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FDA Approves BAVENCIO® (avelumab) Plus INLYTA® (axitinib) Combination for Patients with Advanced Renal Cell Carcinoma

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BAVENCIO is the first anti-PD-L1 in combination with INLYTA approved by FDA for first-line treatment of patients with advanced renal cell carcinoma (RCC) Phase III study showed combination significantly lowered risk of disease progression or death by 31% and extended progression-free survival by 5.4 months for patients with advanced RCC compared with sunitinib Combination approved based on Phase III data in an overall population that included patients regardless of PD-L1 expression and across favorable, intermediate and poor prognostic groups Additional regulatory reviews for BAVENCIO plus INLYTA in advanced RCC are underway worldwide, including in the European Union and Japan

Darmstadt, Germany and New York, US, May 14, 2019 – Merck KGaA, Darmstadt, Germany, which operates its biopharmaceutical business as EMD Serono in the US and Canada, and Pfizer Inc. (NYSE: PFE) today announced that the US Food and Drug Administration (FDA) has approved BAVENCIO® (avelumab) in combination with INLYTA® (axitinib) for the first-line treatment of patients with advanced renal cell carcinoma (RCC). This is the first FDA approval for an anti-PD-L1 therapy as part of a combination regimen for patients with advanced RCC. The approval of BAVENCIO in combination with INLYTA was based on positive results from the Phase III JAVELIN Renal 101 study (NCT02684006), in which the combination significantly improved median progression-free survival (PFS) compared with sunitinib by more than five months in the intent-to-treat (ITT) patient population (HR: 0.69 [95% CI: 0.56–0.84]; 2-sided p-value=0.0002; median PFS for BAVENCIO in combination with INLYTA: 13.8 months [95% CI: 11.1-NE]; sunitinib: 8.4 months [95% CI: 6.9-11.1]). The ITT population included patients regardless of PD-L1 expression and across IMDC (International Metastatic Renal Cell Carcinoma Database) prognostic risk groups (favorable 21%, intermediate 62% and poor 16%).[1]

“As we look to continue to improve outcomes for people with advanced RCC, new treatment approaches have the potential to benefit patients,” said Robert J. Motzer, M.D., Jack and Dorothy Byrne Chair in Clinical Oncology, Memorial Sloan Kettering Cancer Center, New York, US, and principal investigator for JAVELIN Renal 101. “With today’s FDA approval of avelumab in combination with axitinib, we can now offer patients with advanced RCC a first-line treatment option that combines a PD-L1 immunotherapy with a well-known VEGFR TKI to provide a significant reduction in the risk of disease progression or death and doubling of the response rate compared with sunitinib.”

RCC is a type of cancer where PD-L1 expression may contribute to inhibition of the immune response against the tumor.[2] It is also a highly vascular tumor, in which vascular endothelial growth factor (VEGF) plays a key role.[3]

“A kidney cancer diagnosis is life-changing for both patients and their loved ones, and having a treatment strategy for their disease quickly becomes a priority,” said Dena Battle, President, KCCure. “The approval of new treatments such as BAVENCIO in combination with INLYTA gives patients with advanced RCC much-needed options.”

There is a significant unmet need for first-line treatments that delay progression and have an acceptable safety profile. Approximately 20% to 30% of patients are first diagnosed with RCC at the advanced stage, and 30% of patients treated for an earlier stage go on to develop metastases.[4,5] About half of patients living with advanced RCC do not go on to receive additional treatment after first-line therapy,[6,7] for reasons that may include poor performance status or adverse events from their initial treatment.[6,8,9]

“Today’s approval of BAVENCIO in combination with INLYTA builds on Pfizer’s long heritage in bringing innovation to the RCC community with the hopes of making a significant and meaningful impact on the lives of patients,” said Andy Schmeltz, Global President, Pfizer Oncology. “For more than 12 years, Pfizer has led the field in its commitment to developing new treatments for patients with advanced kidney cancer.”

