



## Amgen Showcases Oncology Pipeline At ASCO 2020

May 13, 2020

### Updated Data Evaluating Sotorasib (AMG 510), a First-in-Class Investigational KRAS<sup>G12C</sup> Inhibitor, in Colorectal Cancer and Other Solid Tumors

#### Updated AMG 330 Data in Acute Myeloid Leukemia Highlights Innovative BiTE<sup>®</sup> Technology

THOUSAND OAKS, Calif., May 13, 2020 /PRNewswire/ -- Amgen (NASDAQ:AMGN) today announced that data from its oncology pipeline and marketed portfolio will be presented during the ASCO20 Virtual Scientific Program taking place May 29 - 31, 2020.

Notable data from the oncology pipeline include updated first-in-human studies evaluating sotorasib (AMG 510), a first-in-class investigational KRAS<sup>G12C</sup> inhibitor, in patients with advanced colorectal cancer (CRC) and other solid tumors. Updated results from a Phase 1 dose escalation study of AMG 330, a BiTE<sup>®</sup> (bispecific T cell engager) molecule, in acute myeloid leukemia will be featured in an oral presentation.

"The development of Amgen's innovative medicines is rooted in our deep understanding of human and cancer genomes, which drives the advancement of next generation cancer treatments," said David M. Reese, M.D., executive vice president of Research and Development at Amgen. "At ASCO, the data we are sharing reinforce our commitment to advancing first-in-class therapies that can alter the course of cancer care for patients who need it most."

Amgen's abstracts are available on the ASCO website and include:

#### Clinical Data Abstracts (pipeline)

- **CodeBreak 100: Activity of AMG 510, a Novel Small Molecule Inhibitor of KRAS<sup>G12C</sup>, in Patients With Advanced Colorectal Cancer**  
Abstract #4018, Poster Discussion
- **CodeBreak 100: Phase 1 Study of AMG 510, a Novel Small Molecule KRAS<sup>G12C</sup> Inhibitor in Patients (pts) With Advanced Solid Tumors Other Than Non-Small Lung Cancer (NSCLC) or Colorectal Cancer (CRC)**  
Abstract #3511, Poster Discussion
- **Updated Results From Phase 1 Dose Escalation Study of AMG 330, a Bispecific T Cell Engager Molecule, in Patients With Relapsed/Refractory Acute Myeloid Leukemia (R/R AML)**  
Abstract #7508, Oral Presentation
- **Characterization of Clinical Pharmacokinetics and Exposure-Response Relationships of AMG 330, a Bispecific CD33 T Cell Engager Antibody Construct, in Patients With Relapsed/Refractory AML**  
Abstract #7536, Poster
- **Efficacy and Safety of ABP 798 Compared with Rituximab: Results From the Comparative Clinical Study in Patients with Non-Hodgkin's**  
Abstract #8044, Poster

#### KYPROLIS<sup>®</sup> Clinical Data Abstract

- **Efficacy and Safety of Carfilzomib, Dexamethasone, Daratumumab (KdD) Twice-Weekly at 56 mg/m<sup>2</sup> and Once-Weekly at 70 mg/m<sup>2</sup> in Relapsed or Refractory Multiple Myeloma (RRMM): Cross-Study Comparison of CANDOR and MMY1001**  
Abstract #8526, Poster

#### IMLYGIC<sup>®</sup> Clinical Data Abstracts

- **Early Safety From a Phase I, Multicenter, Open-Label Clinical Trial of Talimogene Laherparepvec (T-VEC) Injected (inj) Into Liver Tumors In Combination With Pembrolizumab (Pem)**  
Abstract #3015, Poster Discussion
- **Association Between Complete Response and Survival in Advanced Melanoma Treated with Talimogene Laherparepvec (T-VEC) Plus Ipilimumab (ipi)**  
Abstract #10029, Poster

#### Amgen Webcast Investor Meeting

Amgen will host a webcast call for the investment community in conjunction with the ASCO20 Virtual Scientific Program on Friday, May 29, at 1:00

p.m. PT. 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 to discuss Amgen's oncology program, including data being presented on the Company's KRAS<sup>G12C</sup> inhibitor sotorasib.

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](http://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.

To learn more about Amgen's innovative pipeline with diverse modalities and genetically validated targets, please visit [www.AmgenOncology.com](http://www.AmgenOncology.com).

