelphia chromosome-positive B-precursor ALL should have failed treatment with at least 2 tyrosine kinase inhibitors (TKIs) and have no alternative treatment options.
- adults with Philadelphia chromosome-negative CD19 positive B-precursor ALL in first or second complete remission with minimal residual disease (MRD) greater than or equal to 0.1%.
- pediatric patients aged 1 year or older with Philadelphia chromosome-negative CD19 positive B-precursor ALL which is refractory or in relapse after receiving at least two prior therapies or in relapse after receiving prior allogeneic hematopoietic stem cell transplantation.
- pediatric patients aged 1 year or older with high-risk first relapsed Philadelphia chromosome-negative CD19 positive B-precursor ALL as part of the consolidation therapy.

BLINCYTO® IMPORTANT SAFETY INFORMATION

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® and treat with corticosteroids 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 15% of patients with R/R ALL and in 7% of patients with MRD-positive ALL. The median time to onset of CRS is 2 days after the start of infusion and the median time to resolution of CRS was 5 days among cases that resolved. Closely monitor and advise patients to contact their healthcare professional 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, and hemophagocytic histiocytosis/macrophage activation syndrome. If severe CRS occurs, interrupt BLINCYTO[®] until CRS resolves. Discontinue BLINCYTO[®] permanently if life-threatening CRS occurs. Administer corticosteroids for severe or life-threatening CRS.
- **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 ($\geq 10\%$) 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 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, 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®.
- Benzyl Alcohol Toxicity in Neonates: Serious adverse reactions, including fatal reactions and the "gaspings syndrome", have been reported in very low birth weight (VLBW) neonates born weighing less than 1500 g, and early preterm neonates (infants born less than 34 weeks gestational age) who received intravenous drugs containing benzyl alcohol as a preservative. Early preterm VLBW neonates may be more likely to develop these reactions, because they may be less able to metabolize benzyl alcohol.

Use the preservative-free preparations of BLINCYTO® where possible in neonates. When prescribing BLINCYTO® (with preservative) for neonatal patients, consider the combined daily metabolic load of benzyl alcohol from all sources including BLINCYTO® (with preservative), other products containing benzyl alcohol or other excipients (e.g., ethanol, propylene glycol) which compete with benzyl alcohol for the same metabolic pathway.

Monitor neonatal patients receiving BLINCYTO® (with preservative) for new or worsening metabolic acidosis. The minimum amount of benzyl alcohol at which serious adverse reactions may occur in neonates is not known. The BLINCYTO® 7-Day bag (with preservative) contains 7.4 mg of benzyl alcohol per mL.

- Embryo-Fetal Toxicity: Based on its mechanism of action, BLINCYTO® may cause fetal harm when administered to a pregnant woman. Advise pregnant women of the potential risk to the fetus. Advise females of reproductive potential to use effective contraception during treatment with BLINCYTO® and for 48 hours after the last dose.

Adverse Reactions

- The most common adverse reactions (≥ 20%) are pyrexia, infusion-related reactions, infections (pathogen unspecified), headache, neutropenia, anemia, and thrombocytopenia.

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).

INDICATIONS

- BLINCYTO® (blinatumomab) is indicated for the treatment of CD19-positive B-cell precursor acute lymphoblastic leukemia (ALL) in first or second complete remission with minimal residual disease (MRD) greater than or equal to 0.1% in adult and pediatric patients.
- BLINCYTO® is indicated for the treatment of relapsed or refractory CD19-positive B-cell precursor acute lymphoblastic leukemia (ALL) in adult and pediatric patients.

Please see BLINCYTO® full [Prescribing Information](#), including **BOXED WARNINGS**.

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 <https://www.amgenoncology.com/bite-platform.html>.

About KYPROLIS® (carfilzomib)

Proteasomes play an important role in cell function and growth by breaking down proteins that are damaged or no longer needed.¹ KYPROLIS has been shown to block proteasomes, leading to an excessive build-up of proteins within cells.² 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.^{1,2}

Since its first approval in 2012, more than 285,000 patients worldwide have received KYPROLIS. KYPROLIS is approved in the U.S. for the following:

- for the treatment of adult patients with relapsed or refractory multiple myeloma who have received one to three lines of

therapy in combination with

- Lenalidomide and dexamethasone; or
 - Dexamethasone; or
 - Daratumumab and dexamethasone.
 - Daratumumab and hyaluronidase-fihj and dexamethasone; or
 - Isatuximab and dexamethasone
- 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, Kazakhstan, Kuwait, Lebanon, Macao, Malaysia, Mexico, Morocco, New Zealand, Oman, Peru, Philippines, Qatar, Russia, Saudi Arabia, Serbia, Singapore, S. Africa, S. Korea, Switzerland, Taiwan, Thailand, Turkey and United Arab Emirates.

