



NEWS RELEASE

New KEYTRUDA® (pembrolizumab) Data from KEYNOTE-010 and KEYNOTE-001 in Advanced Non-Small Cell Lung Cancer, Including Survival Data, To Be Presented at 2016 ASCO Annual Meeting

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New Analysis from KEYNOTE-010, Comparing KEYTRUDA to Chemotherapy, Shows Improved Survival Benefit in Patients with Increased Levels of PD-L1 Expression

KEYNOTE-001 Findings Show Responses Are Durable and Include Two Year Overall Survival Data for KEYTRUDA

KENILWORTH, N.J.--(BUSINESS WIRE)--Merck (NYSE: MRK), known as MSD outside the United States and Canada, today announced new data, including updated response rates, progression-free survival (PFS) and overall survival (OS) with KEYTRUDA® (pembrolizumab), the company's anti-PD-1 therapy, as a monotherapy in patients with advanced non-small cell lung cancer (NSCLC) whose tumors express PD-L1 from two studies: KEYNOTE-010 and KEYNOTE-001. The findings are being presented at the 52nd Annual Meeting of the American Society of Clinical Oncology (ASCO) in Chicago (Abstracts #9015 and #9026).

A sub-analysis from the phase 2/3 KEYNOTE-010 trial includes OS data with KEYTRUDA compared to chemotherapy in previously treated patients with advanced NSCLC based on varying levels of PD-L1 expression; other data from KEYNOTE-010 are currently under review by the U.S. Food and Drug Administration (FDA) and are intended to serve as the basis for the full approval of KEYTRUDA in lung cancer in patients whose tumors express PD-L1. Additionally, updated findings from the phase 1b KEYNOTE-001 trial, the study that supported the accelerated approval of KEYTRUDA in NSCLC, include overall response rate (ORR), PFS, safety and two-year survival data.

“We are particularly excited by the results we are seeing with KEYTRUDA in lung cancer from both studies including longer term follow-up data in KEYNOTE-001 that continues to demonstrate durable responses in treatment-naïve and treatment-experienced patients,” said Dr. Roger Dansey, senior vice president and therapeutic area head, oncology late-stage development, Merck Research Laboratories. “The KEYNOTE-010 data show that there is a correlation between increased levels of PD-L1 expression and improved benefit, which further underscores the importance of understanding a patient’s PD-L1 expression when determining a specific treatment plan.”

Merck has a robust clinical development program for KEYTRUDA (pembrolizumab) in lung cancer, with five registration-enabling studies currently underway. The KEYTRUDA clinical development program includes more than 30 tumor types in more than 270 clinical trials, including more than 100 trials that combine KEYTRUDA with other cancer treatments.

Findings from KEYNOTE-010 (Abstract #9015)

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 advanced NSCLC. The primary endpoints were OS and PFS and were assessed based on patients whose tumors express high levels of PD-L1 (greater than or equal to 50 percent) and in patients with any level of PD-L1 expression (greater than or equal to one percent) – as reflected by tumor proportion scores (TPS). 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 advanced NSCLC. As previously announced, the study met its primary objective showing that KEYTRUDA significantly improved OS compared to chemotherapy in patients with any level of PD-L1 expression. Findings were similar in patients who received the FDA-approved dose of KEYTRUDA (2 mg/kg every three weeks) and the investigational dose of KEYTRUDA (10 mg/kg every three weeks). These findings also served as the basis for the KEYTRUDA application currently under review by the FDA.

Findings from abstract #9015 were based on a sub-analysis of patient outcomes across four PD-L1 expression categories as determined by TPS (one to 24 percent; 25 to 49 percent; 50 to 74 percent; and greater than or equal to 75 percent) (n=1,033). Results showed that the OS, PFS, and overall response rate (ORR) generally increased with increasing levels of PD-L1 expression in those patients treated with KEYTRUDA, but not chemotherapy (docetaxel) – with the longest OS and PFS and highest ORR observed in patients who were in the highest PD-L1 TPS category.

