News Release

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NICE Recommends BAVENCIO® (Avelumab) in Combination with Axitinib for First-Line Treatment of Adult Patients with Advanced Renal Cell Carcinoma (aRCC)

- **This is the first combination of an immunotherapy with a targeted antiangiogenic therapy to be recommended by NICE as a first-line treatment option for aRCC for use within the Cancer Drugs Fund.**

Rockland, MA and New York, US, July 31, 2020 – EMD Serono, the biopharmaceutical business of Merck KGaA, Darmstadt, Germany in the US and Canada, and Pfizer (NYSE: PFE) announced today that the National Institute for Health and Care Excellence (NICE) has recommended the immunotherapy BAVENCIO® (avelumab) in combination with axitinib for the first-line treatment of adult patients with advanced renal cell carcinoma (RCC) for use within the Cancer Drugs Fund.

Kidney cancer is the seventh most common cancer in the UK.[1] Renal cell carcinoma (RCC) is the most common type, accounting for more than 8 out of 10 kidney cancers in adults.[2] Outcomes for patients with advanced RCC remain unacceptably poor, with a five-year survival rate of approximately 12% at the latest stage.[1] Most of the first-line treatment options NICE recommends for advanced RCC are targeted antiangiogenic therapies (e.g. tyrosine kinase inhibitor (TKIs))[3] which many patients have inherent resistance to.[4] About half of patients with metastatic RCC do not receive a second-line therapy,[5,6] for reasons including poor performance status or adverse events from initial treatment.[5,6,7] Therefore, more first-line treatment options are needed for advanced RCC patients from all prognostic groups.

Avelumab is an immune checkpoint inhibitor targeting PD-L1[8] and axitinib is an antiangiogenic VEGF-targeted TKI.[9] The combination of these treatments has complementary mechanisms of action, providing enhanced benefits by targeting two key pathways that tumours use to grow: inhibiting angiogenesis and stimulating the immune system's anti-tumour responses.[4]

The JAVELIN Renal 101 study demonstrated that avelumab in combination with axitinib met the primary endpoint of significantly longer progression-free survival (PFS) in patients with PD-L1-positive clear cell advanced RCC, compared to patients who received sunitinib.[8]

In the overall population, irrespective of PD-L1 status and across all prognostic risk groups, the combination significantly lowered the risk of disease progression or death by 31% (HR: 0.69 [95% CI: 0.574–0.825; p<0.0001]).[10]

It demonstrated superiority in PFS compared to sunitinib alone, improving median PFS in the overall population by 5.3 months (13.3 months [95% CI: 11.1-15.3] vs 8 months [95% CI: 6.7-9.8], HR 0.69 (0.57;0.83; p <0.0001)).[10] The combination therapy also nearly doubled the objective response rate (ORR) compared with sunitinib (ORR; 52.5% [95% CI: 47.7-57.2] vs. 27.3% [95% CI: 23.2-31.6]).[10] The study is ongoing to determine overall survival benefit.

Professor Amit Bahl, a consultant medical oncologist specialised in renal cell carcinoma, said: "*This positive recommendation from NICE provides patients with advanced Renal Cancer an effective and well tolerated treatment option with proven benefits in progression free survival and objective response rates from a randomised Phase 3 trial. This could improve outcomes in this group of patients. The combination of an immunotherapy with a tyrosine kinase inhibitor provides patients a novel treatment option.*"

The incidence of kidney cancer in the UK has risen by 87% since the early 1990s, and it now accounts for 4% of all new cancer cases in the UK.[1] It is more common than cervical cancer and liver cancer combined.[1,11,12]

Approximately 13,056 new cases of kidney cancer are diagnosed in the UK every year.[1] More than 4 in 10 patients are first diagnosed with kidney cancer at a late stage,[1] and 30% of patients treated for localised RCC at an earlier stage go on to develop tumour recurrence.[13]

Nick Turkentine, CEO of Kidney Cancer UK said: *"We are delighted with NICE's decision to give NHS patients access to this new combination therapy, as there is a real need to improve outcomes and increase treatment options for people with advanced renal cell carcinoma."*

The combination demonstrated a safety and tolerability profile consistent with the known safety profiles of avelumab and axitinib as monotherapy, and the frequency of adverse events is similar to treatment with sunitinib.[4] In the overall population, 71.6% of those receiving combination therapy and 71.5% of those receiving sunitinib experienced at least one treatment-emergent adverse event of grade three or above.[10]