“With today’s FDA approval of BAVENCIO in combination with INLYTA, we feel privileged that we can offer patients with first-line advanced renal cell carcinoma a new treatment option,” said Rehan Verjee, President, EMD Serono, and Global Head of Innovative Medicine Franchises, Merck KGaA, Darmstadt, Germany.

In JAVELIN Renal 101, the objective response rate (ORR) was doubled in the ITT population with BAVENCIO in combination with INLYTA versus sunitinib (51.4% [95% CI: 46.6-56.1] vs. 25.7% [95% CI: 21.7-30.0]). With a median overall survival (OS) follow-up of 19 months, data for the trial’s other primary endpoint of OS were immature, with 27% of deaths in the ITT population, and the trial is continuing as planned. The most common adverse reactions (?20%) were diarrhea, fatigue, hypertension, musculoskeletal pain, nausea, mucositis, palmar-plantar erythrodysesthesia, dysphonia, decreased appetite, hypothyroidism, rash, hepatotoxicity, cough, dyspnea, abdominal pain and headache. Serious adverse reactions occurred in 35% of patients receiving BAVENCIO in combination with INLYTA. The incidence of major adverse cardiovascular events (MACE) was higher with BAVENCIO in combination with INLYTA versus sunitinib.[1] Findings from the study have been published in The New England Journal of Medicine.[10]

The European Medicines Agency (EMA) validated the Type II variation application for BAVENCIO in combination with INLYTA in advanced RCC in March 2019, and a supplemental application for BAVENCIO in combination with INLYTA in unresectable or metastatic RCC was submitted in Japan in January 2019.

The alliance is committed to providing patient access and reimbursement support through its CoverOne® program to patients who have been prescribed BAVENCIO. This program provides a spectrum of patient access and reimbursement support services intended to help US patients prescribed BAVENCIO receive appropriate access. CoverOne may be reached by phone at 844-8COVER1 (844-826-8371) or online at www.CoverOne.com .

Pfizer is committed to ensuring that patients who are prescribed INLYTA have access to this innovative therapy. Patients in the US have access to Pfizer Oncology Together™, which offers personalized support and financial assistance resources to help patients access their prescribed Pfizer Oncology medications. For more information, please call 1-877-744-5675 or visit PfizerOncologyTogether.com.

In an effort to streamline the patient enrollment process, EMD Serono and Pfizer have partnered to create a single enrollment form for the BAVENCIO and INLYTA combination for patients with advanced RCC that can be processed through both CoverOne and Pfizer Oncology Together. Each program will independently conduct the access and reimbursement activities for the product for which it is responsible.

About Renal Cell Carcinoma
In 2019, an estimated 73,820 new cases of kidney cancer will be diagnosed in the US, and approximately 14,770 people will die from the disease.[11] RCC is the most common form of kidney cancer, accounting for about 2% to 3% of all cancers in adults.[12,13] Approximately 20% to 30% of patients with kidney cancer are first diagnosed at the advanced stage.[4] The five-year survival rate for patients with metastatic RCC is approximately 12%.[14]

About the JAVELIN Renal 101 study
The Phase III JAVELIN Renal 101 study is a randomized (1:1), multicenter, open-label study of BAVENCIO in combination with INLYTA in 886 patients with untreated advanced RCC regardless of tumor PD-L1 expression [intent-to-treat (ITT) population]. Patients with autoimmune disease or conditions requiring systemic immunosuppression were excluded. The major efficacy outcome measures were PFS as assessed by a Blinded Independent Central Review (BICR) using RECIST v1.1 and OS in patients with PD-L1-positive tumors using a clinical trial assay (PD-L1 expression level ?1%). If PFS was statistically significant in patients with PD-L1-positive tumors, it was then tested in the ITT population. The hazard ratio for PFS in patients with PD-L1-positive tumors was HR 0.61 (95% CI: 0.48, 0.79). PFS and OS in the ITT population, overall response and safety are included as secondary endpoints. The study is continuing for OS.

About the JAVELIN Clinical Development Program
The clinical development program for avelumab, known as JAVELIN, involves at least 30 clinical programs and about 10,000 patients evaluated across more than 15 different tumor types. In addition to RCC, these tumor types include gastric/gastro-esophageal junction cancer, head and neck cancer, Merkel cell carcinoma, non-small cell lung cancer, and urothelial carcinoma.

