Amgen And Allergan's MVASI™ (bevacizumab-awwb) And KANJINTI™ (trastuzumab-anns) Nov Available In The United States

July 19, 2019

First Biosimilar Avastin® and Herceptin® Products to Launch in the United States

THOUSAND OAKS, Calif., July 18, 2019 /PRNewswire/ -- Amgen (NASDAQ:AMGN) and Allergan plc (NYSE:AGN) today announced that MVASI™ (bevacizumab-awwb), a biosimilar to Avastin® (bevacizumab), and KANJINTI™ (trastuzumab-anns), a biosimilar to Herceptin® (trastuzumab), are now available in the United States (U.S.).

MVASI, the first oncology therapeutic biosimilar approved by the U.S. Food and Drug Administration (FDA), is approved for the treatment of five types of cancer: in combination with chemotherapy for metastatic colorectal cancer (mCRC); in combination with chemotherapy for non-squamous non-small cell lung cancer (NSCLC); recurrent glioblastoma; in combination with interferon-alfa for metastatic renal cell carcinoma; and in combination with chemotherapy for persistent, recurrent, or metastatic cervical cancer.

KANJINTI is FDA approved for all approved indications of Herceptin: for the treatment of HER2-overexpressing adjuvant and metastatic breast cancer and HER2-overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma.

"The introduction of biosimilars is an important step in increasing options for treating HER2-positive breast cancers, which account for about 25% of all breast cancers," said Paula Schneider, chief executive officer, Susan G. Komen Breast Cancer Foundation. "As patient advocates, we are working to ensure that patients are educated about biosimilars and understand that these FDA-approved treatments are just as effective as the original biologic drugs."

The Wholesale Acquisition Cost (WAC or "list price") of both MVASI and KANJINTI will be 15% lower than their reference products. MVASI is being made available at a WAC of $677.40 per 100 mg and $2,709.60 per 400 mg single-dose vial, 15% less than the WAC for Avastin. KANJINTI is being made available at a WAC of $3,697.26 per 420 mg multi-dose vial, 15% below the WAC of Herceptin. At launch, MVASI is priced 12% below the current Avastin Average Selling Price (ASP) and KANJINTI is priced 13% below the current Herceptin ASP. Both products will be available from both wholesalers and specialty distributors.

"Several years ago, Amgen made the strategic decision to invest in building a global biosimilars business, leveraging our nearly four decades of experience in developing and manufacturing best-in-class biologics," said Murdo Gordon, executive vice president of Global Commercial Operations at Amgen. "Following several recent launches in Europe, we are excited to be launching our first two biosimilars in the U.S., which will provide for immediate savings for Medicare patients and commercial payers. We have several more biosimilars advancing through our pipeline, even as we continue to drive innovation through novel therapies for cancer and other serious diseases."

The WAC price measure does not account for discounts and rebates and may be significantly higher than out-of-pocket cost for patients, which can vary depending on several factors. Medicare and commercial insurance, for example, will generally pay for MVASI and KANJINTI based on ASP rather than WAC. Out-of-pocket cost may also depend on and be reduced by additional factors, including eligibility for patient assistance.

Actual costs to patients and providers for MVASI and KANJINTI are anticipated to be lower than WAC as WAC does not reflect discounts or rebates. Out-of-pocket costs to patients will vary depending on insurance status and eligibility for patient assistance. MVASI and KANJINTI will be available from both wholesalers and specialty distributors.

"As the first products from our collaboration with Amgen to be launched in the U.S., MVASI and KANJINTI reinforce our ongoing dedication to providing patients with additional treatment options," said David Nicholson, chief research and development officer at Allergan. "We are excited about the progress we've made through this partnership and look forward to continued milestones together with our remaining biosimilar products."

Amgen and Allergan are committed to developing high-quality biosimilars supported by robust analytical and clinical packages. MVASI and KANJINTI were proven to be highly similar to, and to have no clinically meaningful differences in terms of safety and effectiveness from Avastin and Herceptin, respectively, based on a totality of evidence, which included comparative analytical, clinical safety and efficacy data. At the time of FDA approval, KANJINTI was the only trastuzumab biosimilar to incorporate the evaluation of a single transition in the clinical study, in which a portion of patients who began the study on Herceptin made a single transition to KANJINTI. This portion of the study demonstrated similar safety and immunogenicity in patients on KANJINTI who were previously on Herceptin.

