News Release

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Not intended for UK-based media

May 17, 2017

ASCO Abstract #
M7824 (anti-PD-L1/TGF-ß trap): 3006; **Avelumab:** 9086, 9530, 9557, 4528, 3059, 5037, e21070, e21065, e20581; **Tepotinib:** 4087, 8547, e15676, 20541; **M3814 (DNA-PK):** 2556, e14048; **M7583 (BTKi):** e14101

Shaping Cancer Care Today and Tomorrow: Merck, KGaA, Darmstadt, Germany, to Present New Data from Rapidly Evolving Pipeline at ASCO 2017

- **ASCO data highlights Merck, KGaA, Darmstadt, Germany's strong and rapidly accelerating pipeline in oncology, spanning immuno-oncology to DNA damage response**
- **New avelumab data in metastatic Merkel cell carcinoma and previously treated metastatic urothelial carcinoma, following recent U.S. FDA accelerated approvals**
- **Oral presentation on new immuno-oncology approach anti-PD-L1/TGF-ß trap (M7824); potential first-in-class bifunctional immunotherapy**

Darmstadt, Germany, May 17, 2017 – Merck, KGaA, Darmstadt, Germany, a leading science and technology company, today announced that new research from its growing broad oncology portfolio, from immuno-oncology (IO) to DNA damage response (DDR) approaches, will be presented across a broad range of hard-to-treat cancers at this year's American Society of Clinical Oncology annual meeting (ASCO; June 2-6, Chicago). Over 40 abstracts showcase the impact of Merck, KGaA, Darmstadt, Germany's commitment to shaping cancer care today and tomorrow, including data for avelumab*, which is being developed in collaboration with Pfizer, Erbitux® (cetuximab), and pipeline updates on the anti-PD-L1/TGF-ß trap M7824,

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the DNA-PK inhibitor M3814, the BTK inhibitor M7583, and the c-Met inhibitor tepotinib**. In the U.S. and Canada, Merck KGaA, Darmstadt, Germany, operates its biopharmaceutical business as EMD Serono.

“We are focused on delivering innovation that matters to patients, as shown in our ASCO data that spans across IO and DDR approaches to tackle some of the hardest-to-treat cancers,” said Luciano Rossetti, Executive Vice President, Head of Global Research & Development at the biopharma business of Merck, KGaA, Darmstadt, Germany. “Merck, KGaA, Darmstadt, Germany, was among the first to leverage the potential of the PD1/PDL1 pathway for patients, and we continue to build on that progress with our ASCO presence and the two recent FDA accelerated approvals for avelumab.”

Multiple avelumab presentations at ASCO include data in first-line metastatic Merkel cell carcinoma (mMCC) and previously treated metastatic urothelial carcinoma (UC), as well as results from the Phase Ib trial from the avelumab combination trial with axitinib in renal cell carcinoma (RCC). Recently, the U.S. Food and Drug Administration (FDA) granted accelerated approval*** for avelumab for the treatment of mMCC and pretreated patients with locally advanced or metastatic UC. Avelumab is currently being evaluated as both monotherapy and combination therapy in an extensive clinical development program. Beyond mMCC, locally advanced or metastatic UC and RCC, further avelumab abstracts in non-small cell lung cancer and metastatic castrate-resistant prostate cancer, locally advanced squamous cell carcinoma of the head and neck, relapsed or refractory diffuse large B-cell lymphoma will be showcased.

In addition to avelumab data, Merck, KGaA, Darmstadt, Germany, will also feature new research at ASCO on its investigational bifunctional immunotherapy anti-PD-L1/TGF-ß trap (M7824), which is thought to simultaneously block both PD-L1 and TGF-ß. An oral presentation will showcase dose escalation Phase I clinical data exploring the potential of M7824 in advanced solid tumors.

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Pipeline updates at ASCO also include early clinical results for both Tepotinib, an investigational small-molecule inhibitor of the c-Met receptor tyrosine kinase, M7583, an oral, highly selective, covalent inhibitor of Bruton's tyrosine kinase (BTK), and the first clinical data for M3814, an investigational DNA-dependent protein kinase (DNA-PK) inhibitor. Merck, KGaA, Darmstadt, Germany, is investing significant resources in the promising area of DDR to be a leader in this field. Merck, KGaA, Darmstadt, Germany, has recently in-licensed two promising clinical-stage programs from Vertex.

This highly focused approach to research and development channels Merck, KGaA, Darmstadt, Germany's scientific expertise in areas of high unmet need, a legacy started with Erbitux. Multiple presentations at ASCO reinforce Erbitux as a standard-of-care treatment in squamous cell carcinoma of the head and neck (SCCHN) and metastatic colorectal cancer (mCRC), providing valuable information about biomarkers, disease response, and the importance of tumor location in mCRC, to best target treatment to the right patients.

*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.

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

Tepotinib, M7824 and M3814 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 key abstracts slated for presentation are listed below. In addition, a number of investigator-sponsored studies have been accepted, including multiple abstracts related to Erbitux and avelumab (not listed).