About BAVENCIO® (avelumab)
BAVENCIO is a human anti-programmed death ligand-1 (PD-L1) antibody. BAVENCIO has been shown in preclinical models to engage both the adaptive and innate immune functions. By blocking the interaction of PD-L1 with PD-1 receptors, BAVENCIO has been shown to release the suppression of the T cell-mediated antitumor immune response in preclinical models.[15-17] BAVENCIO has also been shown to induce NK cell-mediated direct tumor cell lysis via antibody-dependent cell-mediated cytotoxicity (ADCC) in vitro.[17-19] In November 2014, Merck KGaA, Darmstadt, Germany, and Pfizer announced a strategic alliance to co-develop and co-commercialize BAVENCIO.

BAVENCIO Approved Indication in the US
BAVENCIO® (avelumab) in combination with INLYTA® (axitinib) is indicated in the US for the first-line treatment of patients with advanced renal cell carcinoma (RCC).

BAVENCIO Important Safety Information from the US FDA-Approved Label
BAVENCIO can cause **immune-mediated pneumonitis**, including fatal cases. Monitor patients for signs and symptoms of pneumonitis, and evaluate suspected cases with radiographic imaging. Administer corticosteroids for Grade 2 or greater pneumonitis. Withhold BAVENCIO for moderate (Grade 2) and permanently discontinue for severe (Grade 3), life-threatening (Grade 4), or recurrent moderate (Grade 2) pneumonitis. Pneumonitis occurred in 1.2% of patients, including one (0.1%) patient with Grade 5, one (0.1%) with Grade 4, and five (0.3%) with Grade 3.

BAVENCIO can cause **hepatotoxicity and immune-mediated hepatitis**, including fatal cases. Monitor patients for abnormal liver tests prior to and periodically during treatment. Administer corticosteroids for Grade 2 or greater hepatitis. Withhold BAVENCIO for moderate (Grade 2) immune-mediated hepatitis until resolution and permanently discontinue for severe (Grade 3) or life-threatening (Grade 4) immune-mediated hepatitis. Immune-mediated hepatitis occurred with BAVENCIO as a single agent in 0.9% of patients, including two (0.1%) patients with Grade 5, and 11 (0.6%) with Grade 3.

BAVENCIO in combination with *INLYTA* can cause **hepatotoxicity** with higher than expected frequencies of Grade 3 and 4 alanine aminotransferase (ALT) and aspartate aminotransferase (AST) elevation. Consider more frequent monitoring of liver enzymes as compared to when the drugs are used as monotherapy. Withhold BAVENCIO and INLYTA for moderate (Grade 2) hepatotoxicity and permanently discontinue the combination for severe or life-threatening (Grade 3 or 4) hepatotoxicity. Administer corticosteroids as needed. In patients treated with BAVENCIO in combination with INLYTA, Grades 3 and 4 increased ALT and AST occurred in 9% and 7% of patients, respectively, and immune-mediated hepatitis occurred in 7% of patients, including 4.9% with Grade 3 or 4.

BAVENCIO can cause **immune-mediated colitis**. Monitor patients for signs and symptoms of colitis. Administer corticosteroids for Grade 2 or greater colitis. Withhold BAVENCIO until resolution for moderate or severe (Grade 2 or 3) colitis until resolution. Permanently discontinue for life-threatening (Grade 4) or recurrent (Grade 3) colitis upon reinitiation of BAVENCIO. Immune-mediated colitis occurred in 1.5% of patients, including seven (0.4%) with Grade 3.

BAVENCIO can cause **immune-mediated endocrinopathies**, including adrenal insufficiency, thyroid disorders, and type 1 diabetes mellitus.

Monitor patients for signs and symptoms of **adrenal insufficiency** during and after treatment, and administer corticosteroids as appropriate. Withhold BAVENCIO for severe (Grade 3) or life-threatening (Grade 4) adrenal insufficiency. Adrenal insufficiency was reported in 0.5% of patients, including one (0.1%) with Grade 3.

