NEWS RELEASE

Two New Trials of Merck's KEYTRUDA® (pembrolizumab) as Monotherapy and in Combination with Chemotherapy for First-Line Treatment of Patients with Advanced Non-Small Cell Lung Cancer to be Presented During Presidential Session at ESMO 2016

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Results from KEYNOTE-024, which Studied KEYTRUDA Compared to Chemotherapy in Patients with High Levels of PD-L1 Expression, and KEYNOTE-021G, which Studied KEYTRUDA in Combination with Chemotherapy Compared to Chemotherapy Alone in Patients Regardless of PD-L1 Expression, to be Presented

Comprehensive Data from Merck's Industry-Leading Immuno-Oncology Clinical Development Program to be Presented, with New Data in 12 Cancers

KENILWORTH, N.J.--(**BUSINESS WIRE**)--Merck (NYSE:MRK), known as MSD outside the United States and Canada, today announced that extensive data on KEYTRUDA® (pembrolizumab), the company's anti-PD-1 therapy, have been accepted for presentation at the European Society for Medical Oncology (ESMO) 2016 Congress in Copenhagen, Denmark, Oct. 7 – 11. In total, findings from 30 studies in 12 cancers from Merck's industry-leading clinical development program for KEYTRUDA – both as monotherapy and in combination – will be presented at this year's ESMO. Two studies of KEYTRUDA in first-line treatment of advanced lung cancer have also been selected for presentation at the Presidential Symposium on Oct. 9: KEYNOTE-024, which studied KEYTRUDA as monotherapy compared to chemotherapy in patients whose tumors express high levels of PD-L1 (tumor proportion score of 50 percent or more), and KEYNOTE-021G, which studied KEYTRUDA plus chemotherapy (carboplatin and pemetrexed)

compared to chemotherapy alone in all patients with non-squamous non-small cell lung cancer (NSCLC).

KEYTRUDA-Related Data at the ESMO 2016 Congress

A select listing of the KEYTRUDA late-breaking and oral abstract sessions at ESMO 2016 is included below:

Advanced Non-Small Cell Lung Cancer (NSCLC)

At ESMO, in addition to KEYNOTE-024 and KEYNOTE-021G, which studied KEYTRUDA (pembrolizumab) in previously untreated patients whose tumors were EGFR- and ALK-negative, updated overall survival (OS) data from the phase 2/3 KEYNOTE-010 trial will be presented; KEYNOTE-010 studied previously treated patients with advanced NSCLC whose tumors express PD-L1 (tumor proportion score of one percent or more).

Additional combination data will also be presented from the phase 1b KEYNOTE-098 expansion cohort study investigating KEYTRUDA in combination with the VEGF Receptor 2 antagonist, ramucirumab (under the existing collaboration between Eli Lilly and Company and Merck).

- (Abstract #LBA46_PR) Presidential Symposium: Randomized, phase 2 study of carboplatin and pemetrexed with or without pembrolizumab as first-line therapy for advanced NSCLC: KEYNOTE-021 cohort G. C. Langer. Sunday, October 9, 4:25 – 6:20 pm CEST. Location: Copenhagen.
- (Abstract #LBA8_PR) Presidential Symposium: KEYNOTE-024: Pembrolizumab (pembro) vs platinum-based chemotherapy (chemo) as first-line therapy for advanced NSCLC with a PD-L1 tumor proportion score (TPS) ≥ 50%. M. Reck. Sunday, October 9, 4:25 – 6:20 pm CEST. Location: Copenhagen.
- (Abstract #LBA48) Poster Discussion Session: Pembrolizumab (pembro) vs docetaxel (doce) for previously treated, PD-L1–expressing NSCLC: updated outcomes of KEYNOTE-010. R. Herbst. Sunday, October 9, 2:45 – 4:15 pm CEST. Location: Oslo.
- (Abstract #LBA38) Poster Discussion Session: Interim safety and clinical activity in patients with advanced NSCLC from a multi-cohort phase 1 study of ramucirumab (R) plus pembrolizumab (P). R. Herbst. Monday, October 10, 9:30 – 10:30 am CEST. Location: Berlin.

Advanced Bladder Cancer

At ESMO, data investigating the first-line use of KEYTRUDA in patients with unresectable or advanced urothelial (bladder) cancer will be presented from the phase 2 KEYNOTE-052 trial; results will be featured in the official ESMO press program. This is the first presentation of data investigating KEYTRUDA in the first-line bladder cancer treatment setting.

- (Abstract #LBA32_PR) Proffered Paper Session: Pembrolizumab (pembro) as first-line therapy for

advanced/unresectable or advanced urothelial cancer: Preliminary results from the phase 2 KEYNOTE-052 study. A. Balar. Saturday, October 8, 9:15 – 10:30 am CEST. Location: Madrid.

Advanced Melanoma

At ESMO, final OS data from the phase 2 KEYNOTE-002 trial investigating

KEYTRUDA (pembrolizumab) monotherapy compared to chemotherapy in patients with ipilimumab-refractory advanced melanoma will be presented.

