NEWS RELEASE

European Commission Approves Merck's Anti-PD-1 Therapy, KEYTRUDA® (pembrolizumab), for Both First-line and Previously-treated Patients with Advanced Melanoma

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KEYTRUDA Demonstrated Superior Survival versus Ipilimumab in a Phase 3 Clinical Trial

KENILWORTH, N.J.--(**BUSINESS WIRE**)--Merck (NYSE:MRK), known as MSD outside the United States and Canada, today announced that the European Commission has approved KEYTRUDA® (pembrolizumab), the company's anti-PD-1 therapy, for the treatment of advanced (unresectable or metastatic) melanoma in adults. The European Commission approval of KEYTRUDA is based on data from three clinical studies conducted in more than 1,500 first-line and previously-treated patients with advanced melanoma. KEYTRUDA received European Commission regulatory approval based on Phase 3 data which showed it is the first and only anti-PD-1 therapy to provide a statistically superior survival benefit as a monotherapy compared to ipilimumab, the current standard of care for advanced melanoma. Today's approval allows marketing of KEYTRUDA in all 28 EU member states at the approved dose of 2 mg/kg every three weeks.

"Today's European approval supports our goal of accelerating immuno-oncology research for the benefit of patients around the world," said Dr. Roger M. Perlmutter, president, Merck Research Laboratories. "We believe that the broad data set supporting this approval helps illustrate the significant potential of KEYTRUDA to treat advanced melanoma, a devastating disease."

"Merck has long-believed that innovation and access must go hand-in-hand, which is why we work to bring forward new innovations, and ensure access to those innovations," said Deepak Khanna, senior vice president and regional

president, Europe, MSD Oncology. “Merck is committed to working collaboratively with governments and other stakeholders to ensure that KEYTRUDA will be made available to advanced melanoma patients in Europe as rapidly as possible.”

About KEYNOTE-001, 002 and 006

The European Commission’s approval is based on data from three studies -- KEYNOTE-001, KEYNOTE-002 and KEYNOTE-006. These studies evaluated the efficacy and safety of KEYTRUDA in advanced melanoma patients – across treatment lines, prognostic factors, tumor characteristics, and BRAF mutational status – and established 2 mg/kg every three weeks as the approved dose.

KEYNOTE-001, the largest Phase 1b study to date of an anti-PD-1 antibody, is a single arm, open label study of KEYTRUDA (2 mg/kg every three weeks or 10 mg/kg every two or three weeks) that included patients with advanced melanoma who were previously-treated with ipilimumab (and, if BRAF V600 mutation-positive, a BRAF or MEK inhibitor) and patients who were ipilimumab-naïve. In two cohorts of advanced melanoma patients comparing doses of KEYTRUDA, of the 140 patients receiving the approved 2 mg/kg every three week dose, the overall response rate (ORR) (primary endpoint) for KEYTRUDA was 33 percent in ipilimumab-naïve patients (95% CI, 21, 48) (n=51) and 25 percent in patients previously-treated with ipilimumab (95% CI, 16, 35) (n=89). The secondary endpoints were overall survival (OS), progression-free survival (PFS), and duration of response per RECIST v1.1. Results were similar across dosing schedules.

KEYNOTE-002 is a Phase 2, multi-center, randomized study of KEYTRUDA (2 mg/kg every three weeks or 10 mg/kg every three weeks) compared to investigator-choice chemotherapy in 540 patients with advanced melanoma who were previously-treated with ipilimumab and, if BRAF V600 mutation positive, a BRAF or MEK inhibitor. The primary endpoints were PFS and OS. Both KEYTRUDA doses evaluated were superior compared to chemotherapy for PFS at both six-months and nine-months, with PFS rates of 34 and 24 percent, respectively, for the 2 mg/kg dose (95% CI, 0.57 [0.45, 0.73]) (n=180) and 38 and 29 percent for the 10 mg/kg dose (95% CI, 0.50 [0.39, 0.64]) (n=181), compared to 16 and 8 percent for investigator-choice chemotherapy (n=179). OS data were not mature at the time of the analysis. The secondary endpoints were ORR and duration of response per RECIST v1.1.

KEYNOTE-006 is a Phase 3, multi-center, randomized, study of KEYTRUDA (10 mg/kg every two or three weeks) compared to ipilimumab in 834 patients with advanced melanoma. In the planned interim analysis of the co-primary endpoints, KEYTRUDA demonstrated superior PFS and OS compared to ipilimumab. The estimated 6-month and 9-month PFS rates for KEYTRUDA were 47 and 40 percent, respectively, for the 2-week group (95% CI, 0.58 [0.46, 0.72], p<0.00001) (n=279) and 46 and 42 percent for the 3-week group (95% CI, 0.58 [0.47, 0.72], p<0.00001) (n=277), compared to 27 and 16 percent for ipilimumab (n=278). One-year OS for KEYTRUDA was 74

percent (2-week group) (95% CI, 0.63 [0.47, 0.83], p = 0.00052) and 68 percent (3-week group) (95% CI, 0.69 [0.52, 0.90], p = 0.00358), compared to 58 percent for ipilimumab. The risk of death was reduced by 31 percent for patients treated with KEYTRUDA in the 3-week group (hazard ratio 0.69) and 37 percent in the 2-week group (hazard ratio 0.63). The secondary endpoints were ORR and duration of response per RECIST v1.1.

The safety analysis supporting the European approval of KEYTRUDA was based on 1,012 advanced melanoma patients across three doses (2 mg/kg every three weeks or 10 mg/kg every two or three weeks) in studies KEYNOTE-001 and KEYNOTE-002 combined. The most common adverse reactions (>10%) with KEYTRUDA were diarrhea (15%), nausea (12%), pruritus (25%), rash (25%), arthralgia (13%) and fatigue (33%). 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.

About Melanoma

Melanoma, the most serious form of skin cancer, is characterized by the uncontrolled growth of pigment-producing cells. The incidence of melanoma has been increasing over the past four decades. In Europe, approximately 100,000 new cases were estimated to be diagnosed in 2012, which is almost half of the global incidence of melanoma. The five-year survival rates for advanced or metastatic melanoma (Stage IV) are estimated to be 15 to 20 percent in the United States and 5 to 22 percent in Europe.

About KEYTRUDA

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.

With the European Commission decision, KEYTRUDA is now approved in more than 35 countries for the treatment of advanced melanoma. 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 more than 16,000 patients – both as a monotherapy and in combination with other therapies.

U.S. Indication for KEYTRUDA® (pembrolizumab)

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.

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

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