Amgen has a total of 10 biosimilars in its portfolio, three of which have been approved in the U.S.

About MVASI™ (bevacizumab-awwb) in the U.S.
MVASI is a recombinant humanized monoclonal IgG1 antibody that binds VEGF and prevents the interaction of VEGF to its receptors (Flt-1 and KDR) on the surface of endothelial cells. The interaction of VEGF with its receptors leads to endothelial cell proliferation and new blood vessel formation in in vitro models of angiogenesis. Administration of bevacizumab to xenotransplant models of colon cancer in nude (athymic) mice caused reduction of microvascular growth and inhibition of metastatic disease progression.

MVASI, in combination with intravenous fluorouracil-based chemotherapy, is indicated for the first- or second-line treatment of patients with metastatic colorectal cancer (mCRC).

MVASI, in combination with fluoropyrimidine- irinotecan- or fluoropyrimidine-oxaliplatin-based chemotherapy, is indicated for the second-line treatment of patients with mCRC who have progressed on a first-line bevacizumab-containing regimen.

Limitations of Use: MVASI is not indicated for adjuvant treatment of colon cancer.

MVASI, in combination with carboplatin and paclitaxel, is indicated for the first line treatment of patients with unresectable, locally advanced, recurrent

or metastatic non-squamous non-small cell lung cancer (NSCLC).

MVASI is indicated for the treatment of recurrent glioblastoma (GBM) in adults.

MVAS, in combination with interferon-alfa, is indicated for the treatment of metastatic renal cell carcinoma (mRCC).

MVASI, in combination with paclitaxel and cisplatin or paclitaxel and topotecan, is indicated for the treatment of patients with persistent, recurrent, or metastatic cervical cancer.

MVASI (bevacizumab-awwb) Professional Important Safety Information
Gastrointestinal (GI) perforation

- Serious and sometimes fatal GI perforation occurred at a higher incidence in bevacizumab-treated patients compared to patients treated with chemotherapy
- The incidence of GI perforation ranged from 0.3% to 3% across clinical studies
- Discontinue MVASI™ in patients with GI perforation

Surgery and wound healing complications

- The incidence of wound healing and surgical complications, including serious and fatal complications, is increased in bevacizumab-treated patients
- Withhold MVASI™ for at least 28 days prior to elective surgery. Do not administer MVASI™ for at least 28 days after surgery and until the wound is fully healed
- Discontinue in patients with wound healing complications requiring medical intervention

Hemorrhage

- Severe or fatal hemorrhage, including hemoptysis, GI bleeding, hematemesis, central nervous system hemorrhage, epistaxis, and vaginal bleeding, occurred up to 5-fold more frequently in patients receiving bevacizumab. In clinical studies, the incidence of grade ≥3 hemorrhagic events among patients receiving bevacizumab ranged from 0.4% to 7%
- Do not administer MVASI™ to patients with serious hemorrhage or a recent history of hemoptysis (≥1/2 tsp of red blood)
- Discontinue MVASI™ in patients who develop grade 3-4 hemorrhage

Additional serious and sometimes fatal adverse events with increased incidence in the bevacizumab-treated arm vs chemotherapy arm included:

- Non-GI fistulae (<1% to 1.8%, highest in patients with cervical cancer)
- Arterial thromboembolic events (grade ≥3, 5%, highest in patients with GBM)
- Renal injury and proteinuria
    - Grade 3-4 proteinuria ranged from 0.7% to 7% in clinical studies
    - Nephrotic syndrome (<1%)

Additional serious adverse events with increased incidence in the bevacizumab-treated arm vs chemotherapy arm included:

- Venous thromboembolism (grade ≥3, 11% seen in GOG-0240)
- Hypertension (grade 3-4, 5%-18%)
- Posterior reversible encephalopathy syndrome (PRES) (<0.5%)
- Congestive heart failure (CHF) (1%)

Infusion reactions with the first dose of bevacizumab occurred in <3% of patients, and severe reactions occurred in 0.2% of patients

