Merck KGaA,
Darmstadt, Germany

News Release

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Merck KGaA, Darmstadt, Germany, and Pfizer to Present Data Highlighting Potential of Avelumab in Challenging Cancers at ASCO 2017

- **A total of 13 abstracts across seven hard-to-treat cancers highlight the progress of avelumab as a monotherapy and potential novel combination treatment option**
- **New data in metastatic Merkel cell carcinoma and previously treated metastatic urothelial carcinoma, following recent US FDA accelerated approvals**

Darmstadt, Germany, and New York, US, May 17, 2017 – Merck KGaA, Darmstadt, Germany, and Pfizer today announced that 13 avelumab* abstracts across seven challenging tumor types will be featured at the 53rd American Society of Clinical Oncology (ASCO) Annual Meeting held June 2–6, 2017 in Chicago, IL. Key presentations include data for avelumab in first-line metastatic Merkel cell carcinoma (mMCC) and in previously treated metastatic urothelial carcinoma (UC), as well as results from the Phase Ib trial investigating avelumab in combination with the tyrosine kinase inhibitor axitinib, in advanced renal cell carcinoma (RCC).

"Our ASCO presence adds to what has already been a momentous year for the alliance, coming shortly after the US FDA granted two accelerated approvals for avelumab," said Luciano Rossetti, M.D., Executive Vice President, Global Head of Research & Development at the biopharma business of Merck KGaA, Darmstadt, Germany, which in the US and Canada operates as EMD Serono. "We're particularly

excited to share the latest avelumab data in both metastatic Merkel cell carcinoma in the first-line setting and previously treated metastatic urothelial carcinoma with the cancer community."

"Our data at ASCO this year underscore the potential of avelumab as a monotherapy treatment, as well as part of combination regimens," said Chris Boshoff, M.D., PhD, Senior Vice President and Head of Immuno-Oncology, Early Development, Translational Oncology, Pfizer Global Product Development. "Now with accelerated approvals in two indications for avelumab in the US, we are entering the next chapter of our clinical development program to provide meaningful new treatment options for patients who need them most."

Highlights of avelumab data at ASCO 2017 include the following:

- Preliminary data from the ongoing JAVELIN Merkel 200 trial, an open-label, multicenter study conducted in first-line mMCC investigating avelumab in patients who had no prior systemic treatment for mMCC, will be presented for the first time at a medical congress.
- Data from a pooled analysis of two metastatic UC cohorts of the JAVELIN Solid Tumor trial, a Phase Ib, open-label, single-arm, multicenter study of avelumab in the treatment of various solid tumors, will be presented.
- An oral presentation of results from the JAVELIN Renal 100 trial, a Phase Ib, open-label study evaluating the clinical activity and safety of the combination of avelumab and axitinib for the first-line treatment of advanced RCC.
- Beyond mMCC, metastatic UC and RCC, the alliance between Merck KGaA, Darmstadt, Germany, and Pfizer will also showcase avelumab abstracts in non-small cell lung cancer, metastatic castrate-resistant prostate cancer, locally advanced squamous cell carcinoma of the head and neck and relapsed or refractory diffuse large B-cell lymphoma, as well as updated safety data in solid tumors.

The alliance's rapidly accelerating JAVELIN clinical development program now involves at least 30 clinical programs, including nine Phase III trials, and more than 5,200 patients across more than 15 tumor types. Results from JAVELIN program trials have supported two FDA accelerated approvals in 2017.

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A list of accepted avelumab abstracts is included below. The abstracts are also available on the ASCO website.

Title	Lead Author	Abstract ID / Poster No.	Presentation Date / Time	Session
Oral Presentations				
Renal Cell Carcinoma (JAVELIN Renal 100) First-line avelumab + axitinib therapy in patients with advanced renal cell carcinoma: results from a phase 1b trial	Choueiri TK	4504	Monday, June 5 8:00-11:00 a.m.	Genitourinary (Nonprostate) Cancer
Poster Sessions				
Head and Neck Cancer (TiP) (JAVELIN Head and Neck 100) JAVELIN Head and Neck 100: a phase 3 trial of avelumab in combination with chemoradiotherapy (CRT) vs CRT for 1st-line treatment of locally advanced squamous cell carcinoma of the head and neck (LA SCCHN)	Lee NY	TPS6093	Monday, June 5 1:15-4:45 p.m.	Head and Neck Cancer