Dr Mike England, Medical Director, Merck KGaA, Darmstadt, Germany, UK & Ireland said: *"Through our alliance with Pfizer, we are proud to be bringing innovation to a therapy area where there is a clear unmet need for new treatment options. This is the first immunotherapy and targeted antiangiogenic therapy combination recommended by NICE as a first-line option for patients with advanced RCC in England and Wales, who will now be able to access the potential enhanced benefits of combining these two types of treatment. We are working closely with healthcare professionals to support and help inform their treatment decisions during these unprecedented times, while continuing to provide patients with the best possible care."*

Immune checkpoint inhibitors are a type of immunotherapy that have shown promising results against a variety of cancers.[14] By binding to PD-L1 on tumour cells, avelumab allows the immune system to recognise and kill tumour cells.[8] Axitinib targets vascular endothelial growth factor (VEGF) receptors, which play a role in angiogenesis, tumour growth and metastatic progression.[9]

Dr Olivia Ashman, Oncology Medical Director, Pfizer UK said: *"We are delighted with the decision to make this treatment available to UK patients. The combination has the potential to improve the lives of patients living with RCC as well as help healthcare professionals optimise their patients' treatment. NICE's positive recommendation also addresses the significant need for first-line treatments with a benefit across all prognostic risk groups."*

Avelumab in combination with axitinib was made available as part of the Early Access to Medicines Scheme (EAMS) in August 2019. This has allowed more than 150 patients to gain earlier access to this innovative combination treatment throughout the UK.

As NICE has now published its Final Appraisal Document, the combination is immediately available to NHS patients in England and Wales via the Cancer Drugs Fund.

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About the JAVELIN Renal 101 Study
Bavencio plus axitinib was approved for this indication by the European Commission based on interim data from the ongoing Phase III JAVELIN Renal 101 study; a randomised, multicentre, open-label study of avelumab in combination with axitinib in 886 patients with untreated advanced RCC with a clear cell component. The study included patients across risk groups (International Metastatic Renal Cell Carcinoma Database Consortium [IMDC]: 21% favourable, 62% intermediate and 16% poor). The primary efficacy endpoints were progression-free survival (PFS) as assessed by a Blinded Independent Central Review (BICR) using RECIST v1.1 and overall survival (OS) in the first-line treatment of patients with advanced RCC who have PD-L1-positive tumours (PD-L1 expression level ≥1%). If PFS was statistically significant in patients with PD-L1-positive tumours, it was then assessed in all patients irrespective of PD-L1 expression. PFS based on BICR assessment per RECIST v1.1 and OS irrespective of PD-L1 expression, objective response, time to response (TTR), duration of response (DOR) and safety are included as secondary endpoints. The JAVELIN Renal 101 study is ongoing as patients continue to be followed for overall survival.

About EAMS
The Early Access to Medicines Scheme (EAMS) aims to provide earlier availability to promising new unlicensed medicines for UK patients with high unmet clinical need. A full assessment of the quality, safety and efficacy of the treatment is conducted by the Medicines and Healthcare products Regulatory Agency's assessment teams.

About PD-L1
PD-L1 is a protein expressed on the surface of cells, which binds to PD-1 receptors on T cells of the immune system to stop them from attacking them. Some tumour cells also have PD-L1 proteins on their surface ('PD-L1 positive' status), preventing the immune T cells from recognising and attacking them.[15] BAVENCIO is an antibody which binds to PD-L1 on tumour cells and blocks it from binding to the PD-1 receptors on T cells, allowing the immune system T cells to recognise and kill the cancer cells.[8]

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.[10-12] In November 2014, Merck KGaA, Darmstadt, Germany and Pfizer announced a strategic alliance to co-develop and co-commercialize BAVENCIO.

BAVENCIO Approved Indications

BAVENCIO® (avelumab) is indicated in the US for the maintenance treatment of patients with locally advanced or metastatic urothelial carcinoma (UC) that has not progressed with first-line platinum-containing chemotherapy. BAVENCIO is also indicated for the treatment of patients with locally advanced or metastatic UC who have disease progression during or following platinum-containing chemotherapy, or have disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy.

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

In the US, the FDA granted accelerated approval for BAVENCIO for the treatment of adults and pediatric patients 12 years and older with metastatic Merkel cell carcinoma (MCC). This indication is approved under accelerated approval based on tumor response rate and duration of response. Continued approval may be contingent upon verification and description of clinical benefit in confirmatory trials.

Avelumab is currently approved for patients with MCC in 50 countries globally, with the majority of these approvals in a broad indication that is not limited to a specific line of treatment.

IMPORTANT SAFETY INFORMATION for BAVENCIO

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 fatal, 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 fatal, 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 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.