- (Abstract #1107O) Proffered Paper Session: Final overall survival for KEYNOTE-002: pembrolizumab (pembro) versus investigator-choice chemotherapy (chemo) for ipilimumab (ipi)-refractory melanoma. O. Hamid. Saturday, October 8, 2:45 – 4:15 pm CEST. Location: Copenhagen.

Additional Data from Merck's Oncology Portfolio and Pipeline

Data investigating the use of two compounds from Merck's oncology pipeline and portfolio – EMEND® (fosaprepitant dimeglumine), a substance P/neurokinin-1 (NK1) receptor antagonist, and MK-2206, an investigational AKT inhibitor – were also accepted for presentation at this year's ESMO. For more information, including a complete list of abstract titles, please visit the ESMO website at **https://cslide.ctimeetingtech.com/library/esmo/browse/itinerary/5286**.

About KEYTRUDA ® (pembrolizumab)

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 administered as an intravenous infusion over 30 minutes every three weeks for the approved indications. KEYTRUDA for injection is supplied in a 100 mg single use vial.

KEYTRUDA Indications and Dosing

Melanoma

KEYTRUDA is indicated for the treatment of patients with unresectable or metastatic melanoma at a dose of 2 mg/kg every three weeks.

Lung Cancer

KEYTRUDA (pembrolizumab) is 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, at a dose of 2 mg/kg every three weeks. Patients with EGFR or ALK genomic tumor aberrations should have disease progression on FDA-approved therapy for these aberrations prior to receiving KEYTRUDA. 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.

Head and Neck Cancer

KEYTRUDA is indicated for the treatment of patients with recurrent or metastatic head and neck squamous cell carcinoma (HNSCC) with disease progression on or after platinum-containing chemotherapy at a fixed dose of 200 mg every three weeks. This indication is approved under accelerated approval based on tumor response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trials.

Selected Important Safety Information for KEYTRUDA ® (pembrolizumab)

Immune-mediated pneumonitis, including fatal cases, occurred in patients receiving KEYTRUDA. Pneumonitis occurred in 32 (2.0%) of 1567 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 NSCLC, including Grade 2 (1.1%), 3 (1.3%), 4 (0.4%), or 5 (0.2%) pneumonitis and more frequently in patients with a history of asthma/chronic obstructive pulmonary disease (5.4%) or prior thoracic radiation (6.0%). 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 1567 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 (pembrolizumab) for Grade 2 or 3; permanently discontinue KEYTRUDA for Grade 4 colitis.

Immune-mediated hepatitis occurred in patients receiving KEYTRUDA. Hepatitis occurred in 16 (1%) of 1567 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 1567 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 1567 patients with melanoma, including Grade 2 (0.6%) and 3 (0.1%) hyperthyroidism. Hypothyroidism occurred in 127 (8.1%) of 1567 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. New or worsening hypothyroidism occurred in 28 (14.6%) of 192 patients with HNSCC, including Grade 3 (0.5%) 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 for Grade 3 or 4 hyperthyroidism.

Type 1 diabetes mellitus, including diabetic ketoacidosis, occurred in 3 (0.1%) of 2117 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 patients receiving KEYTRUDA. Nephritis occurred in 7 (0.4%) of 1567 patients with melanoma including, Grade 2 (0.2%), 3 (0.2%), and 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 (pembrolizumab) 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 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 2117 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.

In KEYNOTE-006, 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 with KEYTRUDA vs ipilimumab were fatigue (28% vs 28%), diarrhea (26% with KEYTRUDA), rash (24% vs 23%), 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 (pembrolizumab).

In KEYNOTE-002, 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 maculopapular rash (1%). The most common adverse reactions with KEYTRUDA vs chemotherapy were fatigue (43% with KEYTRUDA), pruritus (28% vs 8%), rash (24% vs 8%), constipation (22% vs 20%), nausea (22% with KEYTRUDA), diarrhea (20% vs 20%), 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 at least 2% 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%), cough (29%), decreased appetite (25%), and dyspnea (23%).

KEYTRUDA was discontinued due to adverse reactions in 17% of 192 patients with HNSCC. Serious adverse reactions occurred in 45% of patients. The most frequent serious adverse reactions reported in at least 2% of patients were pneumonia, dyspnea, confusional state, vomiting, pleural effusion, and respiratory failure. The most common adverse reactions (reported in at least 20% of patients) were fatigue (46%), decreased appetite (22%), and dyspnea (20%).

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.

As part of our focus on cancer, Merck is committed to exploring the potential of immuno-oncology with one of the fastest-growing development programs in the industry. We are currently executing an expansive research program that includes more than 330 clinical trials evaluating our anti-PD-1 therapy across more than 30 tumor types. We also continue to strengthen our immuno-oncology portfolio through strategic acquisitions and are prioritizing the development of several promising immunotherapeutic candidates with the potential to improve the treatment of advanced cancers.

For more information about our oncology clinical trials, visit **www.merck.com/clinicaltrials**.

About Merck

For 125 years, Merck has been 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 2015 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
Kim Hamilton, 908-740-1863
or
Investors:
Teri Loxam, 908-740-1986
Amy Klug, 908-740-1898