Thyroid disorders can occur at any time during treatment. Monitor patients for changes in thyroid function at the start of treatment, periodically during treatment, and as indicated based on clinical evaluation. Manage hypothyroidism with hormone replacement therapy and hyperthyroidism with medical management. Withhold BAVENCIO for severe (Grade 3) or life-threatening (Grade 4) thyroid disorders. Thyroid disorders, including hypothyroidism, hyperthyroidism, and thyroiditis, were reported in 6% of patients, including three (0.2%) with Grade 3.

Type 1 diabetes mellitus including diabetic ketoacidosis: Monitor patients for hyperglycemia or other signs and symptoms of diabetes. Withhold BAVENCIO and administer antihyperglycemics or insulin in patients with severe or life-threatening (Grade ?3) hyperglycemia, and resume treatment when metabolic control is achieved. Type 1 diabetes mellitus without an alternative etiology occurred in 0.1% of patients, including two cases of Grade 3 hyperglycemia.

BAVENCIO can cause **immune-mediated nephritis and renal dysfunction**. Monitor patients for elevated serum creatinine prior to and periodically during treatment. Administer corticosteroids for Grade 2 or greater nephritis. Withhold BAVENCIO for moderate (Grade 2) or severe (Grade 3) nephritis until resolution to Grade 1 or lower. Permanently discontinue BAVENCIO for life-threatening (Grade 4) nephritis. Immune-mediated nephritis occurred in 0.1% of patients.

BAVENCIO can result in **other severe and fatal immune-mediated adverse reactions** involving any organ system during treatment or after treatment discontinuation. For suspected immune-mediated adverse reactions, evaluate to confirm or rule out an immune-mediated adverse reaction and to exclude other causes. Depending on the severity of the adverse reaction, withhold or permanently discontinue BAVENCIO, administer high-dose corticosteroids, and initiate hormone replacement therapy, if appropriate. Resume BAVENCIO when the immune-mediated adverse reaction remains at Grade 1 or lower following a corticosteroid taper. Permanently discontinue BAVENCIO for any severe (Grade 3) immune-mediated adverse reaction that recurs and for any life-threatening (Grade 4) immune-mediated adverse reaction. The following clinically significant immune-

mediated adverse reactions occurred in less than 1% of 1738 patients treated with BAVENCIO as a single agent or in 489 patients who received BAVENCIO in combination with INLYTA: myocarditis including fatal cases, pancreatitis including fatal cases, myositis, psoriasis, arthritis, exfoliative dermatitis, erythema multiforme, pemphigoid, hypopituitarism, uveitis, Guillain-Barré syndrome, and systemic inflammatory response.

BAVENCIO can cause severe or life-threatening **infusion-related reactions**. Premedicate patients with an antihistamine and acetaminophen prior to the first 4 infusions and for subsequent infusions based upon clinical judgment and presence/severity of prior infusion reactions. Monitor patients for signs and symptoms of infusion-related reactions, including pyrexia, chills, flushing, hypotension, dyspnea, wheezing, back pain, abdominal pain, and urticaria. Interrupt or slow the rate of infusion for mild (Grade 1) or moderate (Grade 2) infusion-related reactions. Permanently discontinue BAVENCIO for severe (Grade 3) or life-threatening (Grade 4) infusion-related reactions. Infusion-related reactions occurred in 25% of patients, including three (0.2%) patients with Grade 4 and nine (0.5%) with Grade 3.

BAVENCIO in combination with INLYTA can cause **major adverse cardiovascular events (MACE)** including severe and fatal events. Consider baseline and periodic evaluations of left ventricular ejection fraction. Monitor for signs and symptoms of cardiovascular events. Optimize management of cardiovascular risk factors, such as hypertension, diabetes, or dyslipidemia. Discontinue BAVENCIO and INLYTA for Grade 3-4 cardiovascular events. MACE occurred in 7% of patients with advanced RCC treated with BAVENCIO in combination with INLYTA compared to 3.4% treated with sunitinib. These events included death due to cardiac events (1.4%), Grade 3-4 myocardial infarction (2.8%), and Grade 3-4 congestive heart failure (1.8%).

