NEWS RELEASE

KEYTRUDA® (pembrolizumab) Showed Continued Overall Survival Benefit Compared to Chemotherapy with Longer Follow-Up in Patients with Previously Treated Metastatic Non-Small Cell Lung Cancer in Data to Be Presented at ESMO 2016 Congress

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Results from KEYNOTE-010 Include Improved Patient-Reported Health-Related Quality of Life Outcomes and 18-Month Findings of Overall Survival and Progression-Free Survival in Previously Treated Patients Whose Tumors Express PD-L1 (Tumor Proportion Score of One Percent or More)

KENILWORTH, N.J.--(**BUSINESS WIRE**)--
Merck (NYSE:MRK), known as MSD outside the United States and Canada, today announced that KEYTRUDA® (pembrolizumab), the company's anti-PD-1 therapy, demonstrated superiority in overall survival (OS) at 18 months compared to standard of care chemotherapy (docetaxel) in patients with metastatic non-small cell lung cancer (NSCLC) previously treated with platinum-containing chemotherapy whose tumors expressed PD-L1 (tumor proportion score [TPS] of one percent or more), as well as patients with high levels of PD-L1 expression (TPS of 50 percent or more). These data, from the phase 2/3 KEYNOTE-010 trial, will be presented at the ESMO 2016 Congress, the annual meeting of the European Society for Medical Oncology, in Copenhagen (Abstract #LBA48).

"These findings – which show superior survival with longer follow-up across patients with PD-L1 expression (tumor proportion score of one percent or more), as well as improved quality of life – point to KEYTRUDA as a durable treatment option for many previously treated patients with advanced non-small cell lung cancer," said Roy S. Herbst, M.D., Ph.D., professor of medicine and chief of medical oncology, Yale Cancer Center and Smilow Cancer

Hospital at Yale New Haven. “These data also reinforce the value of using PD-L1 as a biomarker to identify patients who are likely to benefit from KEYTRUDA.”

In additional data at the ESMO 2016 Congress from KEYNOTE-010, an analysis of patient-reported health-related quality of life outcomes showed more patients treated with KEYTRUDA (pembrolizumab) reported positive outcomes compared to patients treated with chemotherapy (Abstract #1219P).

Separately at the ESMO 2016 Congress, researchers presented an analysis of PD-L1 prevalence across three separate studies, including KEYNOTE-010. Overall, 66 percent of patients with metastatic NSCLC expressed any level of PD-L1, and 28 percent expressed high levels of PD-L1 (Abstract #1060P).

“Our research in immuno-oncology continues to show tremendous promise, with our goal being to extend the lives of significant numbers of patients with non-small cell lung cancer,” said Roger Dansey, M.D., senior vice president and therapeutic area head, oncology late-stage development, Merck Research Laboratories. “In this longer-term analysis of KEYNOTE-010, among patients who responded to treatment, four times as many patients receiving KEYTRUDA were still alive without disease progression compared to docetaxel. It is gratifying to see these results continue with additional follow-up.”

Merck has a robust clinical development program for KEYTRUDA in lung cancer, with multiple registration-enabling studies currently underway. The KEYTRUDA clinical development program includes more than 30 tumor types in more than 350 clinical trials, including more than 100 trials that combine KEYTRUDA with other cancer treatments.

Efficacy and Safety Findings from KEYNOTE-010 (Abstract #LBA48)