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Title	Lead Author	Abstract #	Presentation Date / Time (CDT)	Location
M7824 (TGF-ß trap)				
Oral Presentation				
Solid Tumors Preliminary results from a phase 1 trial of M7824 (MSB0011359C), a bifunctional fusion protein targeting PD-L1 and TGF-β, in advanced solid tumors	JL Gulley	3006	June 5 13:15-16:27	Hall D1

Title	Lead Author	Abstract #	Presentation Date / Time (CDT)	Location
Avelumab				
Oral Presentation				
Renal Cell Carcinoma (JAVELIN Renal 100) First-line avelumab + axitinib therapy in patients with advanced renal cell carcinoma: results from a phase 1b trial	TK Choueiri	4504	June 5 8:00-11:00	Arie Crown Theater
Poster Sessions				
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	JL Gulley	9086	June 3 8:00-11:30	Hall A

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Merkel Cell Carcinoma (JAVELIN Merkel 200) First-line avelumab treatment in patients with metastatic Merkel cell carcinoma: preliminary data from an ongoing study	S D'Angelo	9530	June 3 13:15-16:45	Hall A
Merkel Cell Carcinoma (JAVELIN Merkel 200) Exploratory biomarker analysis in patients with chemotherapy-refractory metastatic Merkel cell carcinoma treated with avelumab	I Shapiro	9557	June 3 13:15-16:45	Hall A
Urothelial Carcinoma Updated efficacy and safety of avelumab in metastatic urothelial carcinoma: pooled analysis from 2 cohorts of the phase 1b JAVELIN Solid Tumor study	AB Apolo	4528	June 4 8:00-11:30	Hall A
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)	TK Choueiri	TPS4594	June 4 8:00-11:30	Hall A

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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	K Kelly	3059	June 5 8:00-11:30	Hall A
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)	R Chen	TPS7575	June 5 8:00-11:30	Hall A
Prostate Cancer (JAVELIN Solid Tumor) Avelumab in metastatic castration-resistant prostate cancer (mCRPC)	F Fakhrejahani	5037	June 5 13:15-16:45	Hall A
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)	NY Lee	TPS6093	June 5 13:15-16:45	Hall A
Publications				
Merkel Cell Carcinoma	M Bharmal	e21070	N/A	N/A

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(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				
Merkel Cell Carcinoma (JAVELIN Merkel 200) Patient experiences with avelumab vs chemotherapy for treating Merkel cell carcinoma: results from protocol-specified qualitative research	H Kaufman	e21065	N/A	N/A
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)	Z Feng	e20581	N/A	N/A

Title	Lead Author	Abstract #	Presentation Date / Time (CDT)	Location
Tepotinib				
Poster Sessions				
Hepatocellular Carcinoma Phase Ib trial of tepotinib in Asian patients with advanced hepatocellular carcinoma (HCC):	S Qin	4087	June 3 8:00-11:30	Hall A

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Final data including long-term outcomes				
Non-Small Cell Lung Cancer Phase Ib study of tepotinib in EGFR-mutant/c-Met-positive NSCLC: final data and long-term responders	Y-L Wu	8547	June 3 8:00-11:30	Hall A
Publications				
Hepatocellular Carcinoma Final phase Ib data for the oral c-Met inhibitor tepotinib in patients with previously treated advanced hepatocellular carcinoma	S Faivre	e15676	N/A	N/A
Advanced Lung Adenocarcinoma Phase II trial of the c-Met inhibitor tepotinib in advanced lung adenocarcinoma with MET exon 14 skipping mutations	PK Paik	20541	N/A	N/A

Title	Lead Author	Abstract #	Presentation Date / Time (CDT)	Location
M3814 (DNA-PK)				
Poster Session				
Solid Tumors A multicenter phase I trial of the DNA-dependent protein kinase (DNA-PK) inhibitor M3814 in patients with solid tumors	M van Bussel	2556	June 5 8:00-11:30	Hall A
Publication				
Solid Tumors A phase Ia/Ib trial of the DNA-	B Van Triest	e14048	N/A	N/A

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dependent protein kinase inhibitor (DNA-PKi) M3814 in combination with radiotherapy in patients with advanced solid tumors				

Title	Lead Author	Abstract #	Presentation Date / Time (CDT)	Location
M7583 (BTKi)				
Publication				
B Cell Malignancies Phase I/II, first in human trial of the Bruton's tyrosine kinase inhibitor (BTKi) M7583 in patients with B cell malignancies	S Rule	e14101	N/A	N/A

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 U.S. 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 U.S.

Important Safety Information

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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.

About Erbitux® (cetuximab)
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. Erbitux also targets cytotoxic immune effector cells towards EGFR expressing tumor cells (antibody dependent cell-mediated cytotoxicity, ADCC).

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 RAS wild-type metastatic 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, a registered trademark of ImClone LLC, outside the U.S. and Canada from ImClone LLC, a wholly-owned subsidiary of Eli Lilly and Company, in 1998.

About M3814
M3814 is an investigational small-molecule inhibitor of DNA-dependent protein kinase (DNA-PK). DNA-PK is a key enzyme for non-homologous end-joining (NEHJ), the most important DNA double strand break repair pathway (DSB), and could potentially enhance the efficacy of many commonly used DNA-damaging agents such as radiotherapy and chemotherapy. M3814 complements Merck, KGaA, Darmstadt, Germany's extensive DNA damage response (DDR) portfolio and is currently in Phase I studies.

About M7824
M7824, anti-PD-L1/TGF-ß trap, is an investigational potentially first-in-class bi-functional immunotherapy designed to simultaneously block two immuno-inhibitory pathways (PD-L1 and transforming growth factor beta) that are commonly used by cancer cells to evade the immune system. The aim of this investigational drug is to control tumor growth by restoring and enhancing anti-tumor immune responses. M7824 is currently in Phase I studies for solid tumors.
About Tepotinib
Tepotinib (also known as MSC2156119J) is an investigational small-molecule inhibitor of the c-Met receptor tyrosine kinase. 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.

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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, holds the global rights to the “Merck” name and brand except in the United States and Canada, where the company operates as EMD Serono, MilliporeSigma and EMD Performance Materials.

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