KYPROLIS® IMPORTANT SAFETY INFORMATION

Cardiac Toxicities

- New onset or worsening of pre-existing cardiac failure (e.g., congestive heart failure, pulmonary edema, decreased ejection fraction), 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 reactions 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 (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. Provide thromboprophylaxis for patients being treated with the combination of KYPROLIS® with dexamethasone or with lenalidomide plus dexamethasone or with daratumumab and dexamethasone. The thromboprophylaxis regimen should be based on an assessment of the patient's underlying risks.
- For patients using hormonal contraception associated with a risk of thrombosis, consider an alternative method of effective contraception during treatment.

Infusion-Related Reactions

- Infusion-related reactions, including life-threatening reactions, have occurred. Signs and symptoms include fever, chills, arthralgia, myalgia, facial flushing, facial edema, laryngeal 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-related reactions.

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.

Progressive Multifocal Leukoencephalopathy (PML)

- Cases of PML, including fatal cases, have occurred. In addition to KYPROLIS®, other contributory factors may include prior or concurrent use of immunosuppressive therapy. Consider PML in any patient with new onset of or changes in pre-existing neurological signs or symptoms. If PML is suspected, discontinue and initiate evaluation for PML including neurology consultation.

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 reactions 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.

- Advise pregnant women of the potential risk to a fetus. Females of reproductive potential should use effective contraception during treatment with KYPROLIS® and for 6 months following the final dose. Males of reproductive potential should use effective contraception during treatment with KYPROLIS® and for 3 months following the final dose.

Adverse Reactions

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

[Please see accompanying full Prescribing Information.](#)

INDICATIONS

- KYPROLIS® (carfilzomib) is indicated in combination with dexamethasone, or with lenalidomide plus dexamethasone, or with daratumumab plus dexamethasone, or with daratumumab plus hyaluronidase-fihj plus dexamethasone, or with isatuximab plus dexamethasone for the treatment of adult patients with relapsed or refractory multiple myeloma who have received one to three lines of therapy.
- KYPROLIS® is indicated as a single agent for the treatment of patients with relapsed or refractory multiple myeloma who have received one or more lines of therapy.

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.

Amgen is one of the 30 companies that comprise the Dow Jones Industrial Average and is also part of the Nasdaq-100 index. In 2023, Amgen was named one of "America's Greatest Workplaces" by Newsweek, one of "America's Climate Leaders" by USA Today and one of the "World's Best Companies" by TIME.

For more information, visit [Amgen.com](https://www.amgen.com) and follow us on [X](#) (formerly known as Twitter), [LinkedIn](#), [Instagram](#), [TikTok](#), [YouTube](#) and [Threads](#).

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 Kyowa-Kirin Co., Ltd.), the performance of Otezla® (apremilast) (including anticipated Otezla sales growth and the timing of non-GAAP EPS accretion), the Tenebio, Inc. acquisition, the ChemoCentryx, Inc. acquisition, or the Horizon Therapeutics plc acquisition (including the prospective performance and outlook of Horizon's business, performance and opportunities and any potential strategic benefits, synergies or opportunities expected as a result of such acquisition), 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 on our business, outcomes, progress, 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. There can be no guarantee that we will be able to realize any of the strategic benefits, synergies or opportunities arising from the Horizon acquisition, and such benefits, synergies or opportunities may take longer to realize than expected. We may not be able to successfully integrate Horizon, and such acquisition or integration may take longer, be more difficult or cost more than expected. A breakdown, cyberattack or information security breach of our information technology systems 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 and operations may be negatively affected by the failure, or perceived failure, of achieving our environmental, social and governance objectives. The effects of global climate change and related natural disasters could negatively affect our business and operations. Global economic conditions may magnify certain risks that affect our business. 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.

CONTACT: Amgen, Thousand Oaks
Elissa Snook, 609-251-1407 (media)
Jessica Akopyan, 805-440-5721 (media)
Justin Claeys, 805-313-9775 (investors)

¹ Moreau P, et al. *Blood*. 2012;120(5):947-59.

² Kortuem KM and Stewart AK. *Blood*. 2013;7;121(6):893.



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