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Lymphoma (TiP) (JAVELIN DLBCL) Phase 1b/3 study of avelumab-based combination regimens in patients (pts) with relapsed or refractory diffuse large B-cell lymphoma (R/R DLBCL)	Chen R	TPS7575	Monday, June 5 8:00-11:30 a.m.	Hematologic Malignancies—Lymphoma and Chronic Lymphocytic Leukemia
Merkel Cell Carcinoma (JAVELIN Merkel 200) First-line avelumab treatment in patients with metastatic Merkel cell carcinoma: preliminary data from an ongoing study	D'Angelo SP	9530	Saturday, June 3 1:15-4:45 p.m.	Melanoma/Skin Cancers
Merkel Cell Carcinoma (JAVELIN Merkel 200) Exploratory biomarker analysis in patients with chemotherapy-refractory metastatic Merkel cell carcinoma treated with avelumab	Shapiro I	9557	Saturday, June 3 1:15-4:45 p.m.	Melanoma/Skin Cancers

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Non-Small Cell Lung Cancer (JAVELIN Solid Tumor) Exposure–response and PD-L1 expression analysis of second-line avelumab in patients with advanced NSCLC: data from the JAVELIN Solid Tumor trial	Gulley JL	9086	Saturday, June 3 8:00-11:30 a.m.	Lung Cancer—Non-Small Cell Metastatic
Pan-Tumor (JAVELIN Solid Tumor) Safety profile of avelumab in patients with advanced solid tumors: a JAVELIN pooled analysis of phase 1 and 2 data	Kelly K	3059	Monday, June 5 8:00-11:30 a.m.	Developmental Therapeutics—Immunotherapy
Prostate Cancer (JAVELIN Solid Tumor) Avelumab in metastatic castration-resistant prostate cancer (mCRPC)	Fakhrejahani F	5037	Monday, June 5 1:15-4:45 PM	Genitourinary (Prostate) Cancer
Renal Cell Carcinoma (JAVELIN Renal 101) Avelumab plus axitinib vs sunitinib as first-line treatment of advanced renal cell carcinoma: phase 3 study (JAVELIN Renal 101)	Choueiri TK	TPS4594	Sunday, June 4 8:00-11:30 a.m.	Genitourinary (Nonprostate)

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Urothelial Carcinoma (JAVELIN Solid Tumor) Updated efficacy and safety of avelumab in metastatic urothelial carcinoma: pooled analysis from 2 cohorts of the phase 1b JAVELIN Solid Tumor study	Apolo AB	4528	Sunday, June 4 8:00-11:30 a.m.	Genitourinary (Nonprostate) Cancer
Publications				
Merkel Cell Carcinoma (JAVELIN Merkel 200) Non-progression during avelumab treatment is associated with clinically relevant improvements in health-related quality of life in patients with Merkel cell carcinoma	Bharmal M	e21070		
Merkel Cell Carcinoma (JAVELIN Merkel 200) Patient experiences with avelumab vs chemotherapy for treating Merkel cell carcinoma: results from protocol-specified qualitative research	Kaufman HL	e21065		

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Non-Small Cell Lung Cancer (JAVELIN Solid Tumor) Comparative study of two PD-L1 expression assays in patients with non-small cell lung cancer (NSCLC)	Feng Z	e20581		

*Avelumab is under clinical investigation for treatment of NSCLC, RCC, DLBCL, SSCHN and mCRPC and has not been demonstrated to be safe and effective for these indications. There is no guarantee that avelumab will be approved for NSCLC, RCC, DLBCL, SSCHN and mCRPC by any health authority worldwide.

About Avelumab

Avelumab is a human antibody specific for a protein called PD-L1, or programmed death ligand-1. Avelumab is designed to potentially engage both the adaptive and innate immune systems. By binding to PD-L1, avelumab is thought to prevent tumor cells from using PD-L1 for protection against white blood cells, such as T-cells, exposing them to anti-tumor responses. Avelumab has been shown to induce antibody-dependent cell-mediated cytotoxicity (ADCC) in vitro. In November 2014, Merck KGaA, Darmstadt, Germany, and Pfizer announced a strategic alliance to co-develop and co-commercialize avelumab.

Indications

The US Food and Drug Administration (FDA) granted accelerated approval for avelumab (BAVENCIO®) for the treatment of (i) metastatic Merkel cell carcinoma (mMCC) in adults and pediatric patients 12 years and older and (ii) patients with locally advanced or metastatic urothelial carcinoma (UC) who have disease progression during or following platinum-containing chemotherapy, or who have disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy. Continued approval for these indications may be contingent upon verification and description of clinical benefit in confirmatory trials. Avelumab is not approved for any indication in any market outside the US.

