Merck KGaA
Darmstadt, Germany

News Release

Your Contacts

Merck KGaA, Darmstadt, Germany
Media: Gangolf Schrimpf +49 6151 72 9591
Investor Relations: +49 6151 72 3321

Pfizer Inc., New York, USA
Media: Sally Beatty +1 212 733 6566
Investor Relations: Ryan Crowe +1 212 733 8160

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Merck KGaA, Darmstadt, Germany, and Pfizer Announce First Patient Treated in Phase III Combination Study with Avelumab and INLYTA® in Renal Cell Carcinoma

- **JAVELIN Renal 101 marks first Phase III study to evaluate avelumab in combination with a small molecule tyrosine kinase inhibitor therapy**
- **Combination approach leverages Pfizer's broad oncology portfolio and heritage in renal cell carcinoma**
- **First-line study evaluating avelumab in combination with INLYTA® (axitinib) compared with SUTENT® (sunitinib malate) monotherapy**

Darmstadt, Germany, and New York, US, April 5, 2016 – Merck KGaA, Darmstadt, Germany, and Pfizer (NYSE: PFE) today announced the treatment of the first patient in a Phase III study of avelumab*, an investigational fully human anti-PD-L1 IgG1 monoclonal antibody, in an advanced renal cell carcinoma (RCC) setting. The study, JAVELIN Renal 101, is the first pivotal trial investigating avelumab in combination with INLYTA® (axitinib), a tyrosine kinase inhibitor (TKI), in patients with previously untreated advanced RCC, and the only Phase III trial currently evaluating an anti-PD-L1 immunotherapy in combination with a vascular endothelial growth factor (VEGF)-receptor TKI in this setting. The current 5-year survival rate for patients with distant metastatic RCC is approximately 12 percent.[1]

"Pfizer has a strong heritage in the treatment of metastatic RCC, and through the strategic alliance with Merck KGaA, Darmstadt, Germany, we aim to further accelerate the development of potential therapies to help improve the lives of patients living with this disease," said Chris Boshoff, M.D., PhD., Vice President and Head of Early Development, Translational and Immuno-Oncology at Pfizer Oncology. "As renal cell carcinoma is an

immunogenic type of tumor that can respond to immunotherapy and to anti-angiogenic treatment, there is a strong scientific rationale for combining avelumab with INLYTA® and we believe that this combination may help improve outcomes for patients with this cancer."

JAVELIN Renal 101 is a multicenter, international, randomized (1:1), open-label Phase III trial designed to evaluate the potential superiority, assessed by the progression-free survival (PFS), of first-line avelumab combined with INLYTA® compared with SUTENT® (sunitinib malate) monotherapy, an oral, small-molecule, multi-targeted receptor TKI, in patients with unresectable, locally advanced or metastatic RCC with clear cell component. The study will enroll 583 patients across approximately 170 sites in Asia, Europe, Latin America and North America.

"The first patient receiving treatment in this pivotal trial marks an important milestone in the strategic immuno-oncology alliance between Merck KGaA, Darmstadt, Germany, and Pfizer," said Alise Reicin, M.D., Head of Global Clinical Development at the biopharma business of Merck KGaA, Darmstadt, Germany, which in the US and Canada operates as EMD Serono. "As part of the JAVELIN clinical development program, we are exploring the potential of innovative, rational combination therapies, which combine avelumab with other treatment modalities to address significant unmet needs that exist in challenging cancers, such as advanced renal cell carcinoma."

The clinical development program for avelumab now includes more than 1,600 patients who have been treated across more than 15 tumor types.

INLYTA® is currently approved in the United States for the treatment of advanced RCC after failure of one prior systemic therapy. INLYTA® is also approved by the European Medicines Agency for use in the European Union in adult patients with advanced RCC after failure of prior treatment with SUTENT® or a cytokine. Following its approval in 2012, INLYTA® has become a standard of care for second-line advanced RCC and has been used by an estimated 12,000 metastatic renal cell carcinoma patients in the United States.[2] INLYTA® is under investigation in combination with avelumab for the indication studied in this Phase III trial.

*Avelumab is the proposed International Non-proprietary Name for the anti-PD-L1 monoclonal antibody (MSB0010718C). Avelumab is under clinical investigation and has not been proven to be safe and effective. There is no guarantee any product will be approved in the sought-after indication by any health authority worldwide.