INLYTA
Hypertension including **hypertensive crisis** has been observed. 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 and can be fatal. Use with caution in patients who are at increased risk for, or who have a history of, these events.
Hemorrhagic events, including fatal events, have been reported. 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 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. 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. Monitor thyroid function before initiation of, and periodically throughout, treatment.
INLYTA has the potential to adversely affect **wound healing.** Withhold INLYTA for at least 2 days prior to elective surgery. Do not administer INLYTA for at least 2 weeks following major surgery and until adequate wound healing. The safety of resuming INLYTA after resolution of wound healing complications has not been established.
Reversible Posterior Leukoencephalopathy Syndrome (RPLS) has been observed. If signs or symptoms occur, permanently discontinue treatment.
Monitor for **proteinuria** before initiation of, and periodically throughout, treatment. For moderate to severe proteinuria, reduce the dose or temporarily interrupt treatment with INLYTA.
INLYTA in combination with BAVENCIO® (avelumab) can cause **hepatotoxicity** with higher than expected frequencies of Grades 3 and 4 alanine aminotransferase (ALT) and aspartate aminotransferase (AST) elevation. Monitor ALT, AST, and bilirubin before initiation of, and periodically throughout, treatment. Consider more frequent monitoring of liver enzymes as compared to when the drugs are used for monotherapy. Consider withholding INLYTA and/or BAVENCIO, initiating corticosteroid therapy, and/or permanently discontinuing the combination for severe or life-threatening hepatotoxicity.
For patients with moderate **hepatic impairment,** the starting dose of INLYTA should be decreased. INLYTA has not been studied in patients with severe hepatic impairment.
INLYTA in combination with BAVENCIO can cause severe and fatal **major adverse cardiovascular events (MACE).** Consider baseline and periodic evaluations of left ventricular ejection fraction and monitor for signs and symptoms of cardiovascular events. Optimize management of cardiovascular risk factors, such as hypertension, diabetes, or dyslipidemia. Discontinue INLYTA and BAVENCIO for Grade 3 or 4 cardiovascular events.
INLYTA can cause **fetal harm.** Advise patients of the potential risk to the fetus and to use effective contraception.
Avoid strong **CYP3A4/5 inhibitors.** If unavoidable, reduce the dose of INLYTA. 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.

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%).

Please see full Prescribing Information and Medication Guide for BAVENCIO and full Prescribing Information for INLYTA.

About the Merck KGaA, Darmstadt, Germany-Pfizer Alliance
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 avelumab, an anti-PD-L1 antibody initially discovered and developed by Merck KGaA, Darmstadt, Germany. The immuno-oncology alliance will jointly develop and commercialise avelumab. The alliance is focused on developing high-priority international clinical programmes to investigate avelumab as a monotherapy, as well as in combination regimens, and is striving to find new ways to treat cancer.

About EMD Serono, Inc.
EMD Serono - the biopharmaceutical business of Merck KGaA, Darmstadt, Germany, in the U.S. and Canada - is engaged in the discovery, research and development of medicines for patients with difficult to treat diseases. The business is committed to transforming lives by developing and delivering meaningful solutions that help address the therapeutic and support needs of individual patients. Building on a proven legacy and deep expertise in neurology, fertility and endocrinology, EMD Serono is developing potential new oncology and immuno-oncology medicines while continuing to explore potential therapeutic options for diseases such as psoriasis, lupus and MS. Today, the business has approximately 1,500 employees around the country with commercial, clinical and research operations based in the company's home state of Massachusetts. www.emdserono.com.

About Merck KGaA, Darmstadt, Germany
Merck KGaA, Darmstadt, Germany, a leading science and technology company, operates across healthcare, life science and performance materials. Around 57,000 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 2019, Merck KGaA, Darmstadt, Germany, generated sales of € 16.2 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.: Breakthroughs that change patients' lives
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, including innovative medicines and vaccines. 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 June 30, 2020. 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 in the U.S. for the maintenance treatment of patients with locally advanced or metastatic urothelial carcinoma

that has not progressed with first-line platinum-containing chemotherapy, 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; 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; 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 for first-line maintenance treatment for locally advanced or metastatic urothelial carcinoma in any other jurisdictions or in any jurisdictions for any other potential indications for BAVENCIO or combination therapies; whether and when regulatory authorities in any jurisdictions where any applications are pending or may be submitted for BAVENCIO or combination therapies, including BAVENCIO for locally advanced or metastatic urothelial carcinoma 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, including BAVENCIO for locally advanced or metastatic urothelial carcinoma; the impact of COVID-19 on Pfizer's business, operations and financial results; 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, 2019, 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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