NEWS RELEASE

First Study Evaluating DNA Mismatch Repair as Genetic Guide for Immunotherapy Treatment with Merck's KEYTRUDA® (pembrolizumab) Presented at 2015 ASCO Annual Meeting and Published in the New England Journal of Medicine

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Early Findings Show DNA Mismatch Repair-Deficient Colorectal and Other Tumors Highly Responsive to Checkpoint Blockade with Anti-PD-1 Therapy

Merck Plans to Initiate Phase 2 Registrational Study with KEYTRUDA (KEYNOTE-164) to Evaluate MMR-Deficiency in Colorectal Cancer

KENILWORTH, N.J.--(**BUSINESS WIRE**)--Merck (NYSE:MRK), known as MSD outside the United States and Canada, today announced results from the first study evaluating the correlation of benefit with an immunotherapy based on DNA mismatch repair (MMR) deficiency, a well-established form of genetic instability in many cancers characterized by the loss of function of the MMR pathway. The Phase 2 study, led by researchers from Johns Hopkins Kimmel Cancer Center, evaluated Merck's anti-PD-1 therapy, KEYTRUDA® (pembrolizumab), in 48 evaluable, heavily pre-treated patients with advanced colorectal cancer and other solid tumors. In the colorectal cancer group with MMR-deficient tumors, an objective response rate (ORR) of 62 percent was observed (n=8/13). In contrast, no responses were observed in the colorectal cancer group with MMR-proficient tumors (n=0/25). At the time of analysis, the median progression-free survival (PFS) and overall survival (OS) were not reached in the MMR-deficient colorectal cancer group. These data, featured today in the American Society of Clinical Oncology (ASCO) Press Program and published in the New England Journal of Medicine, will be presented in an oral session by Dr. Dung Le on Saturday,

May 30 at the 2015 ASCO Annual Meeting in Chicago (Abstract #LBA100).

Based on the encouraging results of this early study, Merck will initiate a registrational Phase 2 study (KEYNOTE-164) to evaluate the efficacy and safety of KEYTRUDA based on mismatch repair status in locally advanced unresectable or metastatic (Stage IV) colorectal cancers. This study is expected to begin enrolling patients in mid-2015.

“These exciting results, while early, suggest that evidence of DNA mismatch repair deficiency may be an important way of identifying tumors that are responsive to checkpoint blockade,” said Dr. Roger Dansey, therapeutic area head and senior vice president, oncology late-stage development, Merck Research Laboratories. “DNA mismatch repair deficiency is an established biomarker in many types of cancer and these results open the door for research with KEYTRUDA in colorectal cancer and other tumor types with this potentially clinically meaningful tool. We look forward to initiating a registrational Phase 2 study of KEYTRUDA in patients with colorectal cancer to further explore this genomic biomarker.”

Results from DNA Mismatch Repair Phase 2 Study with KEYTRUDA

The Phase 2 study evaluated the clinical activity of KEYTRUDA monotherapy (10 mg/kg every two weeks) in patients with previously-treated, progressive metastatic disease with or without MMR-deficiency. Three groups were evaluated: MMR-deficient colorectal cancer (n=13), MMR-proficient colorectal cancer (n=25), and MMR-deficient other cancers (n=10). Mismatch-repair status was assessed using a standard polymerase chain reaction (PCR)-based method for detection of microsatellite instability. The primary endpoints of the study were immune-related PFS rate as assessed at 20 weeks and ORR; secondary endpoints included OS, PFS (as measured by RECIST v1.1), and disease control rate. The data presented at ASCO 2015 Annual Meeting were based on an analysis conducted as of May 8, 2015.

