News Release

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Not intended for UK-based media

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ESMO Abstract #
Avelumab: 777PD, 7775PD, 1154P, 842TiP, 844TiP; **Erbitux:** 527P, 491P, 967P, 994P; **Tepotinib:** 1257P, 1287TiP, 1292TiP

Merck KGaA, Darmstadt, Germany to Present New Research Focused on Hard-to-Treat Cancers at ESMO 2016

- **Merck KGaA, Darmstadt, Germany, to feature new research from marketed and pipeline compounds**
- **Preliminary results from combination study with avelumab in renal cell carcinoma, and updates on Phase II tepotinib program in non-small cell lung cancer, to be presented**
- **Merck KGaA, Darmstadt, Germany, to announce 2016 Grant for Oncology Innovation winners coinciding with ESMO**

Darmstadt, Germany, September 28, 2016 – Merck KGaA, Darmstadt, Germany, a leading science and technology company, today announced that new research from their marketed and pipeline compounds will be presented at this year's European Society for Medical Oncology (ESMO; October 7–11, 2016, Copenhagen, Denmark) annual meeting. Presentations will focus on hard-to-treat cancers, and include: study results for Erbitux® (cetuximab) in metastatic colorectal cancer (mCRC) and squamous cell carcinoma of the head and neck (SCCHN); preliminary study results in bladder cancer and renal cell carcinoma (RCC) for avelumab, which is being developed in collaboration with Pfizer; and updates on the Phase II program for tepotinib* in non-small cell lung cancer (NSCLC).

"The data being presented at ESMO reflect our commitment to making a meaningful difference in patients' lives, in particular those who are affected by hard-to-treat cancers," said Luciano Rossetti, Executive Vice President, Head of

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Global Research & Development at the biopharma business of Merck KGaA, Darmstadt, Germany. “We continue to focus on researching the full potential of Erbitux, as well as our ongoing pipeline development programs for avelumab and other early-stage oncology and immune-oncology compounds.”

At ESMO, avelumab will be featured in four posters that add to the growing body of evidence of the potential of this investigational compound. These will include data updates in bladder cancer that confirm avelumab’s potential in this hard-to-treat cancer; and preliminary results from a combination study with axitinib in RCC that support the rationale to evaluate the combination in a Phase III pivotal study. Tepotinib, a highly selective c-Met kinase inhibitor, will also be highlighted in three posters, with updates on the ongoing study program in c-Met-positive metastatic NSCLC.

Several studies, which will be presented at ESMO, once again reaffirm Erbitux as a standard-of-care therapy for mCRC patients with RAS wild-type tumors and patients with SCCHN.

Merck KGaA, Darmstadt, Germany, believes that to truly deliver the promise of innovation for patients, it is vital to support and encourage research from other endeavors. This is demonstrated through Merck KGaA, Darmstadt, Germany’s Grant for Oncology Innovation (GOI) initiative, which awards researchers for their pioneering independent work in pushing the boundaries of creativity and science in order to deliver transformative innovation. The award ceremony will once again coincide with ESMO and takes place on Sunday, October 9, 2016.

*Tepotinib is the proposed nonproprietary name for the c-Met kinase inhibitor (also known as MSC2156119J).

Avelumab and tepotinib are under clinical investigation and have 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.

Notes to Editors
Accepted Merck KGaA, Darmstadt, Germany-supported abstracts are listed below. In addition, a number of investigator-sponsored studies have been accepted, including several related to Erbitux (not listed).

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Title	Lead Author	Abstract #	Presentation date/time (CDT)	Session	Room/ Details
Erbitux					
Impact of tumor epidermal growth factor receptor (EGFR) status on the outcomes of first-line FOLFOX-4 ± cetuximab in patients (pts) with RAS-wild-type (wt) metastatic colorectal cancer (mCRC) in the randomized phase 3 TAILOR trial	S Qin	527P	October 8 13:00–14:00	Poster Display Session	Hall E
Impact of surgical resection of liver metastases on outcome of patients with metastatic colorectal carcinoma (mCRC) treated with a cetuximab-based first-line therapy - Analysis of the KRAS-wildtype exon 2 (KRAS-wt) subgroup of the German non-interventional study ERBITAG	U Neumann	491P	October 8 13:00–14:00	Poster Display Session	Hall E
Observational study of the dose intensity relative to cetuximab in the first-line treatment of recurrent and/or metastatic squamous cell carcinoma of the head and neck: data on the maintenance and bi-weekly use (DIRECT study)	J Guigay	967P	October 9 13:00–14:00	Poster Display Session	Hall E
Cetuximab in combination with platinum-based chemotherapy or radiotherapy in recurent and/or metastatic SCCHN in a non-selected patient cohort (interim analysis of the phase IV SOCCER trial)	M Hecht	994P	October 9 13:00–14:00	Poster Display Session	Hall E