KEYNOTE-010 is a global, open-label, randomized, pivotal phase 2/3 study evaluating KEYTRUDA (2 mg/kg or 10 mg/kg every three weeks) compared to standard of care chemotherapy (docetaxel, 75 mg/m2 every three weeks) in patients with previously treated metastatic NSCLC. The primary endpoints were OS and progression-free survival (PFS) and were assessed based on patients whose tumors expressed PD-L1 (TPS of one percent or more) and high levels of PD-L1 (TPS of 50 percent or more). Secondary endpoints included overall response rate (ORR) and duration of response. KEYNOTE-010 is the first study of its kind to evaluate the potential of an immunotherapy compared to chemotherapy based on prospective measurement of PD-L1 expression in patients with metastatic NSCLC. As previously announced, the study met its primary objective, showing that KEYTRUDA significantly improved OS compared to chemotherapy in patients with PD-L1 expression (TPS of one percent or more). Findings were similar in patients who received the FDA-approved dose of KEYTRUDA (2 mg/kg every three weeks) and an investigational dose of KEYTRUDA (10 mg/kg every three weeks). These data also served as the basis for the KEYTRUDA (pembrolizumab) application approval by the European Medicines Agency (EMA) in July of this year and are currently under review by the U.S. Food and Drug Administration (FDA) for the second-line or greater NSCLC

treatment setting.

At the ESMO 2016 Congress, data from this study of 1,034 patients included six months of additional follow-up, with a median follow-up of 19.2 months (range, 11.7-29.7), and showed superior outcomes of OS, PFS, and ORR with KEYTRUDA compared to docetaxel in patients with PD-L1 expression (TPS of one percent or more) as well as high levels of PD-L1 expression (TPS of 50 percent or more) – with consistency of outcomes across KEYTRUDA doses.

In patients with PD-L1 expression (TPS of one percent or more), OS at 18 months was 37 percent (HR, 0.72 [95% CI, 0.60-0.87]; p=0.0003) with KEYTRUDA 2 mg/kg, 43 percent (HR, 0.60 [95% CI, 0.50-0.73]; p<0.00001) with KEYTRUDA 10 mg/kg, and 24 percent with docetaxel. Among all patients, median OS was 10.5 months with KEYTRUDA 2 mg/kg, 13.6 months with KEYTRUDA 10 mg/kg, and 8.6 months with docetaxel. ORR was 19 percent (95% CI, 15-23, p=0.00025) with KEYTRUDA 2 mg/kg, 20 percent (95% CI, 16-25, p=0.00004) with KEYTRUDA 10 mg/kg and 10 percent (95% CI, 7-13) with docetaxel. Responses to KEYTRUDA continued to be durable; among patients with any level of PD-L1 expression who responded to treatment, 60 percent on each of the KEYTRUDA treatment arms were alive, progression-free, and had not received additional therapy for their disease, compared to 15 percent in the docetaxel treatment arm.

In patients with high levels of PD-L1 expression (TPS of 50 percent or more), OS at 18 months was 46 percent (HR, 0.54 [95% CI, 0.39-0.73]; p=0.00004) with KEYTRUDA 2 mg/kg, 52 percent with KEYTRUDA 10 mg/kg (HR, 0.48 [95% CI, 0.35-0.66]; p<0.00001), and 24 percent with docetaxel. In this group, median OS was 15.8 months with KEYTRUDA 2 mg/kg, 18.8 months with KEYTRUDA 10 mg/kg, and 8.2 months with docetaxel. ORR was 29 percent (95% CI, 22-38, p<0.00001) with KEYTRUDA 2 mg/kg, 32 percent (95% CI, 24-40, p<0.00001) with KEYTRUDA 10 mg/kg, and nine percent (95% CI, 5-14) with docetaxel. Responses to KEYTRUDA continued to be durable; among patients with high levels of PD-L1 expression who responded to treatment, 68 and 63 percent on the KEYTRUDA 2 mg/kg and 10 mg/kg treatment arms, respectively, were alive, progression-free, and had not received additional therapy for their disease, compared to 15 percent in the docetaxel treatment arm.

