NEWS RELEASE

Data for KEYTRUDA® (pembrolizumab) in a Range of Gastrointestinal Cancers to be Presented at 2016 Gastrointestinal Cancers Symposium

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Seven Registration-Enabling Trials Evaluating KEYTRUDA in Patients with Gastrointestinal Cancers are Planned or Underway

Merck (NYSE: MRK), known as MSD outside the United States and Canada, announced today that new and updated findings investigating the use of KEYTRUDA® (pembrolizumab), the company's anti-PD-1 therapy, in multiple gastrointestinal cancers will be presented at this year's Gastrointestinal (GI) Cancers Symposium in San Francisco, Jan. 21 – 23. Updates on pembrolizumab include data on advanced esophageal carcinoma and new preliminary Phase 2 safety data in gastric cancer.

"Advanced gastrointestinal cancers are difficult to treat and new therapies are needed," said Roger Dansey, M.D., senior vice president and therapeutic area head, oncology late-stage development, Merck Research Laboratories. "Through our rapidly advancing clinical program, we have seen promising results with KEYTRUDA in several gastrointestinal cancers, and are hopeful about the potential of KEYTRUDA for these patients."

The KEYTRUDA clinical trials program currently includes more than 30 tumor types in more than 200 clinical trials, including more than 80 trials that combine KEYTRUDA with other cancer treatments. More than 20 of these trials are evaluating KEYTRUDA in gastrointestinal cancers, including seven registration-enabling studies in gastric cancer, colorectal cancer and esophageal cancer. Registration-enabling trials of KEYTRUDA are also currently enrolling patients with melanoma, non-small cell lung cancer, head and neck cancer, bladder cancer, Hodgkin lymphoma, multiple myeloma, and breast cancer, and further trials are being planned for other malignancies.

Merck's Immuno-Oncology Data at the 2016 GI Cancers Symposium

A full listing of KEYTRUDA abstracts for both oral and poster sessions is below:

Oral Presentations

- (Abstract #7) Updated results for the advanced esophageal carcinoma cohort of the phase 1b KEYNOTE-028 study of pembrolizumab (MK-3475). T. Doi. Poster Presentation: Thursday, Jan. 21, 12:30 – 2:00 p.m. and 5:30 – 7:00 p.m. PST. Oral Presentation: Thursday, Jan. 21, 2:00 – 3:30 p.m. PST. Location: Moscone West Building.
- (Abstract #195) PD-1 blockade in mismatch repair deficient non-colorectal gastrointestinal cancers. D. Le. Poster Presentation: Friday, Jan. 22, 12:30 – 2:00 p.m. and 5:30 – 7:00 p.m. PST. Oral Presentation: Friday, Jan. 22, 2:00 – 3:30 p.m. PST. Location: Moscone West Building.