Avoid use in patients with ovarian cancer who have evidence of recto-sigmoid involvement by pelvic examination or bowel involvement on CT scan or clinical symptoms of bowel obstruction

Inform females of reproductive potential of the risk of ovarian failure prior to initiating treatment with MVASI™

Pregnancy warning

- Based on the mechanism of action and animal studies, MVASI™ may cause fetal harm when administered to pregnant women
- Advise female patients that MVASI™ may cause fetal harm, and to inform their healthcare provider of a known or suspected pregnancy
- Advise females of reproductive potential to use effective contraception during treatment with MVASI™ and for 6 months after the last dose
- Advise nursing women that breastfeeding is not recommended during treatment with MVASI™ and for 6 months following their last dose of treatment
- MVASI™ may impair fertility

Most Common Adverse Events

- Across indications, the most common adverse reactions observed in bevacizumab -treated patients at a rate of >10% were: epistaxis, headache, hypertension, rhinitis, proteinuria, taste alteration, dry skin, rectal hemorrhage, lacrimation disorder, back pain, exfoliative dermatitis
- Across all studies, bevacizumab was discontinued in 8% to 22% of patients because of adverse reactions

Indication-Specific Adverse Events

- In CC, grade 3 or 4 adverse reactions in Study GOG-0240, occurring at a higher incidence (≥2%) in 218 patients receiving bevacizumab plus chemotherapy compared to 222 patients receiving chemotherapy alone, were abdominal pain (12% vs 10%), diarrhea (6% vs 3%), anal fistula (4% vs 0%), proctalgia (3% vs 0%), urinary tract infection (8% vs 6%), cellulitis (3% vs 0.5%), fatigue (14% vs 10%), hypertension (11% vs 0.5%), thrombosis (8% vs 3%), hypokalemia (7% vs 4%), hyponatremia (4% vs 1%), dehydration (4% vs 0.5%), neutropenia (8% vs 4%), lymphopenia (6% vs 3%), back pain (6% vs 3%), and pelvic pain (6% vs 1%)
- In mRCC, the most common grade 3-5 adverse events in AVOREN, occurring at a >2% higher incidence in bevacizumab-treated patients vs controls, were fatigue (13% vs 8%), asthenia (10% vs 7%), proteinuria (7% vs 0%), hypertension (6% vs 1%, including hypertension and hypertensive crisis), and hemorrhage (3% vs 0.3%;, including epistaxis, small intestinal hemorrhage, aneurysm ruptured, gastric ulcer hemorrhage, gingival bleeding, hemoptysis, hemorrhage intracranial, large intestinal hemorrhage, respiratory tract hemorrhage, and traumatic hematoma)
- In rGBM Study EORTC 26101, 22% of patients discontinued treatment in the bevacizumab with lomustine arm due to adverse reactions compared with 10% of patients in the lomustine arm. In patients receiving bevacizumab with lomustine, the adverse reaction profile was similar to that observed in other approved indications
- In NSCLC, grade 3-5 (nonhematologic) and grade 4-5 (hematologic) adverse events in Study E4599 occurring at a ≥2% higher incidence in bevacizumab-treated patients vs controls were neutropenia (27% vs 17%), fatigue (16% vs 13%), hypertension (8% vs 0.7%), infection without neutropenia (7% vs 3%), venous thromboembolism (5% vs 3%), febrile neutropenia (5% vs 2%), pneumonitis/pulmonary infiltrates (5% vs 3%), infection with grade 3 or 4 neutropenia (4% vs 2%), hyponatremia (4% vs 1%), headache (3% vs 1%), and proteinuria (3% vs 0%)
- In first-line mCRC, the most common grade 3-4 events in Study 2107, which occurred at a ≥2% higher incidence in the bevacizumab plus IFL vs IFL groups, were asthenia (10% vs 7%), abdominal pain (8% vs 5%), pain (8% vs 5%), hypertension (12% vs 2%), deep vein thrombosis (9% vs 5%), intra-abdominal thrombosis (3% vs 1%), syncope (3% vs 1%), diarrhea (34% vs 25%), constipation (4% vs 2%), leukopenia (37% vs 31%), and neutropenia (21% vs 14%)
- In second-line mCRC, the most common grade 3-5 (nonhematologic) and 4-5 (hematologic) events in Study E3200, which occurred at a higher incidence (≥2%) in the bevacizumab plus FOLFOX4 vs FOLFOX4 groups, were fatigue (19% vs 13%), diarrhea (18% vs 13%), sensory neuropathy (17% vs 9%), nausea (12% vs 5%), vomiting (11% vs 4%), dehydration (10% vs 5%), hypertension (9% vs 2%), abdominal pain (8% vs 5%), hemorrhage (5% vs 1%), other neurological (5% vs 3%), ileus (4% vs 1%), and headache (3% vs 0%). These data are likely to underestimate the true adverse event rates due to the reporting mechanisms used in this study