BAVENCIO can cause **fetal harm** when administered to a pregnant woman. Advise patients of the potential risk to a fetus including the risk of fetal death. Advise females of childbearing potential to use effective contraception during treatment with BAVENCIO and for at least 1 month after the last dose of BAVENCIO. It is not known whether BAVENCIO is excreted in human milk. Advise a lactating woman **not to breastfeed** during treatment and for at least 1 month after the last dose of BAVENCIO due to the potential for serious adverse reactions in breastfed infants.

Please see full US Prescribing Information and Medication Guide available at http://www.BAVENCIO.com.

INLYTA Important Safety Information from the US FDA-Approved Label
Hypertension including **hypertensive crisis** has been observed with INLYTA. Blood pressure should be well controlled prior to initiating INLYTA. Monitor for hypertension and treat as needed. For persistent hypertension, despite use of antihypertensive medications, reduce the dose. Discontinue INLYTA if hypertension is severe and persistent despite use of antihypertensive therapy and dose reduction of INLYTA, and discontinuation should be considered if there is evidence of hypertensive crisis.

Arterial and venous thrombotic events have been observed with INLYTA and can be fatal. Use with caution in patients who are at increased risk or who have a history of these events.

Hemorrhagic events, including fatal events, have been reported with INLYTA. INLYTA has not been studied in patients with evidence of untreated brain metastasis or recent active gastrointestinal bleeding and should not be used in those patients. If any bleeding requires medical intervention, temporarily interrupt the INLYTA dose.

Cardiac failure has been observed with INLYTA and can be fatal. Monitor for signs or symptoms of cardiac failure throughout treatment with INLYTA. Management of cardiac failure may require permanent discontinuation of INLYTA.

Gastrointestinal perforation and fistula, including death, have occurred with INLYTA. Use with caution in patients at risk for gastrointestinal perforation or fistula. Monitor for symptoms of gastrointestinal perforation or fistula periodically throughout treatment.

Hypothyroidism requiring thyroid hormone replacement has been reported with INLYTA. Monitor thyroid function before initiation of, and periodically throughout, treatment.

No formal studies of the effect of INLYTA on **wound healing** have been conducted. Stop INLYTA at least 24 hours prior to scheduled surgery.

Reversible Posterior Leukoencephalopathy Syndrome (RPLS) has been observed with INLYTA. If signs or symptoms occur, permanently discontinue treatment.

Proteinuria has been observed with INLYTA. Monitor for proteinuria before initiation of, and periodically throughout, treatment with INLYTA. For moderate to severe proteinuria, reduce the dose or temporarily interrupt treatment.

Liver enzyme elevation has been observed during treatment with INLYTA. Monitor ALT, AST, and bilirubin before initiation of, and periodically throughout, treatment.

For patients with moderate **hepatic impairment**, the starting dose should be decreased. INLYTA has not been studied in patients with severe hepatic impairment.

INLYTA can cause **fetal harm**. Advise patients of the potential risk to the fetus and to use effective contraception during treatment.

Avoid strong **CYP3A4/5 inhibitors**. If unavoidable, reduce the dose. Grapefruit or grapefruit juice may also increase INLYTA plasma concentrations and should be avoided.

Avoid strong **CYP3A4/5 inducers** and, if possible, avoid moderate CYP3A4/5 inducers.

For more information and full Prescribing Information, visit www.INLYTA.com.

ADVERSE REACTIONS (BAVENCIO + INLYTA)

Fatal adverse reactions occurred in 1.8% of patients with **advanced renal cell carcinoma (RCC)** receiving BAVENCIO in combination with INLYTA. These included sudden cardiac death (1.2%), stroke (0.2%), myocarditis (0.2%), and necrotizing pancreatitis (0.2%).

