NEWS RELEASE

Merck Announces Positive Study Investigating the Use of KEYTRUDA® (pembrolizumab) Compared to Chemotherapy in Patients with Ipilimumab-Refractory Advanced Melanoma

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KEYTRUDA Demonstrated Superiority to Chemotherapy for Primary Endpoint of Progression-Free Survival

Findings Presented for First Time at Society of Melanoma Research (SMR) 2014 International Congress

ZURICH--(**BUSINESS WIRE**)--Merck (NYSE:MRK), known as MSD outside the United States and Canada, announced today that a pre-specified analysis of investigational data from a pivotal Phase 2 study (KEYNOTE-002) showed KEYTRUDA® (pembrolizumab), the company's anti-PD-1 therapy, substantially improved the primary endpoint of progression-free survival (PFS, as assessed by RECIST 1.1, independent central review) (HR 0.57 and 0.50 for 2 mg/kg and 10 mg/kg every three week doses, respectively), compared to chemotherapy (P<0.0001 for both comparisons) in patients with ipilimumab-refractory advanced melanoma (n=540). At six months, the PFS rates for KEYTRUDA were 34 percent at the 2 mg/kg dose (95% CI, 27-41) (n=180) and 38 percent at the 10 mg/kg dose (95% CI, 31-45) (n=181), compared to 16 percent for chemotherapy (95% CI, 10-22) (n=179). The median duration of follow-up at the interim analysis was 10 months.

These findings, including pre-specified analyses of overall response rate (ORR), duration of response, safety and health-related quality of life (HRQoL), were presented today in an oral session by Dr. Antoni Ribas, professor, Hematology/Oncology and Surgery, and director of the Tumor Immunology Program at the Jonsson Comprehensive Cancer Center, University of California, Los Angeles at the Society of Melanoma Research (SMR) 2014 International Congress in Zurich, Switzerland.

KEYTRUDA is indicated in the United States at a dose of 2 mg/kg 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.

“These findings demonstrate KEYTRUDA was superior to chemotherapy in helping more patients with ipilimumab-refractory advanced melanoma achieve progression-free survival,” said Dr. Eric Rubin, vice president, global clinical development for oncology, Merck Research Laboratories. “The comparative efficacy and safety data from the pivotal KEYNOTE-002 study validate and extend the findings from our earlier study in these difficult-to-treat patients, and we look forward to sharing data on overall survival at a future congress.”

For the pre-specified analysis of PFS, no significant differences were observed between KEYTRUDA doses (HR 0.91, range 0.71-1.16) (P<0.44). An assessment of PFS by investigator review was shown to be consistent with the central review findings. In addition, the PFS effect in favor of KEYTRUDA was consistent across all pre-specified sub-groups.

The objective of the pre-specified analysis was to evaluate the superiority of either dose of KEYTRUDA over chemotherapy for PFS (conducted after ≥ 270 PFS events at a 0.25% significance level) (one-sided) (estimated HR, 0.66). The study was designed with co-primary endpoints of PFS and overall survival. An evaluation of overall survival is planned at the pre-specified final analysis in 2015.

Additional Efficacy Data and Safety from the KEYNOTE-002 Study

Overall response rates (confirmed) for KEYTRUDA were five to six times higher compared to chemotherapy. For KEYTRUDA, ORR was 21 percent at 2 mg/kg dose (95% CI, 15-28) and 25 percent at 10 mg/kg dose (95% CI, 19-32), compared to 4 percent for chemotherapy (95% CI, 2-9) (P<0.0001 for both comparisons). At the time of pre-specified analysis, the median duration of response for KEYTRUDA was not reached, and confirmed responses were ongoing in 92 percent of patients receiving 2 mg/kg dose (range 6+ to 50+) and 87 percent receiving 10 mg/kg dose (range 5+ to 48+), respectively. The median duration of response was 37 weeks for chemotherapy arm and 63 percent of responses were ongoing (range 7+ to 41). There was no significant difference in ORR or duration of response between the doses of KEYTRUDA (P=0.21).

In a pre-specified exploratory analysis for HRQoL, patients treated with KEYTRUDA reported a significantly smaller decrement in health status/quality of life score compared to those treated with chemotherapy (based on European Organization for Research and Treatment of Cancer (EORTC) Core Quality of Life Questionnaire or “EORTC QLQ-

C30”). The mean change from baseline at week 12 (difference in least squares) for KEYTRUDA compared to chemotherapy was 6.52 (P=0.011) at 2 mg/kg dose and 6.57 (p=0.009) at 10 mg/kg dose, respectively.

The incidence of adverse events was consistent with previously reported data for KEYTRUDA. Despite longer median treatment duration, the incidence of treatment-related, grade 3-5 adverse events was lower with KEYTRUDA at 2 mg/kg dose (11%) and at 10 mg/kg dose (14%) compared to chemotherapy (26%). Serious treatment-related adverse events were observed for KEYTRUDA at 2 mg/kg dose (8%) and 10 mg/kg dose (11%), and for chemotherapy (10%). Immune-related grade 3 adverse events observed for KEYTRUDA across doses included hepatitis (n=3), colitis (n=2), pneumonitis (n=3), hypophysitis (n=1) and iritis or uveitis (n=1). No grade 4/5 immune-related adverse events were reported. Three percent of patients receiving KEYTRUDA at 2 mg/kg dose and 7 percent at the 10 mg/kg dose, as well as 6 percent receiving chemotherapy discontinued treatment due to investigator assessed, treatment-related adverse events. One treatment-related death was reported for KEYTRUDA and none in the chemotherapy arm.

About the KEYNOTE-002 Study

KEYNOTE-002 is a global, randomized pivotal Phase 2 study (n=540) evaluating KEYTRUDA at doses of 2 mg/kg every three weeks (n=180) and 10mg/kg every three weeks (n=181) compared to investigator’s choice chemotherapy (n=179) (paclitaxel plus carboplatin, paclitaxel, carboplatin, dacarbazine, or temozolomide) in patients with ipilimumab-refractory advanced melanoma. In the study, 83 percent of patients had the most advanced stage of disease (M1c) and 73 percent of patients had received at least two prior systemic therapies including ipilimumab. The co-primary endpoints were PFS and OS; secondary endpoints were ORR, duration of response and safety; and HRQoL as a pre-specified exploratory endpoint. Tumor response was assessed at week 12, then every 6 weeks through week 48, followed by every 12 weeks thereafter by independent, central, blinded radiographic review per RECIST 1.1 (Response Evaluation Criteria in Solid Tumors). Patients on chemotherapy with progressive disease as assessed by blinded central review were able to cross over to KEYTRUDA arms after three months.

About KEYTRUDA (pembrolizumab)

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.

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 biomedical innovations to help people with cancer worldwide. For Merck Oncology, helping people fight cancer is our passion, supporting accessibility to our cancer medicines is our commitment, and pursuing research in immuno-oncology is our focus 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

This news release includes "forward-looking statements" within the meaning of the safe harbor provisions of the United States Private Securities Litigation Reform Act of 1995. These statements are based upon the current beliefs and expectations of Merck'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 healthcare legislation in the United States and internationally; global trends toward healthcare cost containment; technological advances, new products and patents attained by competitors; challenges inherent in new product development, including obtaining regulatory approval; Merck'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 Merck's patents and other protections for innovative products; and the exposure to litigation, including patent litigation, and/or regulatory actions.

Merck 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 Merck's 2013 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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