



NEWS RELEASE

Responses Observed in Three-Quarters of Heavily Pre-Treated Multiple Myeloma Patients Receiving KEYTRUDA® (pembrolizumab) Combined With Lenalidomide and Dexamethasone

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Findings Presented at the 57th American Society of Hematology Annual Meeting Demonstrate Activity of KEYTRUDA Therapy in Previously-Treated Multiple Myeloma Patients When Combined with Lenalidomide and Dexamethasone

KENILWORTH, N.J.--(BUSINESS WIRE)--Merck (NYSE:MRK), known as MSD outside the United States and Canada, announced today new study findings investigating the use of KEYTRUDA® (pembrolizumab), the company's anti-PD-1 therapy, in combination with lenalidomide and low-dose dexamethasone (two commonly used treatments for multiple myeloma) in patients whose disease has progressed after at least two lines of prior therapy, including a proteasome inhibitor and an IMiD (immune modulatory drug). The initial findings from the ongoing Phase 1 KEYNOTE-023 study showed an overall response rate (ORR) of 76 percent (n=13/17), as assessed by the International Myeloma Working Group (IMWG) 2006 Criteria. These results will be presented today at the 57th American Society of Hematology (ASH) Annual Meeting by Jesus San Miguel, M.D., Ph.D., Clínica Universidad de Navarra, Pamplona, Spain (Abstract #505). Based in part on these data, Merck has initiated two Phase 3 studies evaluating KEYTRUDA in the treatment of multiple myeloma.

"Many patients with multiple myeloma relapse after their initial treatment, reinforcing the need for additional treatment options," said Dr. Jesus San Miguel. "These findings highlight the potential of combining KEYTRUDA with an IMiD and dexamethasone in patients who have multiple myeloma."

"Our clinical program explores the potential for KEYTRUDA across broad patient populations, including in



combination with other medicines,” said Roger Dansey, M.D., senior vice president and therapeutic area head, oncology late-stage development, Merck Research Laboratories. “We are encouraged by these results, showing responses in patients who have relapsed following treatment for multiple myeloma when treated with KEYTRUDA in combination with lenalidomide and dexamethasone, and look forward to building on these data.”

Results from KEYNOTE-023 Presented at ASH

In the study with 50 heavily pre-treated patients, initial findings from 17 patients who were treated with KEYTRUDA (pembrolizumab) in combination with lenalidomide and low-dose dexamethasone demonstrated an ORR of 76 percent (n=13/17) (per IMWG 2006), including four very good partial responses (24%) and nine partial responses (53%).

Adverse events in all 50 patients were consistent with previously reported safety data for KEYTRUDA as well as lenalidomide and low-dose dexamethasone. Grade 3 or 4 treatment-related adverse events included: neutropenia (n=11), thrombocytopenia (n=4), diarrhea (n=1), fatigue (n=1), anemia (n=4), hyperglycemia (n=3) and muscle spasms (n=1). Immune-mediated adverse events included: adrenal insufficiency (n=1), hyperthyroidism (n=2), hypothyroidism (n=2), and thyroiditis (n=1). No treatment-related deaths were reported.

About the KEYTRUDA Development Program and KEYNOTE-023

Merck is conducting a broad hematological malignancy program with approximately 20 clinical trials, including four registration-enabling studies and more than 15 combinations across a variety of lymphomas, myeloma, leukemia, and other hematologic malignancies. Registration-enabling trials of KEYTRUDA are currently enrolling patients in melanoma, NSCLC, head and neck cancer, bladder cancer, gastric cancer, colorectal cancer, esophageal cancer, breast cancer, Hodgkin lymphoma, multiple myeloma and other tumors, with further trials in planning for other cancers.

KEYNOTE-023 is a global, open-label, Phase 1 study designed to evaluate KEYTRUDA treatment in combination with dexamethasone and two different doses of lenalidomide in approximately 75 patients with relapsed/refractory multiple myeloma (RRMM). Patients will receive KEYTRUDA (2 mg/kg every two weeks) in combination with lenalidomide (10 mg or 25 mg) or KEYTRUDA (200 mg fixed dose every two weeks) with lenalidomide (10 mg or 25 mg); all patients will receive 40 mg low-dose dexamethasone weekly. Primary endpoints include safety and tolerability; secondary endpoints include ORR, duration of response, progression-free survival (PFS), and overall survival (OS).

About Multiple Myeloma

Multiple myeloma is a cancer of blood plasma cells in which abnormal plasma cells multiply uncontrollably in the bone marrow and occasionally in other parts of the body. Manifestations of the disease often include bone pain and fractures, and may include kidney problems, a weakened immune system weakness, and confusion. Multiple myeloma is the second most common blood cancer. In 2015, an estimated 26,850 people are expected to be diagnosed and an estimated 11,240 people are expected to die of the disease in the U.S. alone.

