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European Medicines Agency Validates Application for BAVENCIO® (avelumab) for First-Line Maintenance Treatment of Locally Advanced or Metastatic Urothelial Carcinoma

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Not intended for UK-based media

Darmstadt, Germany, and New York, US, June 22, 2020 – Merck and Pfizer Inc. (NYSE: PFE) today announced that the European Medicines Agency (EMA) has validated for review the Type II variation application for BAVENCIO® (avelumab) for first-line maintenance treatment of patients with locally advanced or metastatic urothelial carcinoma (UC). With this validation, the application is complete, and the EMA will now begin the review procedure.

The application is based on results from the Phase III JAVELIN Bladder 100 study which showed a statistically significant improvement in overall survival (OS) for BAVENCIO plus best supportive care (BSC) as first-line maintenance treatment following induction chemotherapy versus BSC alone in patients with locally advanced or metastatic UC. The data were presented at the ASCO 2020 Virtual Scientific Meeting.

In the European Union alone, nearly 200,000 people are diagnosed each year with bladder cancer.1 Urothelial carcinoma accounts for approximately 90 percent of bladder cancers.2 Urothelial carcinoma becomes harder to treat as it advances, spreading through the layers of the bladder wall.3 Despite available therapies, more than 60,000 Europeans die from bladder cancer each year.1

Earlier this year, the US Food and Drug Administration (FDA) accepted a supplemental Biologics License Application (sBLA) for first-line maintenance treatment of patients with locally advanced or metastatic UC for Priority Review under the agency’s Real-Time Oncology Review (RTOR) pilot program. The FDA also granted Breakthrough Therapy Designation to BAVENCIO for this indication.

In addition, a supplemental new drug application has also been accepted by Japan's Ministry of Health, Labour and Welfare for BAVENCIO as a first-line maintenance therapy for locally advanced or metastatic UC.

About JAVELIN Bladder 100

JAVELIN Bladder 100 (NCT02603432) is a Phase III, multicenter, multinational, randomized, open-label, parallel-arm study investigating first-line maintenance treatment with BAVENCIO plus BSC versus BSC alone in patients with locally advanced or metastatic UC. A total of 700 patients whose disease had not progressed after platinum-based induction chemotherapy as per RECIST v1.1 were randomly assigned to receive either

BAVENCIO plus BSC or BSC alone. The primary endpoint was OS in the two primary populations of all patients and patients with PD-L1+ tumors defined by the Ventana SP263 assay.

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.4-6 In November 2014, Merck and Pfizer announced a strategic alliance to co-develop and co-commercialize BAVENCIO.

BAVENCIO Approved Indications

The European Commission has authorized the use of BAVENCIO in combination with axitinib for the first-line treatment of adult patients with advanced renal cell carcinoma (RCC). In September 2017, the European Commission granted

conditional marketing authorization for BAVENCIO as a monotherapy for the treatment of adult patients with metastatic Merkel cell carcinoma (MCC).

In the US, BAVENCIO in combination with axitinib is indicated for the first-line treatment of patients with advanced renal cell carcinoma (RCC). Additionally, the US Food and Drug Administration (FDA) granted accelerated approval for avelumab (BAVENCIO®) for the treatment of (i) adults and pediatric patients 12 years and older with metastatic Merkel cell carcinoma (mMCC) and (ii) patients with locally advanced or metastatic urothelial carcinoma (mUC) 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. These indications are approved under accelerated approval based on tumor response rate and duration of response. Continued approval for these indications may be contingent upon verification and description of clinical benefit in confirmatory trials.

BAVENCIO 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.

BAVENCIO Safety Profile from the EU Summary of Product Characteristics (SmPC)

The special warnings and precautions for use for BAVENCIO monotherapy include infusion-related reactions, as well as immune-related adverse reactions that include pneumonitis and hepatitis (including fatal cases), colitis, pancreatitis (including fatal cases), myocarditis (including fatal cases), endocrinopathies, nephritis and renal dysfunction, and other immune-related adverse reactions. The special warnings and precautions for use for BAVENCIO in combination with axitinib include hepatotoxicity.

The SmPC list of the most common adverse reactions with BAVENCIO monotherapy in patients with solid tumors includes fatigue, nausea, diarrhea, decreased appetite, constipation, infusion-related reactions, weight decreased and vomiting. The list of most common adverse reactions with BAVENCIO in combination with axitinib includes diarrhea, hypertension, fatigue, nausea, dysphonia, decreased appetite, hypothyroidism, cough, headache, dyspnea, and arthralgia.

About Merck-Pfizer Alliance

Immuno-oncology is a top priority for Merck and Pfizer. The global strategic alliance between Merck 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. 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.

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About Merck

Merck, 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 generated sales of € 16.2 billion in 66 countries.

Scientific exploration and responsible entrepreneurship have been key to Merck's technological and scientific advances. This is how Merck has thrived since its founding in 1668. The founding family remains the majority owner of the publicly listed company. Merck holds the global rights to the Merck name and brand. The only exceptions are the United States and Canada, where the business sectors of Merck operate as EMD Serono in healthcare, MilliporeSigma in life science, and EMD Performance Materials.

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 22, 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 potential indication for first-line maintenance treatment of patients with locally advanced or metastatic urothelial carcinoma in the EU for BAVENCIO, the alliance between Merck 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 of patients with 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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