In the group with MMR-deficient colorectal cancer, the ORR was 62 percent and the disease control rate (DCR) was 92 percent. No responses were observed in the colorectal cancer group with MMR-proficient tumors and the DCR was 16 percent. In the group with MMR-deficient other cancers, the ORR was 60 percent and DCR was 70 percent. The median PFS and OS were not reached in the MMR-deficient colorectal cancer group. In contrast, PFS was 2.3 months and OS was 7.6 months in the MMR-proficient colorectal cancer group. The median duration of follow-up for all patients was 5.9 months (0.9 to 16.6); 8.3 months (2.2 to 16.6) in the MMR-deficient colorectal group, 4.9 months (0.9 to 15.6) in the MMR-proficient colorectal group, and 7.1 months (2.4 to 16.4) in the MMR-deficient other cancers group. Of the responders, no patients in the MMR-deficient colorectal cancer group and one patient in MMR-deficient other cancers group had progressed at the time of the analysis.

Treatment-related adverse events in the study were generally consistent with previously reported safety data for

KEYTRUDA (n=41). The most common treatment-related adverse events (occurring in greater than or equal to 10% of patients) included: rash/pruritus (17%), pancreatitis (15%), and thyroiditis/hypothyroidism (10%). Grade 3-4 treatment-related adverse events occurred in 2 percent of patients (n=1).

About DNA Mismatch Repair and Microsatellite Instability

DNA mismatch repair (MMR) is a process the body uses to recognize and repair genetic mismatches generated during DNA replication. A defective MMR system allows mismatch mutations to persist. The average tumor has dozens of mutations; however tumors with DNA MMR deficiency harbor thousands, especially in regions of repetitive DNA known as microsatellites. Tumors that are found to have mutations in select microsatellite sequences, called microsatellite instability (MSI), are considered DNA MMR-deficient. These tumors are referred to as “MSI high.” Overall, DNA MMR-deficiency is present in approximately 15-20 percent in Stage II disease, 10 percent in Stage III disease and approximately 5 percent or less in Stage IV disease. In colorectal cancers, MMR-deficiency is seen in approximately 15-20 percent of non-hereditary colorectal cancers and most hereditary colorectal cancers associated with Lynch Syndrome.

About Colorectal Cancer1,2

Colorectal cancer starts in either the colon or the rectum, and can also be referred to separately as colon cancer and rectal cancer. An estimated 1,361,000 new cases of colorectal cancer were diagnosed globally in 2012, and an estimated 694,000 people died. Colorectal cancer is the third most common cancer found in men and the second most common in women around the world. Overall, the lifetime risk of developing colorectal cancer is about 1 in 20. The five-year survival rates for advanced or metastatic colon or rectal cancer (Stage IV) are estimated to be 11 and 12 percent, respectively.

About KEYTRUDA® (pembrolizumab)

KEYTRUDA (pembrolizumab) is a humanized monoclonal antibody that blocks the interaction between PD-1 and its ligands, PD-L1 and PD-L2. By binding to the PD-1 receptor and blocking the interaction with the receptor ligands, KEYTRUDA releases the PD-1 pathway-mediated inhibition of the immune response, including the anti-tumor immune response.

KEYTRUDA is indicated in the United States at a dose of 2 mg/kg administered as an intravenous infusion over 30 minutes every three weeks for the treatment of patients with unresectable or metastatic melanoma and disease progression following ipilimumab and, if BRAF V600 mutation positive, a BRAF inhibitor. This indication is approved under accelerated approval based on tumor response rate and durability of response. An improvement in survival or disease-related symptoms has not yet been established. Continued approval for this indication may be

contingent upon verification and description of clinical benefit in the confirmatory trials.

Merck is advancing a broad and fast-growing clinical development program for KEYTRUDA with more than 100 clinical trials – across more than 30 tumor types and enrolling over 16,000 patients – both as a monotherapy and in combination with other therapies.

Selected Important Safety Information for KEYTRUDA

Pneumonitis occurred in 12 (2.9%) of 411 patients with advanced melanoma receiving KEYTRUDA (the approved indication in the United States), including Grade 2 or 3 cases in 8 (1.9%) and 1 (0.2%) patients, respectively. Monitor patients for signs and symptoms of pneumonitis. Evaluate suspected pneumonitis with radiographic imaging. Administer corticosteroids for Grade 2 or greater pneumonitis. Withhold KEYTRUDA for Grade 2; permanently discontinue KEYTRUDA for Grade 3 or 4 pneumonitis.