The most common adverse reactions (all grades, ?20%) in patients with **advanced RCC** receiving BAVENCIO in combination with INLYTA (vs sunitinib) were diarrhea (62% vs 48%), fatigue (53% vs 54%), hypertension (50% vs 36%), musculoskeletal pain (40% vs 33%), nausea (34% vs 39%), mucositis (34% vs 35%), palmar-plantar erythrodysesthesia (33% vs 34%), dysphonia (31% vs 3.2%), decreased appetite (26% vs 29%), hypothyroidism (25% vs 14%), rash (25% vs 16%), hepatotoxicity (24% vs 18%), cough (23% vs 19%), dyspnea (23% vs 16%), abdominal pain (22% vs 19%), and headache (21% vs 16%).

Selected laboratory abnormalities (all grades, ?20%) worsening from baseline in patients with **advanced RCC** receiving BAVENCIO in combination with INLYTA (vs sunitinib) were blood triglycerides increased (71% vs 48%), blood creatinine increased (62% vs 68%), blood cholesterol increased (57% vs 22%), alanine aminotransferase increased (ALT) (50% vs 46%), aspartate aminotransferase increased (AST) (47% vs 57%), blood sodium decreased (38% vs 37%), lipase increased (37% vs 25%), blood potassium increased (35% vs 28%), platelet count decreased (27% vs 80%), blood bilirubin increased (21% vs 23%), and hemoglobin

decreased (21% vs 65%).

The most common adverse reactions (all grades, ?20%) in patients with **advanced RCC** receiving BAVENCIO in combination with INLYTA (vs sunitinib) were diarrhea (62% vs 48%), fatigue (53% vs 54%), hypertension (50% vs 36%), musculoskeletal pain (40% vs 33%), nausea (34% vs 39%), mucositis (34% vs 35%), palmar-plantar erythrodysesthesia (33% vs 34%), dysphonia (31% vs 3.2%), decreased appetite (26% vs 29%), hypothyroidism (25% vs 14%), rash (25% vs 16%), hepatotoxicity (24% vs 18%), cough (23% vs 19%), dyspnea (23% vs 16%), abdominal pain (22% vs 19%), and headache (21% vs 16%).

Selected laboratory abnormalities (all grades, ?20%) worsening from baseline in patients with **advanced RCC** receiving BAVENCIO in combination with INLYTA (vs sunitinib) were blood triglycerides increased (71% vs 48%), blood creatinine increased (62% vs 68%), blood cholesterol increased (57% vs 22%), alanine aminotransferase increased (ALT) (50% vs 46%), aspartate aminotransferase increased (AST) (47% vs 57%), blood sodium decreased (38% vs 37%), lipase increased (37% vs 25%), blood potassium increased (35% vs 28%), platelet count decreased (27% vs 80%), blood bilirubin increased (21% vs 23%), and hemoglobin decreased (21% vs 65%).

About Merck KGaA, Darmstadt, Germany-Pfizer Alliance
Immuno-oncology is a top priority for Merck KGaA, Darmstadt, Germany and Pfizer. The global strategic alliance between Merck KGaA, Darmstadt, Germany and Pfizer enables the companies to benefit from each other's strengths and capabilities and further explore the therapeutic potential of BAVENCIO, an anti-PD-L1 antibody initially discovered and developed by Merck KGaA, Darmstadt, Germany. The immuno-oncology alliance is jointly developing and commercializing BAVENCIO. The alliance is focused on developing high-priority international clinical programs to investigate BAVENCIO as a monotherapy as well as combination regimens, and is striving to find new ways to treat cancer.

All Merck KGaA, Darmstadt, Germany, press releases are distributed by e-mail at the same time they become available on the EMD Group Website. In case you are a resident of the USA or Canada please go to www.emdgroup.com/subscribe to register again for your online subscription of this service as our newly introduced geo-targeting requires new links in the email. You may later change your selection or discontinue this service.

About Merck KGaA, Darmstadt, Germany
Merck KGaA, Darmstadt, Germany, a leading science and technology company, operates across healthcare, life science and performance materials. Around 52,000 employees work to make a positive difference to millions of people's lives every day by creating more joyful and sustainable ways to live. From advancing gene editing technologies and discovering unique ways to treat the most challenging diseases to enabling the intelligence of devices – the company is everywhere. In 2018, Merck KGaA, Darmstadt, Germany, generated sales of € 14.8 billion in 66 countries.