#### **About KRAS**

The subject of almost four decades of research, the RAS gene family are the most frequently mutated oncogenes in human cancers.<sup>1,2</sup> Within this family, KRAS is the most prevalent variant and is particularly common in solid tumors.<sup>2</sup> A specific mutation known as KRAS G12C is found in approximately 13% of non-small cell lung cancers, three to five percent of colorectal cancers and one to two percent of numerous other solid tumors.<sup>3</sup> KRAS<sup>G12C</sup> has been considered "undruggable" due to a lack of traditional small molecule binding pockets on the protein. Amgen is exploring the potential of KRAS<sup>G12C</sup> inhibition across a broad variety of tumor types.

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

BiTE<sup>®</sup> (bispecific T cell engager) technology is a targeted immuno-oncology platform that is designed to engage patient's own T cells to any tumor-specific antigen, activating the cytotoxic potential of T cells to eliminate detectable cancer. The BiTE immuno-oncology platform has the potential to treat different tumor types through tumor-specific antigens. The BiTE platform has a goal of leading to off-the-shelf solutions, which have the potential to make innovative T cell treatment available to all providers when their patients need it. Amgen is advancing more than a dozen BiTE molecules across a broad range of hematologic malignancies and solid tumors, further investigating BiTE technology with the goal of enhancing patient experience and therapeutic potential. To learn more about BiTE technology, visit [www.AmgenBiTETechnology.com](http://www.AmgenBiTETechnology.com).

#### **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.<sup>4</sup> KYPROLIS has been shown to block proteasomes, leading to an excessive build-up of proteins within cells.<sup>5</sup> 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.<sup>4,5</sup>

Since its first approval in 2012, approximately 150,000 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, Peru, Philippines, Qatar, Russia, Saudi Arabia, Singapore, S. Korea, Switzerland, Taiwan, Thailand, Turkey and United Arab Emirates.

#### **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. 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. Pre-medicate 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).

### About IMLYGIC® (talimogene laherparepvec)

IMLYGIC is a genetically modified herpes simplex type 1 virus that is injected directly into tumors. IMLYGIC replicates inside tumor cells and produces GM-CSF, an immunostimulatory protein. IMLYGIC then causes the cell to rupture and die in a process called lysis. The rupture of the cancer cells causes the release of tumor-derived antigens, which together with virally derived GM-CSF may help to promote an anti-tumor immune response. The exact mechanism of action continues to be investigated.

IMLYGIC is the first and only oncolytic viral therapy approved by the U.S. Food and Drug Administration (FDA), the European Medicines Agency (EMA), and other regulatory authorities, based on therapeutic benefit demonstrated in a pivotal Phase 3 study. IMLYGIC is indicated for the local treatment of melanoma in patients with unresectable cutaneous, subcutaneous, or nodal lesions after initial surgery.

The IMLYGIC clinical program continues to investigate the role of IMLYGIC both as monotherapy and in combination with other therapies across a variety of cancers and treatment settings.

### INDICATION & LIMITATIONS OF USE

IMLYGIC® (talimogene laherparepvec) is a genetically modified oncolytic viral therapy indicated for the local treatment of unresectable cutaneous, subcutaneous, and nodal lesions in patients with melanoma recurrent after initial surgery.

Limitations of use: IMLYGIC® has not been shown to improve overall survival or have an effect on visceral metastases.

### IMPORTANT SAFETY INFORMATION

#### Contraindications

- Do not administer IMLYGIC® to immunocompromised patients, including those with a history of primary or acquired immunodeficient states, leukemia, lymphoma, AIDS or other clinical manifestations of infection with human immunodeficiency viruses, and those on immunosuppressive therapy, due to the risk of life-threatening disseminated herpetic infection.
- Do not administer IMLYGIC® to pregnant patients.

#### Warnings and Precautions

- Accidental exposure to IMLYGIC® may lead to transmission of IMLYGIC® and herpetic infection, including during preparation and administration. Health care providers, close contacts, pregnant women, and newborns should avoid direct

contact with injected lesions, dressings, or body fluids of treated patients. The affected area in exposed individuals should be cleaned thoroughly with soap and water and/or a disinfectant.

