Merck’s KEYTRUDA® (pembrolizumab) Shows Superior Overall Survival Compared to Chemotherapy in Patients with Previously Treated Advanced Non-Small Cell Lung Cancer Whose Tumors Express PD-L1

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Merck Plans Regulatory Submissions in the U.S. in late 2015 and in the European Union in Early 2016

KENILWORTH, N.J.--(BUSINESS WIRE)--Merck (NYSE: MRK), known as MSD outside the United States and Canada, today announced topline results from the KEYNOTE-010 study of KEYTRUDA® (pembrolizumab) in advanced non-small-cell lung cancer (NSCLC) demonstrating that the trial met its primary objective.

KEYNOTE-010 is a randomized, pivotal Phase 2/3 trial comparing two doses of KEYTRUDA (the FDA-approved 2mg/kg dose and a higher, investigational 10mg/kg dose, each given every 3 weeks), to docetaxel, a commonly used chemotherapy. Patients were enrolled who had failed prior systemic therapy for advanced NSCLC and whose tumors had PD-L1 (programmed death ligand-1) expression tumor proportion scores (TPS) of 1 percent or more. Outcomes were assessed in patients whose tumors were strongly PD-L1 positive (defined as TPS of 50 percent or more), and in all PD-L1 positive patients. A topline analysis revealed that treatment with KEYTRUDA was associated with longer overall survival (OS) compared with docetaxel treatment. This was true for both the approved and the investigational dose of KEYTRUDA, which showed similar efficacy. It was also true in both the first set of patients analyzed – those with a TPS of 50 percent or greater – and for all enrolled patients, all of whom had a TPS of 1 percent or greater. Treatment with KEYTRUDA, at both doses, also provided superior progression-free survival (PFS) versus that achieved following treatment with docetaxel in patients whose tumors had TPS values equal to or greater than 50 percent. For PFS, KEYTRUDA treatment was numerically but not statistically superior to docetaxel in the all PD-L1 positive group, again at both doses. The safety profile of KEYTRUDA in this trial was consistent with that observed in previously reported studies in patients with advanced NSCLC.

“The results from this trial provide part of a growing body of evidence supporting the potential of KEYTRUDA in the treatment of non-small-cell lung cancer,” said Dr. Roger M. Perlmutter, president, Merck Research Laboratories. “Advancing the standard of care in cancer requires a collaborative effort, and we are grateful to the patients, institutions and caregivers who participated in this study. We look forward to sharing our complete data with the scientific community and with regulatory agencies in the near future.”

About the KEYNOTE-010 Study

KEYNOTE-010 is a global, open-label, randomized, pivotal Phase 2/3 study (ClinicalTrials.gov, NCT01905657) evaluating two doses of KEYTRUDA (2 mg/kg or 10 mg/kg every three weeks) compared to docetaxel (75 mg/m^2 every three weeks) in 1034 patients with NSCLC who experienced disease progression after platinum-containing systemic therapy and whose tumors expressed PD-L1. The primary endpoints were OS and PFS. Tumor response was assessed at week 12, then every 6 weeks thereafter per RECIST 1.1 criteria by independent, central, blinded, radiographic review and investigator-assessed, immune-related response criteria.

About KEYTRUDA® (pembrolizumab) in the U.S.

In lung cancer, 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. In melanoma, KEYTRUDA is indicated 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 duration of response. The label for KEYTRUDA currently says that an improvement in survival or disease-related symptoms has not yet been established, and the continued approval for these indications may be contingent upon verification and description of clinical benefit in the confirmatory trials.
Selected Safety Information for KEYTRUDA® (pembrolizumab)

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 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 recurrent Grade 2 pneumonitis.

Colitis occurred in 4 (0.7%) of 550 patients, 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 (pembrolizumab). 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 indicated. Withhold KEYTRUDA for Grade 2 and withhold or discontinue for Grade 3 or Grade 4 hypophysitis.

Hyperthyroidism occurred in 10 (1.8%) of 550 patients, including Grade 2 (0.7%) or 3 (0.3%). Hypothyroidism occurred in 38 (6.9%) of 550 patients, 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. 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.

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.

The following clinically significant, immune-mediated adverse reactions occurred in patients treated with KEYTRUDA: rash, vasculitis, hemolytic anemia, serum sickness, myasthenia gravis, bullous pemphigoid, and Guillain-Barré syndrome.

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 (pembrolizumab).

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.

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 four percent.

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.

Merck’s Commitment to Access for KEYTRUDA

Merck provides multiple programs to help ensure patients who are prescribed KEYTRUDA have access to our anti-PD-1 therapy. The Merck Access Program provides reimbursement support for eligible patients receiving KEYTRUDA, including help with out-of-pocket costs and co-pay assistance. Merck also offers financial assistance for eligible patients who are uninsured through our patient assistance program. More information is available by calling 1-855-257-3932 or visiting www.merckaccessprogram-keytruda.com.

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, NJ, USA

This news release of Merck & Co., Inc., Kenilworth, NJ, USA (the “company”) 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 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 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; 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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