The company holds the global rights to the name and trademark "Merck" internationally. The only exceptions are the United States and Canada, where the business sectors of Merck KGaA, Darmstadt, Germany operate as EMD Serono in healthcare, MilliporeSigma in life science, and EMD Performance Materials. Since its founding 1668, scientific exploration and responsible entrepreneurship have been key to the company's technological and scientific advances. To this day, the founding family remains the majority owner of the publicly listed company.

Pfizer Inc.: Working together for a healthier world®
At Pfizer, we apply science and our global resources to bring therapies to people that extend and significantly improve their lives. We strive to set the standard for quality, safety and value in the discovery, development and manufacture of health care products. Our global portfolio includes medicines and vaccines as well as many of

the world's best-known consumer health care products. Every day, Pfizer colleagues work across developed and emerging markets to advance wellness, prevention, treatments and cures that challenge the most feared diseases of our time. Consistent with our responsibility as one of the world's premier innovative biopharmaceutical companies, we collaborate with health care providers, governments and local communities to support and expand access to reliable, affordable health care around the world. For more than 150 years, we have worked to make a difference for all who rely on us. We routinely post information that may be important to investors on our website at www.pfizer.com. In addition, to learn more, please visit us on www.pfizer.com and follow us on Twitter at @Pfizer and @Pfizer_News, LinkedIn, YouTube and like us on Facebook at Facebook.com/Pfizer.

Pfizer Disclosure Notice
The information contained in this release is as of May 14, 2019. Pfizer assumes no obligation to update forward-looking statements contained in this release as the result of new information or future events or developments.

This release contains forward-looking information about BAVENCIO (avelumab), including a new indication approved in the U.S. for BAVENCIO in combination with INLYTA (axitinib) for the treatment of patients with advanced renal cell carcinoma, the alliance between Merck KGaA, Darmstadt, Germany, and Pfizer involving BAVENCIO and clinical development plans, including their potential benefits, that involves substantial risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. Risks and uncertainties include, among other things, uncertainties regarding the commercial success of BAVENCIO and INLYTA; the uncertainties inherent in research and development, including the ability to meet anticipated clinical endpoints, commencement and/or completion dates for our clinical trials, regulatory submission dates, regulatory approval dates and/or launch dates, as well as the possibility of unfavorable new clinical data and further analyses of existing clinical data and uncertainties regarding whether the other primary endpoint of JAVELIN Renal 101 will be met; risks associated with interim data; the risk that clinical trial data are subject to differing interpretations and assessments by regulatory authorities; whether regulatory authorities will be satisfied with the design of and results from our clinical studies; whether and when any drug applications may be filed for BAVENCIO in combination with INLYTA in any other jurisdictions or in any jurisdictions for any other potential indications for BAVENCIO or combination therapies; whether and when the pending applications in the European Union and Japan for BAVENCIO in combination with INLYTA may be approved and whether and when regulatory authorities in any jurisdictions where any other applications are pending or may be submitted for BAVENCIO or combination therapies, including BAVENCIO in combination with INLYTA may approve any such applications, which will depend on myriad factors, including making a determination as to whether the product's benefits outweigh its known risks and determination of the product's efficacy, and, if approved, whether they will be commercially successful; decisions by regulatory authorities impacting labeling, manufacturing processes, safety and/or other matters that could affect the availability or commercial potential of BAVENCIO or combination therapies, including BAVENCIO in combination with INLYTA; and competitive developments.

A further description of risks and uncertainties can be found in Pfizer's Annual Report on Form 10-K for the fiscal year ended December 31, 2018, and in its subsequent reports on Form 10-Q, including in the sections thereof captioned "Risk Factors" and "Forward-Looking Information and Factors That May Affect Future Results", as well as in its subsequent reports on Form 8-K, all of which are filed with the U.S. Securities and Exchange Commission and available at www.sec.gov and www.pfizer.com.

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