Poster Presentations

- (Abstract #TPS161) Pembrolizumab (MK-3475) plus 5-fluorouracil (5-FU) and cisplatin for first-line treatment of advanced gastric cancer: Preliminary safety data from KEYNOTE-059. C. Fuchs. Thursday, Jan. 21, 12:30 – 2:00 p.m. and 5:30 – 7:00 p.m. PST. Location: Moscone West Building.
- (Abstract #TPS183) Pembrolizumab (MK-3475) versus paclitaxel as second-line therapy for advanced gastric or gastroesophageal junction (GEJ) adenocarcinoma: Phase 3 KEYNOTE-061 study. A. Ohtsu. Thursday, Jan. 21, 12:30 – 2:00 p.m. and 5:30 – 7:00 p.m. PST. Location: Moscone West Building.
- (Abstract #TPS184) Pembrolizumab (MK-3475) for recurrent or metastatic gastric or gastroesophageal junction (GEJ) adenocarcinoma: Multicohort phase II KEYNOTE-059 study. C. Fuchs. Thursday, Jan. 21, 12:30 – 2:00 p.m. and 5:30 – 7:00 p.m. PST. Location: Moscone West Building.
- (Abstract #TPS185) KEYNOTE-062: Phase III study of pembrolizumab (MK-3475) alone or in combination with chemotherapy versus chemotherapy alone as first-line therapy for advanced gastric or gastroesophageal junction (GEJ) adenocarcinoma. J. Tabernero. Thursday, Jan. 21, 12:30 – 2:00 p.m. and 5:30 – 7:00 p.m. PST. Location: Moscone West Building.
- (Abstract #TPS189) Pembrolizumab (MK-3475) for previously treated metastatic adenocarcinoma or squamous cell carcinoma of the esophagus: Phase II KEYNOTE-180 study. M. Shah. Thursday, Jan. 21, 12:30 – 2:00 p.m. and 5:30 – 7:00 p.m. PST. Location: Moscone West Building.
- (Abstract #465) Phase 1/2a study of double immune suppression blockade by combining a CSF1R inhibitor (pexidartinib/PLX3397) with an anti PD-1 antibody (pembrolizumab) to treat advanced melanoma and other solid tumors. Z. Wainberg. Friday, Jan. 22, 12:30 – 2:00 p.m. and 5:30 – 7:00 p.m. PST. Location: Moscone West Building.
- (Abstract #TPS787) KEYNOTE-164: Phase II study of pembrolizumab (MK-3475) for patients with previously

treated, microsatellite instability-high advanced colorectal carcinoma. D. Le. Saturday, Jan. 23, 7:00 – 7:55 a.m. and 12:30 – 2:00 p.m. PST. Location: Moscone West Building.

- (Abstract #TPS789) KEYNOTE-177: First-line, open-label, randomized, phase 3 study of pembrolizumab (MK-3475) versus investigator-choice chemotherapy for mismatch repair deficient or microsatellite instability-high metastatic colorectal carcinoma. L Diaz. Saturday, Jan. 23, 7:00 – 7:55 a.m. and 12:30 – 2:00 p.m. PST. Location: Moscone West Building.

About Gastrointestinal Cancer

Gastrointestinal cancer is a term for a group of cancers that affect the digestive system, including cancers of the esophagus, gallbladder, liver, pancreas, stomach, small intestine, colon, rectum, and anus. Cancer of the colon or rectum, also called colorectal cancer, is the third most common cancer in men and the second most common cancer in women worldwide, accounting for more than 600,000 cases each year. Esophageal cancer, a type of cancer that begins in the inner layer of the esophagus, is the eighth most common cancer worldwide with an estimated 456,000 new cases diagnosed in 2012.

About KEYTRUDA® (pembrolizumab) Injection 100 mg

KEYTRUDA is a humanized monoclonal antibody that works by increasing the ability of the body's immune system to help detect and fight tumor cells. KEYTRUDA blocks the interaction between PD-1 and its ligands, PD-L1 and PD-L2, thereby activating T lymphocytes which may affect both tumor cells and healthy cells.

KEYTRUDA is indicated in the United States for the treatment of patients with unresectable or metastatic melanoma.

KEYTRUDA is also indicated for the treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumors express PD-L1 as determined by an FDA-approved test with disease progression on or after platinum-containing chemotherapy. Patients with EGFR or ALK genomic tumor aberrations should have disease progression on FDA-approved therapy for these aberrations prior to receiving KEYTRUDA. The NSCLC 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.

KEYTRUDA is administered at a dose of 2 mg/kg as an intravenous infusion over 30 minutes every three weeks for the approved indications.

Selected Important Safety Information for KEYTRUDA® (pembrolizumab)

Immune-mediated pneumonitis, including fatal cases, occurred in patients receiving KEYTRUDA. Pneumonitis occurred in 32 (2%) of 1,567 patients with melanoma, including Grade 1 (0.8%), 2 (0.8%), and 3 (0.4%) pneumonitis. Pneumonitis occurred in 19 (3.5%) of 550 patients with non-small cell lung cancer (NSCLC), including Grade 2 (1.1%), 3 (1.3%), 4 (0.4%), or 5 (0.2%) pneumonitis. 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 or recurrent Grade 2 pneumonitis.