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 at a dose of 2 mg/kg administered as an intravenous infusion over 30 minutes every three weeks 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. KEYTRUDA is also indicated at the same dosing for the treatment of patients with unresectable or metastatic melanoma and disease progression following ipilimumab and, if BRAF V600 mutation positive, a BRAF inhibitor. These indications are 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 these indications may be contingent upon verification and description of clinical benefit in the confirmatory trials.

Selected Important Safety Information for KEYTRUDA® (pembrolizumab)

Pneumonitis, including fatal cases, occurred in patients receiving KEYTRUDA. Pneumonitis occurred in 12 (2.9%) of 411 melanoma patients, including Grade 2 or 3 cases in 8 (1.9%) and 1 (0.2%) patients, respectively, receiving KEYTRUDA. 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 in patients, receiving KEYTRUDA. 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.

Colitis (including microscopic colitis) occurred in 4 (1%) of 411 patients with melanoma, including Grade 2 or 3 cases in 1 (0.2%) and 2 (0.5%) patients, respectively, receiving KEYTRUDA. Colitis occurred in 4 (0.7 %) of 550 patients with NSCLC, including Grade 2 (0.2%) or 3 (0.4%) colitis in patients 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 occurred in patients receiving KEYTRUDA. Hepatitis (including autoimmune hepatitis) occurred in 2 (0.5%) of 411 patients with melanoma, 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 with melanoma, including a Grade 2 case in 1 and a Grade 4 case in 1 (0.2% each) patient, receiving KEYTRUDA. 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 indicated. Withhold KEYTRUDA for Grade 2 and withhold or discontinue for Grade 3 or Grade 4 hypophysitis.

Hyperthyroidism occurred in 5 (1.2%) of 411 patients with melanoma, 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 with melanoma, including a Grade 3 case in 1 (0.2%) patient, receiving KEYTRUDA. Hyperthyroidism occurred in 10 (1.8%) of 550 patients with NSCLC, including Grade 2 (0.7%) or 3 (0.3%). Hypothyroidism occurred in 38 (6.9%) of 550 patients with NSCLC, including Grade 2 (5.5%) or 3 (0.2%). 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 Grade 4 hyperthyroidism.

Type 1 diabetes mellitus, including diabetic ketoacidosis, has occurred in patients receiving KEYTRUDA. 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.

Nephritis occurred in patients receiving KEYTRUDA. Nephritis occurred in 3 (0.7%) patients with melanoma, 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.

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 of the adverse reaction to Grade 1 or less, initiate corticosteroid taper and continue to taper over at least 1 month. Resume

KEYTRUDA when the adverse reaction remains at Grade 1 or less following steroid taper. Permanently discontinue KEYTRUDA for any severe or Grade 3 immune-mediated adverse reaction that recurs and for any life-threatening immune-mediated adverse reaction.

Across clinical studies with KEYTRUDA, the following clinically significant, immune-mediated adverse reactions have occurred: bullous pemphigoid and Guillain-Barré syndrome. The following clinically significant, immune-mediated adverse reactions occurred in less than 1% of patients with melanoma treated with KEYTRUDA: exfoliative dermatitis, uveitis, arthritis, myositis, 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 treated with KEYTRUDA: rash, vasculitis, hemolytic anemia, serum sickness, and myasthenia gravis.

Infusion-related reactions, including severe and life-threatening reactions, have occurred in patients receiving KEYTRUDA. Monitor patients for signs and symptoms of infusion related reactions including rigors, chills, wheezing, pruritus, flushing, rash, hypotension, hypoxemia, and fever. For severe or life-threatening 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.

Among the 411 patients with metastatic melanoma, KEYTRUDA was discontinued for adverse reactions in 9% of 411 patients. Adverse reactions, reported in at least two patients that led to discontinuation of KEYTRUDA were: pneumonitis, renal failure, and pain. Serious adverse reactions occurred in 36% of patients. The most frequent serious adverse reactions, reported in 2% or more of patients, were renal failure, dyspnea, pneumonia, and cellulitis. The most common adverse reactions (reported in at least 20% of patients) were fatigue (47%), cough (30%), nausea (30%), pruritus (30%), rash (29%), decreased appetite (26%), constipation (21%), arthralgia (20%), and diarrhea (20%).

Among the 550 patients with metastatic NSCLC, KEYTRUDA was discontinued due to adverse reactions in 14% of patients. 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%), dyspnea (23%), and cough (29%).

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).

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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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