NEWS RELEASE

Merck's KEYTRUDA® (pembrolizumab) Approved by the European Commission for Patients with Advanced Non-Small Cell Lung Cancer (NSCLC) Whose Tumors Express PD-L1

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Approval Based on Trial Results Demonstrating Superior Overall Survival Compared to Chemotherapy in Previously-Treated Patients

KENILWORTH, N.J.--(**BUSINESS WIRE**)--Merck (NYSE:MRK), known as MSD outside the United States and Canada, today announced that the European Commission (EC) has approved KEYTRUDA® (pembrolizumab), the company's anti-PD-1 therapy, at a dose of 2 mg/kg every three weeks, for patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) in patients whose tumors express PD-L1 and who have received at least one prior chemotherapy regimen. Patients with EGFR or ALK positive tumor mutations should also have received approved therapy for these mutations prior to receiving KEYTRUDA. The EC approval allows marketing of KEYTRUDA in all 28 EU member states.

The approval is based on findings from KEYNOTE-010, a pivotal study which showed KEYTRUDA significantly improved overall survival (OS) compared to standard of care chemotherapy.

"This approval provides an important new treatment regimen for patients in Europe with advanced lung cancer, one of the most common and challenging cancers," said Dr. Roger Dansey, senior vice president and therapeutic area head, oncology late-stage development, Merck Research Laboratories. "In the KEYNOTE-010 trial, patients with advanced lung cancer who had failed prior regimens experienced improved overall survival when treated with KEYTRUDA as compared with those treated with traditional chemotherapy."

“The survival benefit for KEYTRUDA observed in previously-treated patients who express PD-L1 is promising,” said Dr. Luis Paz-Ares, chair of the medical oncology department, Hospital Universitario, Madrid, Spain. “There is a significant unmet need for lung cancer patients, and with this approval, we now have a new personalized treatment option which uses biomarker testing to predict which patients are most likely to benefit from treatment.”

About KEYNOTE-010

KEYNOTE-010 is a global, open-label, randomized, pivotal phase 2/3 study evaluating KEYTRUDA (pembrolizumab) (2 mg/kg or 10 mg/kg every three weeks) compared to standard of care chemotherapy (docetaxel, 75 mg/m2 every three weeks) in 1,033 patients with squamous and non-squamous NSCLC who experienced disease progression after platinum-containing systemic therapy and whose tumors expressed PD-L1. The primary endpoints were OS and progression-free survival (PFS) and were assessed based on patients with any level of PD-L1 expression (greater than or equal to one percent) and in patients whose tumors express higher levels of PD-L1 (greater than or equal to 50 percent) – as reflected by tumor proportion score (TPS).

In the total study population (all levels of PD-L1 expression), both doses of KEYTRUDA studied significantly improved OS compared with docetaxel. Specifically, KEYTRUDA resulted in a 29 percent improvement in OS for the 2 mg/kg dose (HR 0.71 [95% CI, 0.58-0.88; P=0.001]) and a 39 percent improvement in OS for the 10 mg/kg dose (HR 0.61 [95% CI, 0.49-0.75; P<0.001]), compared to docetaxel. Median OS for KEYTRUDA was 10.4 months (95% CI, 9.4-11.9) and 12.7 months (95% CI, 10.0-17.3), respectively, compared to 8.5 months for docetaxel (95% CI, 7.5-9.8).

Among patients with higher levels of PD-L1 expression (a TPS score of 50 percent or greater), OS was superior for both KEYTRUDA doses compared with docetaxel. Specifically, KEYTRUDA improved OS by 46 percent for the 2 mg/kg dose (HR 0.54 [95% CI, 0.38-0.77; P=0.001]) and by 50 percent for the 10 mg/kg dose (HR 0.50 [95% CI, 0.36-0.70; P<0.001]), compared to docetaxel. Median OS for KEYTRUDA (2 mg/kg and 10 mg/kg, respectively) was 14.9 months (95% CI, 10.4 to not reached) and 17.3 months (95% CI, 11.8 to not reached), compared to 8.2 months for docetaxel (95% CI, 6.4-10.7).

Among patients in the total study population treated with KEYTRUDA (2 mg/kg and 10 mg/kg, respectively), median PFS was 3.9 months (95% CI, 3.1-4.1) and 4.0 months (95% CI, 2.6-4.3), compared to 4.0 months for docetaxel (95% CI, 3.1-4.2). KEYTRUDA numerically reduced the risk of progression or death (PFS) at both doses (HR 0.88 [95% CI, 0.73-1.04] for 2 mg/kg; HR 0.79 [95% CI, 0.66-0.94] for 10 mg/kg). PFS results in the overall population were not statistically significant for either dose based on protocol-specified statistical testing requirements.

Patients with higher levels of PD-L1 expression who were treated with KEYTRUDA had significantly prolonged PFS compared to docetaxel (HR 0.58 [95% CI, 0.43-0.77; P=0.001] for 2 mg/kg; HR 0.59 [95% CI, 0.45-0.78; P<0.001] for 10

mg/kg). Among patients treated with KEYTRUDA (pembrolizumab) (2 mg/kg and 10 mg/kg, respectively), median PFS was 5.2 months (95% CI, 4.0-6.5) and 5.2 months (95% CI, 4.1-8.1), compared to 4.1 months for docetaxel (95% CI, 3.6-4.3).

The safety analysis supporting the European approval of KEYTRUDA was based on 2,799 patients with advanced melanoma or NSCLC across three doses (2 mg/kg every three weeks or 10 mg/kg every two or three weeks) in studies KEYNOTE-001, KEYNOTE-002 and KEYNOTE-010 combined. The most common adverse reactions (>10%) with KEYTRUDA were fatigue (24%), rash (19%), pruritus (18%), diarrhea (12%), nausea (11%) and arthralgia (10%). The majority of adverse reactions reported were of Grade 1 or 2 severity. The most serious adverse reactions were immune-related adverse reactions and severe infusion-related reactions.

“We are thrilled that the European Union will now have a new treatment option for certain patients with advanced non-small cell lung cancer who have not responded to chemotherapy,” said Stefania Vallone, president, Lung Cancer Europe. “Lung cancer represents the leading cause of cancer death worldwide, and this milestone underscores the importance of innovation and commitment to developing new treatments that can have a positive impact for patients living with this disease.”

About Lung Cancer

Lung cancer, which forms in the tissues of the lungs, usually within cells lining the air passages, is the leading cause of cancer death worldwide. Each year, more people die of lung cancer than die of colon, breast, and prostate cancers combined. The two main types of lung cancer are non-small cell and small cell. NSCLC is the most common type of lung cancer, accounting for about 85 percent of all cases. The five-year relative survival rate for patients suffering from highly advanced, metastatic (Stage IV) lung cancers is estimated to be two percent.

About KEYTRUDA ® (pembrolizumab) Injection 100 mg in the U.S.

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 for the treatment of patients with unresectable or metastatic melanoma.

KEYTRUDA (pembrolizumab) is also indicated for the treatment of patients with advanced 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.

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 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 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 (pembrolizumab) 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.

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%).

No formal pharmacokinetic drug interaction studies have been conducted with KEYTRUDA (pembrolizumab).

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 300 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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