

## News Release

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### **Not intended for UK-based media**

## **New Data for BAVENCIO® (avelumab) for Advanced Cancers to Be Presented at ESMO 2019**

- **Analyses from the Phase III JAVELIN Renal 101 study support efficacy of BAVENCIO plus axitinib across multiple subgroups of patients with advanced renal cell carcinoma (RCC)**
- **Abstracts highlight data on BAVENCIO as a monotherapy and in combination in multiple advanced cancers**

Darmstadt, Germany, and New York, US, September 27, 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 the presentation of multiple analyses from the JAVELIN clinical development program assessing BAVENCIO® (avelumab) alone or as part of combination regimens for the treatment of advanced cancers, including renal cell carcinoma (RCC), metastatic Merkel cell carcinoma (mMCC) and some other solid tumors at the European Society for Medical Oncology (ESMO) Congress 2019 in Barcelona, Spain.

“These data at ESMO underscore the clinical activity of treatment with BAVENCIO across multiple tumor types and patient populations,” said Chris Boshoff, M.D., Ph.D., Chief Development Officer, Oncology, Pfizer Global Product Development. “Furthermore, these presentations demonstrate our commitment to identifying the patients most likely to benefit from this immunotherapy as a single agent, or in combination approaches.”

“The immunotherapy era has led to vast progress in the treatment of cancer, yet we know that many patients with advanced or aggressive cancers still need additional treatment options,” said Luciano Rossetti, M.D., Executive Vice President, Head of Global R&D for the Biopharma

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business of Merck KGaA, Darmstadt, Germany. “We are committed to continued research of BAVENCIO as we seek to further advance treatment options for patients with certain cancers.”

Data to be presented at ESMO include three subgroup analyses of the Phase III JAVELIN Renal 101 study (NCT02684006), a randomized, multicenter, open-label study of BAVENCIO in combination with axitinib in 886 patients with untreated advanced RCC from patients across all International Metastatic RCC Database Consortium (IMDC) risk groups. This study, results of which were published in *The New England Journal of Medicine* in February 2019, demonstrated that BAVENCIO in combination with axitinib significantly improved progression-free survival (PFS) compared with sunitinib in patients with advanced RCC, with a generally acceptable safety tolerability profile, including serious adverse events.<sup>1</sup>

Results from new analyses of JAVELIN Renal 101 being presented at ESMO, which assessed the effect of BAVENCIO in combination with axitinib in subgroups including patients who did not undergo cytoreductive nephrectomy, patients with sarcomatoid histology, and Japanese patients, are consistent with findings from the overall JAVELIN Renal 101 study population and provide a better understanding of the combination in a broad range of patients with advanced RCC. In May 2019, the U.S. Food and Drug Administration (FDA) approved BAVENCIO in combination with axitinib for the first-line treatment of patients with advanced RCC.<sup>2</sup> The Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) adopted a positive opinion recommending approval of BAVENCIO in combination with axitinib for the first-line treatment of adult patients with advanced RCC in September 2019.

### **Presentation #908PD: Phase III JAVELIN Renal 101 Study Subgroup Analysis of Patients with Advanced RCC who did not Undergo Upfront Cytoreductive Nephrectomy**

- Sunday, September 29, 15:20 – 15:20: Pamplona Auditorium (Hall 2)

A post-hoc analysis of JAVELIN Renal 101 evaluated patients with advanced RCC who did not undergo prior surgery to remove as much of the visible tumors on the kidneys as possible (cytoreductive nephrectomy), which comprised 20.2% of participants in the study. The findings showed that patients with advanced RCC treated with BAVENCIO in combination with axitinib who did not undergo an upfront cytoreductive nephrectomy experienced greater shrinkage of the primary renal tumor versus sunitinib ( $\geq 30\%$  shrinkage for best percent change in renal target lesions from baseline in 34.5% versus 9.7%, respectively).<sup>3</sup> The majority of patients with advanced RCC undergo nephrectomy before starting systemic treatment,<sup>4</sup> and those who do

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undergo nephrectomy may experience complications or delays in treatment.<sup>5</sup> These results are the first of their kind to report the efficacy of an immunotherapy plus a tyrosine kinase inhibitor in patients with advanced RCC when there is still a primary tumor present.<sup>3</sup>

### ***Presentation #910PD: Phase III JAVELIN Renal 101 Study Subgroup Analysis of Patients with Advanced RCC with Sarcomatoid Histology***

- Sunday, September 29, 15:20 – 15:20: Pamplona Auditorium (Hall 2)