You may report side effects to the FDA at (800) FDA-1088 or **www.fda.gov/medwatch**.
You may also report side effects to Amgen at 1-800-772-6436.

Please see full Prescribing Information at www.Amgen.com.

About KANJINTI™ (trastuzumab-anns) in the U.S.
KANJINTI is a biosimilar to Herceptin, a recombinant DNA-derived humanized monoclonal immunoglobulin G1 kappa antibody. The active ingredient of KANJINTI is a humanized monoclonal antibody that has the same amino acid sequence, structure and function as Herceptin. KANJINTI has the same pharmaceutical dosage form and same strength after reconstitution as Herceptin.

In the U.S., KANJINTI is approved for:

Adjuvant Breast Cancer
KANJINTI is indicated for adjuvant treatment of HER2-overexpressing node-positive or node-negative (ER/PR-negative or with one high-risk feature*) breast cancer:

- As part of a treatment regimen containing doxorubicin, cyclophosphamide and either paclitaxel or docetaxel
- As part of treatment with docetaxel and carboplatin
- As a single agent following multi-modality anthracycline-based therapy

Select patients for therapy based on an FDA-approved companion diagnostic for a trastuzumab product.

* High-risk is defined as ER/PR positive with one of the following features: tumor size >2 cm, age <35 years, or tumor grade 2 or 3.

Metastatic Breast Cancer
KANJINTI is indicated:

- In combination with paclitaxel for the first line treatment of HER2-overexpressing metastatic breast cancer
- As a single agent for treatment of HER2-overexpressing breast cancer in patients who have received one or more chemotherapy regimens for metastatic disease

Select patients for therapy based on an FDA-approved companion diagnostic for a trastuzumab product.

Metastatic Gastric Cancer
KANJINTI is indicated, in combination with cisplatin and capecitabine or 5-fluorouracil, for the treatment of patients with HER2-overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma, who have not received prior treatment for metastatic disease.

Select patients for therapy based on an FDA-approved companion diagnostic for a trastuzumab product.

KANJINTI ™U.S. Boxed WARNINGS and Important Safety Information

Boxed WARNINGS and Additional Important Safety Information

Cardiomyopathy

- **Trastuzumab products administration can result in sub-clinical and clinical cardiac failure. The incidence and severity was highest in patients receiving trastuzumab with anthracycline-containing chemotherapy regimens**
- **Evaluate left ventricular function in all patients prior to and during treatment with KANJINTI™. Discontinue KANJINTI™ treatment in patients receiving adjuvant therapy and withhold KANJINTI™ in patients with metastatic disease for clinically significant decrease in left ventricular function**

Infusion Reactions; Pulmonary Toxicity

- **Trastuzumab products administration can result in serious and fatal infusion reactions and pulmonary toxicity. Symptoms usually occur during or within 24 hours of administration. Interrupt KANJINTI™ infusion for dyspnea or clinically significant hypotension. Monitor patients until symptoms completely resolve. Discontinue KANJINTI™ for anaphylaxis, angioedema, interstitial pneumonitis, or acute respiratory distress syndrome**

Embryo-Fetal Toxicity

- **Exposure to trastuzumab products during pregnancy can result in oligohydramnios and oligohydramnios sequence manifesting as pulmonary hypoplasia, skeletal abnormalities, and neonatal death. Advise patients of these risks and the need for effective contraception**