Immune-mediated colitis occurred in 31 (2%) of 1,567 patients with melanoma, including Grade 2 (0.5%), 3 (1.1%), and 4 (0.1%) colitis. Immune-mediated colitis occurred in 4 (0.7%) of 550 patients with NSCLC, including Grade 2 (0.2%) or 3 (0.4%) colitis. 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.

Immune-mediated hepatitis occurred in 16 (1%) of 1,567 patients with melanoma, including Grade 2 (0.1%), 3 (0.7%), and 4 (0.1%) hepatitis. 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 13 (0.8%) of 1,567 patients with melanoma, including Grade 2 (0.3%), 3 (0.3%), and 4 (0.1%) hypophysitis. Hypophysitis occurred in 1 (0.2%) of 550 patients with NSCLC, which was Grade 3 in severity. Monitor patients for signs and symptoms of hypophysitis (including hypopituitarism and adrenal insufficiency). Administer corticosteroids and hormone replacement as clinically indicated. Withhold KEYTRUDA for Grade 2; withhold or discontinue for Grade 3 or 4 hypophysitis.

Hyperthyroidism occurred in 51 (3.3%) of 1,567 patients with melanoma, including Grade 2 (0.6%) and 3 (0.1%) hyperthyroidism. Hypothyroidism occurred in 127 (8.1%) of 1,567 patients with melanoma, including Grade 3 (0.1%) hypothyroidism. Hyperthyroidism occurred in 10 (1.8%) of 550 patients with NSCLC, including Grade 2 (0.7%) or 3 (0.3%) hyperthyroidism. Hypothyroidism occurred in 38 (6.9%) of 550 patients with NSCLC, including Grade 2 (5.5%) or 3 (0.2%) hypothyroidism. 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 replacement hormones for hypothyroidism and manage hyperthyroidism with thionamides and beta-blockers as appropriate. Withhold or discontinue KEYTRUDA (pembrolizumab) for Grade 3 or 4 hyperthyroidism.

Type 1 diabetes mellitus, including diabetic ketoacidosis, occurred in 3 (0.1%) of 2,117 patients. Monitor patients for hyperglycemia or other signs and symptoms of diabetes. Administer insulin for type 1 diabetes, and withhold KEYTRUDA and administer anti-hyperglycemics in patients with severe hyperglycemia.

Immune-mediated nephritis occurred in 7 (0.4%) of 1,567 patients with melanoma, including Grade 2 (0.2%), 3 (0.2%) and Grade 4 (0.1%) nephritis. 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.

Other clinically important immune-mediated adverse reactions can occur. 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 to Grade 1 or less, initiate corticosteroid taper and continue to taper over at least 1 month. Based on limited data from clinical studies in patients whose immune-related adverse reactions could not be controlled with corticosteroid use, administration of other systemic immunosuppressants can be considered. Resume KEYTRUDA when the immune-mediated adverse reaction remains at Grade 1 or less following corticosteroid taper. Permanently discontinue KEYTRUDA for any Grade 3 immune-mediated adverse reaction that recurs and for any life-threatening immune-mediated adverse reaction.

The following clinically significant, immune-mediated adverse reactions occurred in less than 1% (unless otherwise indicated) of 1567 patients with melanoma: arthritis (1.6%), exfoliative dermatitis, bullous pemphigoid, uveitis, myositis, Guillain-Barré syndrome, myasthenia gravis, vasculitis, pancreatitis, hemolytic anemia, and partial seizures arising in a patient with inflammatory foci in brain parenchyma. The following clinically significant, immune-mediated adverse reactions occurred in less than 1% of 550 patients with NSCLC: rash, vasculitis, hemolytic anemia, serum sickness, and myasthenia gravis.