In patients treated with KEYTRUDA (pembrolizumab), median OS was 16.6 months in patients in the highest PD-L1 TPS category (95% CI, 11.2-NR) and 9.7 months in patients in the lowest PD-L1 TPS category (95% CI, 8.9-11.6); median PFS was 6.2 months in patients in the highest PD-L1 TPS category (95% CI, 4.2-8.2) and 2.6 months in the lowest PD-L1 TPS category (95% CI, 2.1-3.4); ORR was 33.7 percent in patients in the highest PD-L1 TPS category and

8.6 percent in the lowest PD-L1 TPS category.

In patients treated with chemotherapy, median OS was 8.2 months in patients in the highest PD-L1 TPS category (95% CI, 5.8-10.9) and 8.5 months in patients in the lowest PD-L1 TPS category (95% CI, 7.5-9.9); median PFS was 4.0 months in patients in the highest PD-L1 TPS category (95% CI, 2.2-4.5) and 4.0 months in the lowest PD-L1 TPS category (95% CI, 2.3-5.5); ORR was 7.0 percent in patients in the highest PD-L1 TPS category and 10.9 percent in the lowest PD-L1 TPS category.

The safety profile of KEYTRUDA was consistent with that observed in previously reported studies of KEYTRUDA.

On June 4, these data will be presented in a poster session from 8:00 – 11:30 a.m. CDT (Location: Hall A) and in a poster discussion from 3:00 – 4:15 p.m. CDT (Location: E354b).

Findings from KEYNOTE-001 (Abstract #9026)

KEYNOTE-001 is a multicenter, open-label, multi-cohort, activity-estimating phase 1b trial evaluating KEYTRUDA (2 mg/kg every three weeks or 10 mg/kg every two or three weeks) in various advanced cancers, including lung cancer. The lung cancer cohort included treatment-naïve and previously treated patients with advanced NSCLC. The primary efficacy outcome measure was confirmed ORR as assessed by blinded independent central review using RECIST v1.1. Tumor response was assessed every nine weeks. The secondary outcome measures included PFS, OS, and duration of response. Findings from this study supported the accelerated approval of KEYTRUDA in previously treated NSCLC based on ORR and safety data.

Primary outcome measures observed in treatment-naïve patients (n=101) showed ORR of 58.3 percent (TPS greater than or equal to 50 percent), 17.4 percent (TPS of one to 49 percent), and 10.0 percent (TPS of less than one percent); and ORR in previously treated patients (n=449) of 38.3 percent (TPS greater than or equal to 50 percent), 12.9 percent (TPS of one to 49 percent), and 9.9 percent (TPS of less than one percent). Data at ASCO also assessed secondary outcome measures, including OS. In treatment-naïve patients, results showed a median OS of 22.1 months (95% CI, 16.8-27.2) with an 18-month OS rate of 58.1 percent and a 24-month OS rate of 44.5 percent. In previously treated patients, results showed a median OS of 10.6 months (95% CI, 8.6-13.3) with an 18-month OS rate of 36.6 percent and a 24-month OS rate of 30.4 percent.

Outcomes were further assessed based on three PD-L1 TPS categories (greater than or equal to 50 percent; one to 49 percent; and less than one percent). Results of this analysis showed that while a benefit was observed across all PD-L1 categories, the greatest benefit was observed in treatment-naïve patients with higher levels of PD-L1 expression (greater than or equal to 50 percent of cells expressing PD-L1). In this group, the 18-month OS rate was 72.7 percent and the 24-month OS rate was 60.6 percent; the median OS had not been reached at the time of

analysis.

The safety profile of KEYTRUDA (pembrolizumab) was consistent with that observed in previously reported KEYTRUDA studies. Immune-mediated adverse events of Grade 3-5 were hypothyroidism, pneumonitis, hyperthyroidism, severe skin toxicities, colitis, adrenal insufficiency, and hypophysitis. There were two treatment-related deaths (one case each of interstitial lung disease and cardiopulmonary arrest).

These data will be presented in a poster session on June 4, 8:00 – 11:30 a.m. CDT (Location: Hall A).

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 for the treatment of patients with unresectable or metastatic melanoma.

KEYTRUDA is also 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. 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.

KEYTRUDA (pembrolizumab) 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 and administer anti-hyperglycemics in patients with severe hyperglycemia.

Immune-mediated nephritis occurred in patients receiving KEYTRUDA (pembrolizumab). 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.

It is not known whether KEYTRUDA (pembrolizumab) 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 270 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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