Important Safety Information

The warnings and precautions for BAVENCIO include immune-mediated adverse reactions (such as pneumonitis, hepatitis, colitis, endocrinopathies, nephritis and renal dysfunction and other adverse reactions), infusion-related reactions and embryo-fetal toxicity.

Common adverse reactions (reported in at least 20% of patients) in patients treated with avelumab include fatigue, musculoskeletal pain, diarrhea, nausea, infusion-related reaction, peripheral edema, decreased appetite/hypophagia, urinary tract infection and rash.

For full prescribing information and medication guide for BAVENCIO, please see www.BAVENCIO.com.

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Alliance between Merck KGaA, Darmstadt, Germany, and Pfizer Inc., New York, US
Immuno-oncology is a top priority for Merck KGaA, Darmstadt, Germany, and Pfizer Inc. The global strategic alliance between Merck KGaA, Darmstadt, Germany, and Pfizer Inc., New York, US, 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 commercialize avelumab and advance Pfizer's PD-1 antibody. The alliance is focused on developing high-priority international clinical programs to investigate avelumab as a monotherapy, as well as in combination regimens, and is striving to find new ways to treat cancer.

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About Merck KGaA, Darmstadt, Germany
Merck KGaA, Darmstadt, Germany, is a leading science and technology company in healthcare, life science and performance materials. Around 50,000 employees work to further develop technologies that improve and enhance life – from biopharmaceutical therapies to treat cancer or multiple sclerosis, cutting-edge systems for scientific research and production, to liquid crystals for smartphones and LCD televisions. In 2016, Merck KGaA, Darmstadt, Germany, generated sales of €15.0 billion in 66 countries.
Founded in 1668, Merck KGaA, Darmstadt, Germany, is the world's oldest pharmaceutical and chemical company. The founding family remains the majority owner of the publicly listed corporate group. Merck KGaA, Darmstadt, Germany, operates as EMD Serono, MilliporeSigma and EMD Performance Materials in the United States and Canada.

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 at 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 17, 2017. 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), the alliance between Merck KGaA, Darmstadt, Germany, and Pfizer involving anti-PD-L1 and anti-PD-1 therapies, 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 study commencement and completion dates and regulatory submission dates, as well as the possibility of unfavorable study results, including unfavorable new clinical data and additional analyses of existing clinical data; risks associated with interim data; the risk that clinical trial data are subject to differing interpretations, and, even when we view data as sufficient to support the safety and/or effectiveness of a product candidate, regulatory authorities may not share our views and may require additional data or may deny approval altogether; whether and when drug applications may be filed in any other jurisdictions for the Indication or in any jurisdictions for any other potential indications for BAVENCIO, combination therapies or other product candidates; whether and when any such applications (including the pending application for BAVENCIO for metastatic Merkel cell carcinoma in the EU) may be approved by regulatory authorities, which will depend on the assessment by such regulatory authorities

of the benefit-risk profile suggested by the totality of the efficacy and safety information submitted; decisions by regulatory authorities regarding labeling and other matters that could affect the availability or commercial potential of BAVENCIO, combination therapies or other product candidates; and competitive developments. This release contains forward-looking information about BAVENCIO (avelumab), the Merck KGaA, Darmstadt, Germany, Pfizer Alliance involving anti-PD-L1 and anti-PD-1 therapies, 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 study commencement and completion dates and regulatory submission dates, as well as the possibility of unfavorable study results, including unfavorable new clinical data and additional analyses of existing clinical data; risks associated with interim data; the risk that clinical trial data are subject to differing interpretations, and, even when we view data as sufficient to support the safety and/or effectiveness of a product candidate, regulatory authorities may not share our views and may require additional data or may deny approval altogether; whether and when drug applications may be filed in any jurisdictions for potential indications for BAVENCIO, combination therapies or other product candidates; whether and when any such applications (including the pending application for BAVENCIO for metastatic Merkel cell carcinoma in the EU) may be approved by regulatory authorities, which will depend on the assessment by such regulatory authorities of the benefit-risk profile suggested by the totality of the efficacy and safety information submitted; decisions by regulatory authorities regarding labeling and other matters that could affect the availability or commercial potential of BAVENCIO, combination therapies or other product candidates; 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, 2016, 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.