- Caregivers should wear protective gloves when assisting patients in applying or changing occlusive dressings and observe safety precautions for disposal of used dressings, gloves, and cleaning materials. Exposed individuals should clean the affected area thoroughly with soap and water and/or a disinfectant.
- To prevent possible inadvertent transfer of IMLYGIC<sup>®</sup> to other areas of the body, patients should be advised to avoid touching or scratching injection sites or occlusive dressings.
- Herpetic infections: Herpetic infections (including cold sores and herpetic keratitis) have been reported in IMLYGIC<sup>®</sup>-treated patients. Disseminated herpetic infection may also occur in immunocompromised patients. Patients who develop suspicious herpes-like lesions should follow standard hygienic practices to prevent viral transmission.
- Patients or close contacts with suspected signs or symptoms of a herpetic infection should contact their health care provider to evaluate the lesions. Suspected herpetic lesions should be reported to Amgen at 1-855-IMLYGIC (1-855-465-9442). Patients or close contacts have the option of follow-up testing for further characterization of the infection.
- IMLYGIC<sup>®</sup> is sensitive to acyclovir. Acyclovir or other antiviral agents may interfere with the effectiveness of IMLYGIC<sup>®</sup>. Consider the risks and benefits of IMLYGIC<sup>®</sup> treatment before administering antiviral agents to manage herpetic infection.
- Injection Site Complications: Necrosis or ulceration of tumor tissue may occur during IMLYGIC<sup>®</sup> treatment. Cellulitis and systemic bacterial infection have been reported in clinical studies. Careful wound care and infection precautions are recommended, particularly if tissue necrosis results in open wounds.
- Impaired healing at the injection site has been reported. IMLYGIC<sup>®</sup> may increase the risk of impaired healing in patients with underlying risk factors (e.g., previous radiation at the injection site or lesions in poorly vascularized areas). If there is persistent infection or delayed healing of the injection site, consider the risks and benefits of continuing treatment.
- Immune-Mediated events including glomerulonephritis, vasculitis, pneumonitis, worsening psoriasis, and vitiligo have been reported in patients treated with IMLYGIC<sup>®</sup>. Consider the risks and benefits of IMLYGIC<sup>®</sup> before initiating treatment in patients who have underlying autoimmune disease or before continuing treatment in patients who develop immune-mediated events.
- Plasmacytoma at the Injection Site: Plasmacytoma in proximity to the injection site has been reported in a patient with smoldering multiple myeloma after IMLYGIC<sup>®</sup> administration in a clinical study. Consider the risks and benefits of IMLYGIC<sup>®</sup> in patients with multiple myeloma or in whom plasmacytoma develops during treatment.
- Obstructive Airway Disorder: Obstructive airway disorder has been reported following IMLYGIC<sup>®</sup> treatment. Use caution when injecting lesions close to major airways.

#### **Adverse Reactions**

- The most commonly reported adverse drug reactions (≥ 25%) in IMLYGIC<sup>®</sup>-treated patients were fatigue, chills, pyrexia, nausea, influenza-like illness, and injection site pain. Pyrexia, chills, and influenza-like illness can occur at any time during IMLYGIC<sup>®</sup> treatment, but were more frequent during the first 3 months of treatment.
- The most common Grade 3 or higher adverse reaction was cellulitis.

Please see [www.lmlygic.com](http://www.lmlygic.com) for full Prescribing Information, including Medication Guide.

#### **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 about Amgen Biosimilars, 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).

#### **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 Adaptive Biotechnologies (including statements regarding such collaboration's ability to discover and develop fully-human neutralizing antibodies targeting SARS-CoV-2 to potentially prevent or treat COVID-19), BeiGene, Ltd., or the Otezla® (apremilast) acquisition, including anticipated Otezla sales growth and the timing of non-GAAP EPS accretion, as well as estimates of revenues, operating margins, capital expenditures, cash, other financial metrics, expected legal, arbitration, political, regulatory or clinical results or practices, customer and prescriber patterns or practices, reimbursement activities and outcomes, effects of pandemics or other widespread health problems such as the ongoing COVID-19 pandemic on our business, outcomes, progress, or effects relating to studies of Otezla as a potential treatment for COVID-19, and other such estimates and results. Forward-looking statements involve significant risks and uncertainties, including those discussed below and more fully described in the Securities and Exchange Commission reports filed by Amgen, including our most recent annual report on Form 10-K and any subsequent periodic reports on Form 10-Q and current reports on Form 8-K. Unless otherwise noted, Amgen is providing this information as of the date of this news release and does not undertake any obligation to update any forward-looking statements contained in this document as a result of new information, future events or otherwise.