The safety profile of KEYTRUDA was consistent with that observed in previously reported studies of KEYTRUDA. Treatment-related adverse events remained lower with KEYTRUDA compared to docetaxel. Among the total study population, 13, 17, and 36 percent of patients experienced Grades 3-5 treatment-related adverse events with KEYTRUDA (pembrolizumab) 2 mg/kg, KEYTRUDA 10 mg/kg, and docetaxel, respectively. Compared with the previous analysis, two additional patients in the KEYTRUDA 2 mg/kg arm and five patients in the KEYTRUDA 10 mg/kg arm experienced immune-mediated adverse events, none of which led to death. Grade 3-5 immune-mediated adverse events that occurred in two or more patients included pneumonitis (n=14), severe skin toxicities (n=8), and colitis (n=4). Additional immune-mediated adverse events observed in at least two patients in the KEYTRUDA arms of the study included hypothyroidism, hyperthyroidism, pancreatitis, adrenal insufficiency,

myositis, thyroiditis, hepatitis, hypophysitis, and type 1 diabetes mellitus. In this study to date, there have been 10 treatment-related adverse events that led to death, two with KEYTRUDA 2 mg/kg, three with KEYTRUDA 10 mg/kg, and five with docetaxel.

These data will be presented in a poster discussion session on Oct. 9 from 2:45 – 4:15 p.m. CEST (Abstract #LBA48) (Location: Oslo).

Patient-Reported Outcomes Findings from KEYNOTE-010 (Abstract #1219P)

Also reported at the ESMO 2016 Congress were health-related quality of life (HRQoL) outcomes from the KEYNOTE-010 trial. Findings were based on patient-reported assessments using the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Core 30 (EORTC QLQ-C30), EORTC QLQ Lung Cancer 13, and EuroQol-5D-3L instruments to measure for outcomes such as physical, role, emotional, cognitive, and social functioning, as well as lung cancer and treatment-related symptoms, among other measures.

Overall, from baseline to the 12-week assessment, patients treated with KEYTRUDA (2 mg/kg or 10 mg/kg every three weeks) reported numeric improvements, some of which were significant, in HRQoL and prolonged time to deterioration of lung cancer symptoms (defined using a composite endpoint of cough, dyspnea, and chest pain) compared with docetaxel (75 mg/m2 every three weeks).

These findings, along with results from additional patient-reported outcomes analyses, suggest that HRQoL and symptoms were maintained or improved more with KEYTRUDA than with docetaxel.

These data were presented in a poster session on Oct. 8 from 1 – 2 p.m. CEST (Location: Hall E).

PD-L1 Prevalence Findings from KEYNOTE-001, -010, and -024 (Abstract #1060P)

Results from a third NSCLC abstract at the ESMO 2016 Congress explored, for the first time, the prevalence of PD-L1 in patients screened across multiple studies. The analysis assessed 4,784 patients with NSCLC who had tumors evaluable for PD-L1 expression and were screened for eligibility in three registrational studies of KEYTRUDA (pembrolizumab) – KEYNOTE-001, KEYNOTE-010, and KEYNOTE-024. Based on this pooled analysis, 66 percent of patients across all three trials were determined to express PD-L1 (TPS of one percent or more) and 28 percent were determined to have high levels of PD-L1 expression (TPS of 50 percent or more). These findings were similar across demographic and disease characteristics examined, including prior lines of therapy, age, tumor source (primary and metastases), and histology (squamous and non-squamous).

These data will be presented in a poster session on Oct. 9 from 1 – 2 p.m. CEST (Location: Hall E).

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 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 (pembrolizumab) 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 occurred in 19 (3.5%) of 550 patients, including Grade 2 (1.1%), 3 (1.3%), 4 (0.4%), or 5 (0.2%) pneumonitis and occurred 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 4 (0.7%) of 550 patients, 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 patients 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 1 (0.2%) of 550 patients, 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 10 (1.8%) of 550 patients, including Grade 2 (0.7%) or 3 (0.3%) hyperthyroidism. Hypothyroidism occurred in 38 (6.9%) of 550 patients, 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 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. 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 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% of 550 patients: 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 (pembrolizumab).

KEYTRUDA was discontinued due to adverse reactions in 14% of 550 patients. 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%).

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 350 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** .

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