References

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About Renal Cell Carcinoma

Renal cell carcinoma accounts globally for 2-3% of all malignancies.[3] As of 2012, more than 338,000 new cases of kidney cancer were diagnosed per year worldwide.[4] In general, higher incidence rates of renal cell carcinoma occur in Eastern Asia, North America and Central/Eastern Europe.[5] Early-stage renal cancers tend to have a better prognosis, compared with advanced/metastatic renal cancers.[6]

The five-year survival rate for localized kidney and renal pelvis cancer is approximately 90%.[1] The five-year overall survival rate for patients with distant metastatic RCC is approximately 12%.[1]

In the past 7 years, major advances have been made in the improvement of clinical outcomes with the introduction of new therapies.[7] The introduction of these therapies has extended median survival rates for metastatic renal cell carcinoma.[7]

About Avelumab

Avelumab (also known as MSB0010718C) is an investigational fully human anti-PD-L1 IgG1 monoclonal antibody. By inhibiting PD-L1 interactions, avelumab is thought to enable the activation of T-cells and the adaptive immune system. By retaining a native Fc-region, avelumab is thought to potentially engage the innate immune system and induce antibody-dependent cell-mediated cytotoxicity (ADCC). In November 2014, Merck KGaA, Darmstadt, Germany, and Pfizer announced a strategic alliance to co-develop and co-commercialize avelumab.

About INLYTA® (axitinib)

INLYTA is indicated for the treatment of advanced RCC after failure of one prior systemic therapy. INLYTA, a kinase inhibitor, is an oral therapy that is designed to inhibit tyrosine kinases, including vascular endothelial growth factor (VEGF) receptors 1, 2 and 3; these receptors can influence tumor growth, vascular angiogenesis and progression of cancer (the spread of tumors).

Selected Safety Information for INLYTA® (axitinib)

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 anti-hypertensive medications, reduce the INLYTA 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 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 with INLYTA.

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. 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.

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.

Women of childbearing potential should be advised of the potential hazard to the fetus and to avoid becoming pregnant while receiving INLYTA.

The most common (≥20%) adverse reactions are diarrhea, hypertension, fatigue, decreased appetite, nausea, dysphonia, palmar-plantar erythrodysesthesia (hand-foot) syndrome, weight decreased, vomiting, asthenia, and constipation.

The most common (≥20%) lab abnormalities occurring in patients receiving INLYTA (all grades, vs sorafenib) included increased creatinine, decreased bicarbonate, hypocalcemia, decreased hemoglobin, decreased lymphocytes (absolute), increased ALP, hyperglycemia, increased lipase, increased amylase, increased ALT, and increased AST.

INLYTA is indicated for the treatment of advanced renal cell carcinoma (RCC) after failure of one prior systemic therapy.

For more information on INLYTA and Pfizer Oncology, including Full Prescribing Information, please visit www.pfizer.com.

About SUTENT® (sunitinib malate)
SUTENT is an oral multi-kinase inhibitor that works by blocking multiple molecular targets implicated in the growth, proliferation and spread of cancer. SUTENT was approved in 2006 and is indicated for the treatment of advanced/metastatic renal cell carcinoma.

Selected Safety Information for SUTENT® (sunitinib malate)
Boxed Warning/Hepatotoxicity: Hepatotoxicity has been observed in clinical trials and post-marketing experience. This hepatotoxicity may be severe, and deaths have been reported. Monitor liver function tests before initiation of treatment, during each cycle of treatment, and as clinically indicated. SUTENT should be interrupted for Grade 3 or 4 drug-related hepatic adverse events and discontinued if there is no resolution. Do not restart SUTENT if patients subsequently experience severe changes in liver function tests or have other signs and symptoms of liver failure.

Women of childbearing potential should be advised of the potential hazard to the fetus and to avoid becoming pregnant.

Given the potential for serious adverse reactions (ARs) in nursing infants, a decision should be made whether to discontinue nursing or SUTENT.

Cardiovascular events, including heart failure, cardiomyopathy, myocardial ischemia, and myocardial infarction, some of which were fatal, have been reported. Use SUTENT with caution in patients who are at risk for, or who

have a history of, these events. Monitor patients for signs and symptoms of congestive heart failure (CHF) and, in the presence of clinical manifestations, discontinuation is recommended. Patients who presented with cardiac events, pulmonary embolism, or cerebrovascular events within the previous 12 months were excluded from clinical studies.