No forward-looking statement can be guaranteed and actual results may differ materially from those we project. Discovery or identification of new product candidates or development of new indications for existing products cannot be guaranteed and movement from concept to product is uncertain; consequently, there can be no guarantee that any particular product candidate or development of a new indication for an existing product will be successful and become a commercial product. Further, preclinical results do not guarantee safe and effective performance of product candidates in humans. The complexity of the human body cannot be perfectly, or sometimes, even adequately modeled by computer or cell culture systems or animal models. The length of time that it takes for us to complete clinical trials and obtain regulatory approval for product marketing has in the past varied and we expect similar variability in the future. Even when clinical trials are successful, regulatory authorities may question the sufficiency for approval of the trial endpoints we have selected. We develop product candidates internally and through licensing collaborations, partnerships and joint ventures. Product candidates that are derived from relationships may be subject to disputes between the parties or may prove to be not as effective or as safe as we may have believed at the time of entering into such relationship. Also, we or others could identify safety, side effects or manufacturing problems with our products, including our devices, after they are on the market.

Our results may be affected by our ability to successfully market both new and existing products domestically and internationally, clinical and regulatory developments involving current and future products, sales growth of recently launched products, competition from other products including biosimilars, difficulties or delays in manufacturing our products and global economic conditions. In addition, sales of our products are affected by pricing pressure, political and public scrutiny and reimbursement policies imposed by third-party payers, including governments, private insurance plans and managed care providers and may be affected by regulatory, clinical and guideline developments and domestic and international trends toward managed care and healthcare cost containment. Furthermore, our research, testing, pricing, marketing and other operations are subject to extensive regulation by domestic and foreign government regulatory authorities. Our business may be impacted by government investigations, litigation and product liability claims. In addition, our business may be impacted by the adoption of new tax legislation or exposure to additional tax liabilities. If we fail to meet the compliance obligations in the corporate integrity agreement between us and the U.S. government, we could become subject to significant sanctions. Further, while we routinely obtain patents for our products and technology, the protection offered by our patents and patent applications may be challenged, invalidated or circumvented by our competitors, or we may fail to prevail in present and future intellectual property litigation. We perform a substantial amount of our commercial manufacturing activities at a few key facilities, including in Puerto Rico, and also depend on third parties for a portion of our manufacturing activities, and limits on supply may constrain sales of certain of our current products and product candidate development. An outbreak of disease or similar public health threat, such as COVID-19, and the public and governmental effort to mitigate against the spread of such disease, could have a significant adverse effect on the supply of materials for our manufacturing activities, the distribution of our products, the commercialization of our product candidates, and our clinical trial operations, and any such events may have a material adverse effect on our product development, product sales, business and results of operations. We rely on collaborations with third parties for the development of some of our product candidates and for the commercialization and sales of some of our commercial products. In addition, we compete with other companies with respect to many of our marketed products as well as for the discovery and development of new products. Further, some raw materials, medical devices and component parts for our products are supplied by sole third-party suppliers. Certain of our distributors, customers and payers have substantial purchasing leverage in their dealings with us. The discovery of significant problems with a product similar to one of our products that implicate an entire class of products could have a material adverse effect on sales of the affected products and on our business and results of operations. Our efforts to collaborate with or acquire other companies, products or technology, and to integrate the operations of companies or to support the products or technology we have acquired, may not be successful. A breakdown, cyberattack or information security breach could compromise the confidentiality, integrity and availability of our systems and our data. Our stock price is volatile and may be affected by a number of events. Our business performance could affect or limit the ability of our Board of Directors to declare a dividend or our ability to pay a dividend or repurchase our common stock. We may not be able to access the capital and credit markets on terms that are favorable to us, or at all.

The scientific information discussed in this news release related to our product candidates is preliminary and investigative. Such product candidates are not approved by the U.S. Food and Drug Administration, and no conclusions can or should be drawn regarding the safety or effectiveness of the product candidates. Further, any scientific information discussed in this news release relating to new indications for our products is preliminary and investigative and is not part of the labeling approved by the U.S. Food and Drug Administration for the products. The products are not approved for the investigational use(s) discussed in this news release, and no conclusions can or should be drawn regarding the safety or effectiveness of the products for these uses.

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