Cardiomyopathy

- **Administration of trastuzumab products can result in sub-clinical and clinical cardiac failure. The incidence and severity was highest in patients receiving trastuzumab with anthracycline-containing chemotherapy regimens. In a pivotal adjuvant breast cancer trial, one patient who developed CHF died of cardiomyopathy**
- Trastuzumab products can cause left ventricular cardiac dysfunction, arrhythmias, hypertension, disabling cardiac failure, cardiomyopathy, and cardiac death
- Trastuzumab products can also cause asymptomatic decline in left ventricular ejection fraction (LVEF)
- Discontinue KANJINTI™ treatment in patients receiving adjuvant breast cancer therapy and withhold KANJINTI™ in patients with metastatic disease for clinically significant decrease in left ventricular function

Cardiac Monitoring

- **Evaluate cardiac function prior to and during treatment. For adjuvant breast cancer therapy, also evaluate cardiac function after completion of KANJINTI™**
- Conduct thorough cardiac assessment, including history, physical examination, and determination of LVEF by echocardiogram or MUGA scan
- Monitor frequently for decreased left ventricular function during and after KANJINTI™ treatment
- Monitor more frequently if KANJINTI™ is withheld for significant left ventricular cardiac dysfunction

Infusion Reactions

- **KANJINTI™ administration can result in serious and fatal infusion reactions**
- **Symptoms usually occur during or within 24 hours of KANJINTI™ administration**
- **Interrupt KANJINTI™ infusion for dyspnea or clinically significant hypotension**
- **Monitor patients until symptoms completely resolve**
- **Discontinue KANJINTI™ for infusion reactions manifesting as anaphylaxis, angioedema, interstitial pneumonitis, or acute respiratory distress syndrome. Strongly consider permanent discontinuation in all patients with severe**

infusion reactions

- Infusion reactions consist of a symptom complex characterized by fever and chills, and on occasion include nausea, vomiting, pain (in some cases at tumor sites), headache, dizziness, dyspnea, hypotension, rash, and asthenia

Embryo-Fetal Toxicity

- **Exposure to trastuzumab products during pregnancy can result in oligohydramnios and oligohydramnios sequence manifesting as pulmonary hypoplasia, skeletal abnormalities, and neonatal death. Advise patients of these risks and the need for effective contraception**
- Verify the pregnancy status of females of reproductive potential prior to the initiation of KANJINTI™
- Advise pregnant women and females of reproductive potential that exposure to KANJINTI™ during pregnancy or within 7 months prior to conception can result in fetal harm
- Advise females of reproductive potential to use effective contraception during treatment and for at least 7 months following the last dose of KANJINTI™. Advise female patients to contact their healthcare provider with a known or suspected pregnancy
- Consider the developmental and health benefits of breastfeeding along with the mother's clinical need for KANJINTI™ treatment and any potential adverse effects on the breastfed child from KANJINTI™ or from the underlying maternal condition

Pulmonary Toxicity

- **Trastuzumab products can result in serious and fatal pulmonary toxicity,** which includes dyspnea, interstitial pneumonitis, pulmonary infiltrates, pleural effusions, noncardiogenic pulmonary edema, pulmonary insufficiency and hypoxia, acute respiratory distress syndrome, and pulmonary fibrosis. Such events can occur as sequelae of infusion reactions
- Patients with symptomatic intrinsic lung disease or with extensive tumor involvement of the lungs, resulting in dyspnea at rest, appear to have more severe toxicity
- Discontinue KANJINTI™ in patients experiencing pulmonary toxicity

Exacerbation of Chemotherapy-Induced Neutropenia

- In randomized, controlled clinical trials, the per-patient incidences of NCI-CTC Grade 3-4 neutropenia and of febrile neutropenia were higher in patients receiving trastuzumab in combination with myelosuppressive chemotherapy as compared to those who received chemotherapy alone. The incidence of septic death was similar among patients who received trastuzumab and those who did not

Most Common Adverse Reactions

- The most common adverse reactions associated with trastuzumab products in breast cancer were fever, nausea, vomiting, infusion reactions, diarrhea, infections, increased cough, headache, fatigue, dyspnea, rash, neutropenia, anemia, and myalgia
- The most common adverse reactions associated with trastuzumab products in metastatic gastric cancer were neutropenia, diarrhea, fatigue, anemia, stomatitis, weight loss, upper respiratory tract infections, fever, thrombocytopenia, mucosal inflammation, nasopharyngitis, and dysgeusia

You may report side effects to the FDA at (800) FDA-1088 or **www.fda.gov/medwatch**.
You may also report side effects to Amgen at 1-800-772-6436.