SUTENT has been shown to prolong QT interval in a dose-dependent manner, which may lead to an increased risk for ventricular arrhythmias including Torsades de Pointes, which has been seen in <0.1% of patients. Monitoring with on-treatment electrocardiograms and electrolytes should be considered.
Hypertension may occur. Monitor blood pressure and treat as needed with standard antihypertensive therapy. In cases of severe hypertension, temporary suspension of SUTENT is recommended until hypertension is controlled.

There have been (<1%) reports, some fatal, of subjects presenting with seizures and radiological evidence of reversible posterior leukoencephalopathy syndrome (RPLS).

Hemorrhagic events, including tumor-related hemorrhage such as pulmonary hemorrhage, have occurred. Some of these events were fatal. Perform serial complete blood counts (CBCs) and physical examinations.

Cases of Tumor Lysis Syndrome (TLS) have been reported primarily in patients with high tumor burden. Monitor these patients closely and treat as clinically indicated.

Thrombotic microangiopathy (TMA), including thrombotic thrombocytopenic purpura and hemolytic uremic syndrome, sometimes leading to renal failure or a fatal outcome, has been reported in patients who received SUTENT as monotherapy and in combination with bevacizumab. Discontinue SUTENT in patients developing TMA. Reversal of the effects of TMA has been observed after treatment was discontinued.

Proteinuria and nephrotic syndrome have been reported. Some of these cases have resulted in renal failure and fatal outcomes. Perform baseline and periodic urinalysis during treatment, with follow-up measurement of 24-hour urine protein as clinically indicated. Interrupt SUTENT and dose-reduce if 24-hour urine protein is ≥3 g; discontinue SUTENT in cases of nephrotic syndrome or repeat episodes of urine protein ≥3 g despite dose reductions.

Severe cutaneous reactions have been reported, including cases of erythema multiforme (EM), Stevens-Johnson syndrome (SJS), and toxic epidermal necrolysis (TEN), some of which were fatal. If signs or symptoms of EM, SJS, or TEN are present, SUTENT treatment should be discontinued. If a diagnosis of SJS or TEN is suspected, treatment must not be re-started. Necrotizing fasciitis, including fatal cases, has been reported, including of the perineum and secondary to fistula formation. Discontinue SUTENT in patients who develop necrotizing fasciitis.

SUTENT has been associated with symptomatic hypoglycemia, which may result in loss of consciousness or require hospitalization. Reductions in blood glucose levels may be worse in patients with diabetes. Check blood glucose levels regularly during and after discontinuation of SUTENT. Assess whether antidiabetic drug dosage needs to be adjusted to minimize the risk of hypoglycemia.

The most common adverse reactions (≥20%) are fatigue, asthenia, fever, diarrhea, nausea, mucositis/stomatitis, vomiting, dyspepsia, abdominal pain, constipation, hypertension, peripheral edema, rash, hand-foot syndrome, skin discoloration, dry skin, hair color changes, altered taste, headache, back pain, arthralgia, extremity pain, cough, dyspnea, anorexia, and bleeding.

For more information on SUTENT and Pfizer Oncology, including Full Prescribing Information, including Boxed warning, please visit www.pfizer.com.

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 investigational 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.

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 healthcare products. Our global portfolio includes medicines and vaccines as well as many of the

world's best-known consumer healthcare 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, Pfizer has worked to make a difference for all who rely on us. For more information, please visit us at www.pfizer.com. In addition, to learn more, follow us on Twitter at @Pfizer and @Pfizer_News, LinkedIn, YouTube, and like us on Facebook at Facebook.com/Pfizer.

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 2015, Merck KGaA, Darmstadt, Germany, generated sales of € 12.85 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, holds the global rights to the Merck KGaA, Darmstadt, Germany, name and brand. The only exceptions are the United States and Canada, where the company operates as EMD Serono, MilliporeSigma and EMD Performance Materials.

Pfizer Disclosure Notice
The information contained in this release is as of April 5, 2016. 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 avelumab (MSB0010718C), including a potential indication for avelumab in combination with axitinib for the treatment of advanced renal cell carcinoma, Pfizer's and Merck KGaA, Darmstadt, Germany's immuno-oncology 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, the uncertainties inherent in research and development, including the ability to meet anticipated clinical study commencement and completion dates as well as the possibility of unfavorable study results; 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 any potential indications for avelumab, combination therapies or other product candidates; whether and when any such applications 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 avelumab, 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, 2015, 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.