Severe and life-threatening infusion-related reactions have been reported in 3 (0.1%) of 2,117 patients. Monitor patients for signs and symptoms of infusion related reactions including rigors, chills, wheezing, pruritus, flushing, rash, hypotension, hypoxemia, and fever. For Grade 3 or 4 reactions, stop infusion and permanently discontinue KEYTRUDA.

Based on its mechanism of action, KEYTRUDA can 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 (pembrolizumab).

In Trial 6, KEYTRUDA was discontinued due to adverse reactions in 9% of 555 patients with advanced melanoma; adverse reactions leading to discontinuation in more than one patient were colitis (1.4%), autoimmune hepatitis (0.7%), allergic reaction (0.4%), polyneuropathy (0.4%), and cardiac failure (0.4%). Adverse reactions leading to interruption of KEYTRUDA occurred in 21% of patients; the most common (≥1%) was diarrhea (2.5%). The most

common adverse reactions were fatigue (28% with KEYTRUDA vs. 28% with ipilimumab), diarrhea (26% with KEYTRUDA), rash (24% with KEYTRUDA vs. 23% with ipilimumab), and nausea (21% with KEYTRUDA). Corresponding incidence rates are listed for ipilimumab only for those adverse reactions that occurred at the same or lower rate than with KEYTRUDA.

In Trial 2, KEYTRUDA was discontinued due to adverse reactions in 12% of 357 patients with advanced melanoma; the most common (≥1%) were general physical health deterioration (1%), asthenia (1%), dyspnea (1%), pneumonitis (1%), and generalized edema (1%). Adverse reactions leading to interruption of KEYTRUDA occurred in 14% of patients; the most common (≥1%) were dyspnea (1%), diarrhea (1%), and maculo-papular rash (1%). The most common adverse reactions were fatigue (43% with KEYTRUDA), pruritus (28% with KEYTRUDA vs. 8% with chemotherapy), rash (24% with KEYTRUDA vs. 8% with chemotherapy), constipation (22% with KEYTRUDA vs. 20% with chemotherapy), nausea (22% with KEYTRUDA), diarrhea (20% with KEYTRUDA vs. 20% with chemotherapy), and decreased appetite (20% with KEYTRUDA). Corresponding incidence rates are listed for chemotherapy only for those adverse reactions that occurred at the same or lower rate than with KEYTRUDA.

KEYTRUDA was discontinued due to adverse reactions in 14% of 550 patients with NSCLC. Serious adverse reactions occurred in 38% of patients. The most frequent serious adverse reactions reported in 2% or more of patients were pleural effusion, pneumonia, dyspnea, pulmonary embolism, and pneumonitis. The most common adverse reactions (reported in at least 20% of patients) were fatigue (44%), decreased appetite (25%), cough (29%), and dyspnea (23%).

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 and for 4 months after the final dose.

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 health care 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 health care through far-reaching policies, programs and partnerships. For more information, visit **www.merck.com** and connect with us on **Twitter**, **Facebook**, **YouTube** and **LinkedIn**.

Forward-Looking Statement of Merck & Co., Inc., Kenilworth, N.J., USA

This news release of Merck & Co., Inc., Kenilworth, N.J., USA (the "company") includes "forward-looking statements" within the meaning of the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995. These statements are based upon the current beliefs and expectations of the company'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 health care legislation in the United States and internationally; global trends toward health care cost containment; technological advances, new products and patents attained by competitors; challenges inherent in new product development, including obtaining regulatory approval; the company'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 the company's patents and other protections for innovative products; and the exposure to litigation, including patent litigation, and/or regulatory actions.

The company 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 the company'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 Patient Information/Medication Guide for KEYTRUDA at **http://www.merck.com/product/usa/pi_circulars/k/keytruda/keytruda_mg.pdf**.

Merck
Media:
Pamela Eisele, 267-305-3558
An Phan, 908-255-6325
or
Investors:
Teri Loxam, 908-740-1986
Justin Holko, 908-740-1879