Please see full Prescribing Information, including Boxed WARNINGS, at www.Amgen.com.

About the Amgen and Allergan Collaboration
In December 2011, Amgen and Allergan plc. (then Watson Pharmaceuticals, Inc.) formed a collaboration to develop and commercialize, on a worldwide basis, four oncology antibody biosimilar medicines. This collaboration reflects the shared belief that the development and commercialization of biosimilar products will not follow a pure brand or generic model and will require significant expertise, infrastructure, and investment to ensure safe, reliably supplied therapies for patients. Under the terms of the agreement, Amgen assumes primary responsibility for developing, manufacturing and initially commercializing the oncology antibody products.

About Amgen Biosimilars
Amgen is committed to building upon Amgen's experience in the development and manufacturing of innovative human therapeutics to expand Amgen's reach to patients with serious illnesses. Biosimilars will help to maintain Amgen's commitment to connect patients with vital medicines, and Amgen is well positioned to leverage its nearly four decades of experience in biotechnology to create high-quality biosimilars and reliably supply them to patients worldwide.

For more information, visit www.amgenbiosimilars.com and follow us on www.twitter.com/amgenbiosim.

About Amgen Oncology
Amgen is searching for and finding answers to incredibly complex questions that will advance care and improve lives for cancer patients and their

families. Our research drives us to understand the disease in the context of the patient's life – not just their cancer journey – so they can take control of their lives.

For the last four decades, we have been dedicated to discovering the firsts that matter in oncology and to finding ways to reduce the burden of cancer. Building on our heritage, Amgen continues to advance the largest pipeline in the Company's history, moving with great speed to advance those innovations for the patients who need them.

At Amgen, we are driven by our commitment to transform the lives of cancer patients and keep them at the center of everything we do.

For more information, follow us on www.twitter.com/amgenoncology

About Amgen
Amgen is committed to unlocking the potential of biology for patients suffering from serious illnesses by discovering, developing, manufacturing and delivering innovative human therapeutics. This approach begins by using tools like advanced human genetics to unravel the complexities of disease and understand the fundamentals of human biology.

Amgen focuses on areas of high unmet medical need and leverages its expertise to strive for solutions that improve health outcomes and dramatically improve people's lives. A biotechnology pioneer since 1980, Amgen has grown to be one of the world's leading independent biotechnology companies, has reached millions of patients around the world and is developing a pipeline of medicines with breakaway potential.

For more information, visit www.amgen.com and follow us on www.twitter.com/amgen.

About Allergan plc
Allergan plc (NYSE: AGN), headquartered in Dublin, Ireland, is a bold, global pharmaceutical leader. Allergan is focused on developing, manufacturing and commercializing branded pharmaceutical, device, biologic, surgical and regenerative medicine products for patients around the world.

Allergan markets a portfolio of leading brands and best-in-class products primarily focused on four key therapeutic areas including central nervous system, eye care, medical aesthetics and gastroenterology.

Allergan is an industry leader in Open Science, a model of research and development, which defines our approach to identifying and developing game-changing ideas and innovation for better patient care. With this approach, Allergan has built one of the broadest development pipelines in the pharmaceutical industry.

Allergan's success is powered by our global colleagues' commitment to being Bold for Life. Together, we build bridges, power ideas, act fast and drive results for our customers and patients around the world by always doing what is right.

With commercial operations in approximately 100 countries, Allergan is committed to working with physicians, healthcare providers and patients to deliver innovative and meaningful treatments that help people around the world live longer, healthier lives every day.

For more information, visit Allergan's website at www.Allergan.com.