Colitis (including microscopic colitis) occurred in 4 (1%) of 411 patients, including Grade 2 or 3 cases in 1 (0.2%) and 2 (0.5%) patients respectively, receiving KEYTRUDA. Monitor patients for signs and symptoms of colitis. Administer corticosteroids for Grade 2 or greater colitis. Withhold KEYTRUDA for Grade 2 or 3; permanently discontinue KEYTRUDA for Grade 4 colitis.

Hepatitis (including autoimmune hepatitis) occurred in 2 (0.5%) of 411 patients, including a Grade 4 case in 1 (0.2%) patient, receiving KEYTRUDA. Monitor patients for changes in liver function. Administer corticosteroids for Grade 2 or greater hepatitis and, based on severity of liver enzyme elevations, withhold or discontinue KEYTRUDA.

Hypophysitis occurred in 2 (0.5%) of 411 patients, including a Grade 2 case in 1 and a Grade 4 case in 1 (0.2% each) patient, receiving KEYTRUDA. Monitor for signs and symptoms of hypophysitis. Administer corticosteroids for Grade 2 or greater hypophysitis. Withhold KEYTRUDA for Grade 2; withhold or discontinue for Grade 3; and permanently discontinue KEYTRUDA for Grade 4 hypophysitis.

Nephritis occurred in 3 (0.7%) patients receiving KEYTRUDA, consisting of one case of Grade 2 autoimmune nephritis (0.2%) and two cases of interstitial nephritis with renal failure (0.5%), one Grade 3 and one Grade 4. Monitor patients for changes in renal function. Administer corticosteroids for Grade 2 or greater nephritis. Withhold KEYTRUDA for Grade 2; permanently discontinue KEYTRUDA for Grade 3 or 4 nephritis.

Hyperthyroidism occurred in 5 (1.2%) of 411 patients, including Grade 2 or 3 cases in 2 (0.5%) and 1 (0.2%) patients respectively, receiving KEYTRUDA. Hypothyroidism occurred in 34 (8.3%) of 411 patients, including a Grade 3 case in 1 (0.2%) patient, receiving KEYTRUDA. 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) and for clinical signs and symptoms of thyroid disorders. Administer corticosteroids for Grade 3 or greater hyperthyroidism. Withhold KEYTRUDA for Grade 3; permanently discontinue KEYTRUDA for Grade 4 hyperthyroidism. Isolated hypothyroidism may be managed with replacement therapy without treatment interruption and without corticosteroids.

Other clinically important immune-mediated adverse reactions can occur. The following clinically significant, immune-mediated adverse reactions occurred in less than 1% of patients treated with KEYTRUDA: exfoliative dermatitis, uveitis, arthritis, myositis, pancreatitis, hemolytic anemia, partial seizures arising in a patient with inflammatory foci in brain parenchyma, adrenal insufficiency, myasthenic syndrome, optic neuritis, and rhabdomyolysis.

For suspected immune-mediated adverse reactions, ensure adequate evaluation to confirm etiology or exclude other causes. Based on the severity of the adverse reaction, withhold KEYTRUDA and administer corticosteroids. Upon improvement of the adverse reaction to Grade 1 or less, initiate corticosteroid taper and continue to taper over at least 1 month. Restart KEYTRUDA if the adverse reaction remains at Grade 1 or less. Permanently discontinue KEYTRUDA for any severe or Grade 3 immune-mediated adverse reaction that recurs and for any life-threatening immune-mediated adverse reaction.

Based on its mechanism of action, KEYTRUDA may cause fetal harm when administered to a pregnant woman. If used during pregnancy, or if the patient becomes pregnant during treatment, apprise the patient of the potential hazard to a fetus. Advise females of reproductive potential to use highly effective contraception during treatment and for 4 months after the last dose of KEYTRUDA.

For the treatment of advanced melanoma, KEYTRUDA was discontinued for adverse reactions in 6% of 89 patients who received the recommended dose of 2 mg/kg and 9% of 411 patients across all doses studied. Serious adverse reactions occurred in 36% of patients receiving KEYTRUDA. The most frequent serious adverse drug reactions reported in 2% or more of patients were renal failure, dyspnea, pneumonia, and cellulitis.