A post-hoc analysis of JAVELIN Renal 101 in patients with advanced RCC with sarcomatoid histology, an aggressive subtype of RCC<sup>6</sup> that carries the worst prognosis for patients with renal tumors,<sup>7,8</sup> included 12.2% of participants in the trial. The results presented at ESMO showed that BAVENCIO plus axitinib improved PFS and objective response rate (ORR) versus sunitinib in patients with advanced RCC with sarcomatoid histology (median PFS: 7.0 months versus 4.0 months, HR 0.57 [95% CI, 0.325-1.003]; median ORR: 46.8% versus 21.3%). These findings provide insight into the biology of sarcomatoid histology and treatment with this immunotherapy in this subgroup of patients.<sup>9</sup>

### ***Presentation #956P: Phase III JAVELIN Renal 101 Study Subgroup Analysis of Japanese Patients with Advanced RCC***

- Monday, September 30, 12:20 - 12:20: Poster Area (Hall 4)

An analysis assessing the efficacy and safety of Japanese patients with advanced RCC (n=67) in JAVELIN Renal 101 study showed that BAVENCIO in combination with axitinib improved median PFS compared to sunitinib in Japanese patients with advanced RCC regardless of PD-L1 expression (16.6 months versus 11.2 months, respectively; HR, 0.66; [95% CI, 0.30-1.46]). Common treatment-emergent adverse events (grade  $\geq$ 3) in each arm included hand-foot syndrome (9% versus 9%), hypertension (30% versus 18%), and platelet count decreased (0% versus 32%).<sup>10</sup> A supplemental application for BAVENCIO in combination with axitinib in unresectable or metastatic RCC was submitted in Japan in January 2019.

Additional presentations at ESMO show the potential impact of BAVENCIO as a monotherapy and as a component of novel combinations:

- An analysis of health-related quality of life (HRQoL) from the Phase II JAVELIN Merkel 200 study, in which patients with mMCC, an aggressive form of skin cancer with poor outcomes,<sup>11</sup> treated with BAVENCIO reported stable or improved HRQoL across various time points (presentation #1320P).<sup>12</sup>

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- Interim results from the Phase Ib JAVELIN IL-12 study evaluating BAVENCIO in combination with M9241, Merck KGaA, Darmstadt, Germany's investigational IL-12 fusion protein containing an anti-DNA antibody, in patients with solid tumors, which informed the recommended dosing for Phase II of this study (presentation #1224P).<sup>13</sup>
- Post-hoc analyses from the JAVELIN Solid Tumor Phase I trial (presentation #1493P)<sup>14</sup> and Phase III JAVELIN Lung 200 study (presentation #1492P)<sup>15</sup> that further elucidate the effects of BAVENCIO in patients with advanced non-small cell lung cancer.

### **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.<sup>16-18</sup> BAVENCIO has also been shown to induce NK cell-mediated direct tumor cell lysis via antibody-dependent cell-mediated cytotoxicity (ADCC) in vitro.<sup>18-20</sup> 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) 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 (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.

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

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### **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 axitinib* 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 axitinib 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 axitinib, 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.

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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  $\geq 3$ ) 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

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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 axitinib*: 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 axitinib* 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 axitinib for Grade 3-4 cardiovascular events. MACE occurred in 7% of patients with advanced RCC treated with BAVENCIO in combination with axitinib 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

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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>.

### **Axitinib Important Safety Information from the US FDA-Approved Label**

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

**Arterial and venous thrombotic events** have been observed with axitinib 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 axitinib. Axitinib 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 axitinib dose.

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

**Gastrointestinal perforation and fistula**, including death, have occurred with axitinib. 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 axitinib. Monitor thyroid function before initiation of, and periodically throughout, treatment.

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

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

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

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

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

Axitinib 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 axitinib plasma concentrations and should be avoided.

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

Please see full [Prescribing Information](#) for axitinib.

### **ADVERSE REACTIONS (BAVENCIO + AXITINIB)**

**Fatal adverse reactions** occurred in 1.8% of patients with **advanced renal cell carcinoma (RCC)** receiving BAVENCIO in combination with axitinib. 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,  $\geq 20\%$ ) in patients with **advanced RCC** receiving BAVENCIO in combination with axitinib (vs sunitinib) were diarrhea (62% vs 48%),

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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,  $\geq 20\%$ ) worsening from baseline in patients with **advanced RCC** receiving BAVENCIO in combination with axitinib (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,  $\geq 20\%$ ) in patients with **advanced RCC** receiving BAVENCIO in combination with axitinib (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%).

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### **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



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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](http://www.sec.gov) and [www.pfizer.com](http://www.pfizer.com).

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