Amgen Forward-Looking Statements
This news release contains forward-looking statements that are based on the current expectations and beliefs of Amgen. All statements, other than statements of historical fact, are statements that could be deemed forward-looking statements, including estimates of revenues, operating margins, capital expenditures, cash, other financial metrics, expected legal, arbitration, political, regulatory or clinical results or practices, customer and prescriber patterns or practices, reimbursement activities and outcomes and other such estimates and results. Forward-looking statements involve significant risks and uncertainties, including those discussed below and more fully described in the Securities and Exchange Commission reports filed by Amgen, including its 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 Amgen projects. 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 Amgen to complete clinical trials and obtain regulatory approval for product marketing has in the past varied and Amgen expects similar variability in the future. Even when clinical trials are successful, regulatory authorities may question the sufficiency for approval of the trial endpoints Amgen has selected. Amgen develops 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 Amgen may have believed at the time of entering into such relationship. Also, Amgen or others could identify safety, side effects or manufacturing problems with its products, including its devices, after they are on the market.

Amgen's results may be affected by its 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 its products and global economic conditions. In addition, sales of Amgen's 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, Amgen's research, testing, pricing, marketing and other operations are subject to extensive regulation by domestic and foreign government regulatory authorities. Amgen's business may be impacted by government investigations, litigation and product liability claims. In addition, Amgen's business may be impacted by the adoption of new tax legislation or exposure to additional tax liabilities. If Amgen fails to meet the compliance obligations in the corporate integrity agreement between Amgen and the U.S. government, Amgen could become subject to significant sanctions. Further, while Amgen routinely obtains patents for its products and technology, the protection offered by its patents and patent applications may be challenged, invalidated or circumvented by its competitors, or Amgen may fail to prevail in present and future intellectual property litigation. Amgen performs a substantial amount of its commercial manufacturing activities at a few key facilities, including in

Puerto Rico, and also depends on third parties for a portion of its manufacturing activities, and limits on supply may constrain sales of certain of its current products and product candidate development. Amgen relies on collaborations with third parties for the development of some of its product candidates and for the commercialization and sales of some of its commercial products. In addition, Amgen competes with other companies with respect to many of its marketed products as well as for the discovery and development of new products. Further, some raw materials, medical devices and component parts for Amgen's products are supplied by sole third-party suppliers. Certain of Amgen's distributors, customers and payers have substantial purchasing leverage in their dealings with Amgen. The discovery of significant problems with a product similar to one of Amgen's products that implicate an entire class of products could have a material adverse effect on sales of the affected products and on its business and results of operations. Amgen's efforts to acquire other companies or products and to integrate the operations of companies Amgen has acquired may not be successful. A breakdown, cyberattack or information security breach could compromise the confidentiality, integrity and availability of Amgen's systems and Amgen's data. Amgen's stock price may be volatile and may be affected by a number of events. Amgen's business performance could affect or limit the ability of the Amgen Board of Directors to declare a dividend or its ability to pay a dividend or repurchase its common stock. Amgen may not be able to access the capital and credit markets on terms that are favorable to it, or at all.

Allergan plc Forward-Looking Statements
Statements contained in this press release that refer to future events or other non-historical facts are forward-looking statements that reflect Allergan's current perspective on existing trends and information as of the date of this release. Actual results may differ materially from Allergan's current expectations depending upon a number of factors affecting Allergan's business. These factors include, among others, the difficulty of predicting the timing or outcome of FDA approvals or actions, if any; the impact of competitive products and pricing; market acceptance of and continued demand for Allergan's products; the impact of uncertainty around timing of generic entry related to key products, including RESTASIS®, on our financial results; risks associated with divestitures, acquisitions, mergers and joint ventures; risks related to impairments; uncertainty associated with financial projections, projected cost reductions, projected debt reduction, projected synergies, restructurings, increased costs, and adverse tax consequences; difficulties or delays in manufacturing; and other risks and uncertainties detailed in Allergan's periodic public filings with the Securities and Exchange Commission, including but not limited to Allergan's Annual Report on Form 10-K for the year ended December 31, 2018 and Allergan's Quarterly Report on Form 10-Q for the period ended March 31, 2019. Except as expressly required by law, Allergan disclaims any intent or obligation to update these forward-looking statements.

Herceptin® and Avastin® are registered trademarks of Genentech, Inc.

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