The most common adverse reactions (reported in ≥20% of patients) were fatigue (47%), cough (30%), nausea (30%), pruritus (30%), rash (29%), decreased appetite (26%), constipation (21%), arthralgia (20%), and diarrhea (20%).

The recommended dose of KEYTRUDA is 2 mg/kg administered as an intravenous infusion over 30 minutes every three weeks until disease progression or unacceptable toxicity. No formal pharmacokinetic drug interaction studies have been conducted with KEYTRUDA. It is not known whether KEYTRUDA is excreted in human milk. Because many drugs are excreted in human milk, instruct women to discontinue nursing during treatment with KEYTRUDA. Safety and effectiveness of KEYTRUDA have not been established in pediatric patients.

Our Focus on Cancer

Our goal is to translate breakthrough science into innovative oncology medicines to help people with cancer worldwide. At Merck Oncology, helping people fight cancer is our passion and supporting accessibility to our cancer medicines is our commitment. Our focus is on pursuing research in immuno-oncology and we are accelerating every step in the journey – from lab to clinic – to potentially bring new hope to people with cancer. For more information about our oncology clinical trials, visit **www.merck.com/clinicaltrials**.

About Merck

Today's Merck is a global healthcare leader working to help the world be well. Merck is known as MSD outside the United States and Canada. Through our prescription medicines, vaccines, biologic therapies and animal health products, we work with customers and operate in more than 140 countries to deliver innovative health solutions. We also demonstrate our commitment to increasing access to healthcare through far-reaching policies, programs and partnerships. For more information, visit **www.merck.com** and connect with us on **Twitter**, **Facebook** and **YouTube**.

Forward-Looking Statement

This news release includes "forward-looking statements" within the meaning of the safe harbor provisions of the United States Private Securities Litigation Reform Act of 1995. These statements are based upon the current beliefs and expectations of Merck's management and are subject to significant risks and uncertainties. There can be no guarantees with respect to pipeline products that the products will receive the necessary regulatory approvals or that they will prove to be commercially successful. If underlying assumptions prove inaccurate or risks or uncertainties materialize, actual results may differ materially from those set forth in the forward-looking statements.

Risks and uncertainties include, but are not limited to, general industry conditions and competition; general economic factors, including interest rate and currency exchange rate fluctuations; the impact of pharmaceutical industry regulation and healthcare legislation in the United States and internationally; global trends toward healthcare cost containment; technological advances, new products and patents attained by competitors; challenges inherent in new product development, including obtaining regulatory approval; Merck's ability to accurately predict future market conditions; manufacturing difficulties or delays; financial instability of international economies and sovereign risk; dependence on the effectiveness of Merck's patents and other protections for innovative products; and the exposure to litigation, including patent litigation, and/or regulatory actions.

Merck undertakes no obligation to publicly update any forward-looking statement, whether as a result of new

information, future events or otherwise. Additional factors that could cause results to differ materially from those described in the forward-looking statements can be found in Merck's 2014 Annual Report on Form 10-K and the company's other filings with the Securities and Exchange Commission (SEC) available at the SEC's Internet site (**www.sec.gov**).

Please see Prescribing Information for KEYTRUDA (pembrolizumab) at **http://www.merck.com/product/usa/pi_circulars/k/keytruda/keytruda_pi.pdf** and the Medication Guide for KEYTRUDA at **http://www.merck.com/product/usa/pi_circulars/k/keytruda/keytruda_mg.pdf**.

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1 American Cancer Society. Colorectal Cancer. Available at: **http://www.cancer.org/acs/groups/cid/documents/webcontent/003096-pdf.pdf**

2 World Health Organization. GLOBOCAN 2012: Estimated Cancer Incidence, Mortality and Prevalence Worldwide in 2012. Available at: **http://globocan.iarc.fr/Pages/fact_sheets_cancer.aspx**

Merck
Media:
Pamela Eisele, 267-664-0282
Claire Mulhearn, 908-200-1889
or
Investors:
Joseph Romanelli, 908-740-1986
Justin Holko, 908-740-1879