Title	Lead Author	Abstract #	Presentation date/time (CDT)	Session	Room/ Details
Avelumab					
Avelumab (MSB0010718C; anti-PD-L1) in patients with metastatic urothelial carcinoma progressed after platinum-based therapy or platinum ineligible	M Patel	777PD	October 9 16:30–17:30	Poster Discussion Session Genitourinary tumors, non-prostate	Athens
Phase 1b dose-finding study of avelumab (anti-PD-L1) + axitinib in treatment-naïve patients with advanced renal cell carcinoma	J Larkin	775PD	October 9 16:30–17:30	Poster Discussion Session Genitourinary tumors, non-prostate	Athens
Evaluation of real world treatment outcomes in patients with metastatic Merkel cell carcinoma (MCC) following second line chemotherapy	J Becker	1154P	October 9 13:00–14:00	Poster Display Session	Hall E
A multicenter, international, randomized, open-label phase 3 trial of avelumab + best supportive care (BSC) vs BSC alone as maintenance therapy	T Powles	842TiP	October 9 13:00–14:00	Poster Display Session	Hall E

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after first-line platinum-based chemotherapy in patients with advanced urothelial cancer (JAVELIN Bladder 100)					
Phase 3 study of avelumab in combination with axitinib versus sunitinib as first-line treatment for patients with advanced renal cell carcinoma (aRCC)	R Motzer	844TiP	October 9 13:00–14:00	Poster Display Session	Hall E

Title	Lead author	Abstract #	Presentation date / time (CDT)	Session	Room / Details
Tepotinib					
Tepotinib plus gefitinib in patients with c-Met-positive/EGFR-mutant NSCLC: recommended phase II dose (RP2D), tolerability, and efficacy	Y-L Wu	1257P	October 8 13:00–14:00	Poster Display Session	Hall E
Design of a phase II trial comparing tepotinib + gefitinib with cisplatin + pemetrexed in EGFR inhibitor-resistant, c-Met+ NSCLC	Y-L Wu	1287TiP	October 8 13:00–14:00	Poster Display Session	Hall E
A phase II trial investigating the highly selective c-Met inhibitor tepotinib in stage IIIB/IV lung adenocarcinoma with MET exon 14 alterations after failure of at least one prior therapy	P Paik	1292TiP	October 8 13:00–14:00	Poster Display Session	Hall E

For further information and press materials please visit:
http://www.emdgroup.com/emd/media/media_center_oncology.html

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About Avelumab
Avelumab (also known as MSB0010718C) is an investigational, fully human antibody specific for a protein found on tumor cells called PD-L1, or programmed death ligand-1. Avelumab is thought to have a dual mechanism of action which may enable the immune system to find and attack cancer cells. 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 is also thought to help white blood cells such as natural killer (NK) cells find and attack tumors in a process known as ADCC, or antibody-dependent cell-mediated cytotoxicity. In November 2014, Merck KGaA, Darmstadt, Germany, and Pfizer announced a strategic alliance to co-develop and co-commercialize avelumab.

About Erbitux
Erbitux® is a highly active IgG1 monoclonal antibody targeting the epidermal growth factor receptor (EGFR). As a monoclonal antibody, the mode of action of Erbitux is distinct from standard non-selective chemotherapy treatments in that it specifically targets and binds to the EGFR. This binding inhibits the activation of the receptor and the subsequent signal-transduction pathway, which results in reducing both the invasion of normal tissues by tumor cells and the spread of tumors to new sites. It is also believed to inhibit the ability of tumor cells to repair the damage caused by chemotherapy and radiotherapy and to inhibit the formation of new blood vessels inside tumors, which appears to lead to an overall suppression of tumor growth.

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The most commonly reported side effect with Erbitux is an acne-like skin rash. In approximately 5% of patients, hypersensitivity reactions may occur during treatment with Erbitux; about half of these reactions are severe.

Erbitux has already obtained market authorization in over 90 countries world-wide for the treatment of colorectal cancer and for the treatment of squamous cell carcinoma of the head and neck (SCCHN). Merck KGaA, Darmstadt, Germany, licensed the right to market Erbitux outside the US and Canada from ImClone LLC, a wholly-owned subsidiary of Eli Lilly and Company, in 1998. Merck KGaA, Darmstadt, Germany, has an ongoing commitment to the advancement of oncology treatment and is currently investigating novel therapies in highly targeted areas.

About Tepotinib
Tepotinib (also known as MSC2156119J) is an investigational small-molecule inhibitor of the c-Met receptor tyrosine kinase capable of inhibiting both hepatocyte growth factor-dependent and -independent c-MET activation in low nanomolar concentrations. Alterations of the c-Met signaling pathway are found in various cancer types and correlate with aggressive tumor behavior and poor clinical prognosis. Tepotinib is currently under evaluation in Phase I/II trials.

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 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.