New Data Investigating Merck’s KEYTRUDA® (pembrolizumab) in Advanced Non-Small Cell Lung Cancer and Mesothelioma to Be Presented in Clinical Trials Plenary Session at AACR 2015

Release Date: Wednesday, March 18, 2015 4:19 pm EDT

Terms: Oncology, Oncology Newsroom, Prescription Medicine News, Corporate News, Latest News

Dateline City: KENILWORTH, N.J.

Data to be Presented Across Multiple Tumor Types for KEYTRUDA and MK-8628 (OTX015), an Investigational BET-Bromodomain Inhibitor

KENILWORTH, N.J.--(BUSINESS WIRE) -- Merck (NYSE:MRK), known as MSD outside the United States and Canada, today announced that new data evaluating KEYTRUDA® (pembrolizumab), the company's anti-PD-1 therapy, in both advanced non-small cell lung cancer (NSCLC) and malignant pleural mesothelioma will be presented as part of the Clinical Trials Plenary Session on Sunday, April 19 at the American Association for Cancer Research (AACR) Annual Meeting in Philadelphia, April 18 - 22.

The NSCLC data will be the first presentation of new efficacy and safety findings for KEYTRUDA from 495 patients, including validation of PD-L1 expression (abstract #CT104). These data are from the largest, multi-center Phase 1b (KEYNOTE-001) study of an anti-PD-1 therapy. With the mesothelioma findings (abstract #CT103), data evaluating KEYTRUDA will have been presented in eight different types of cancer.

“Our clinical program is investigating the potential of KEYTRUDA in a broad range of cancers where innovative approaches are truly needed – these data to be presented at AACR illustrate this effort,” said Dr. Roger Dansey, senior vice president, Late-Stage Oncology Clinical Development, Merck Research Laboratories. “At AACR, we look forward to sharing new data for KEYTRUDA across a range of challenging cancer types, especially in non-small cell lung cancer and mesothelioma.”

Presentations of Merck Oncology Compounds

In total, data from 14 abstracts evaluating KEYTRUDA or MK-8628 (OTX015), Merck’s investigational BET-bromodomain inhibitor, will be presented at AACR 2015. Pre-clinical and early phase data to be presented span multiple tumor types – such as prostate cancer, blood cancer and NSCLC. A full listing of abstracts included in the 2015 AACR program is below:

KEYTRUDA (pembrolizumab)

• (Abstract #CT104) Late-Breaker Presentation: Efficacy of pembrolizumab (MK-3475) and relationship with PD-L1 expression in patients with non-small cell lung cancer (NSCLC): Findings from KEYNOTE-001. E. Garon. Sunday, April 19, 1:05 PM EDT. Location: Terrace Ballroom I (400 Level).

• (Abstract #CT103) Late-Breaker Presentation: Clinical safety and efficacy of pembrolizumab (MK-3475) in patients with malignant pleural mesothelioma (MPM): Preliminary results from KEYNOTE-028. E. Alley. Sunday, April 19, 12:45 PM EDT. Location: Terrace Ballroom I (400 Level).

• (Abstract #256) Poster Presentation: Identification of additional cancers likely to respond to anti-PD-1 therapy (pembrolizumab): Evaluation of PD-L1 expression in a large molecular tumor profiling gene expression database. M. Ayers. Sunday, April 19, 1:00 PM-5:00 PM EDT. Location: Section 12.

• (Abstract #269) Poster Presentation: Evaluation of the antitumor activity of anti-PD-1 immunotherapy as a single agent and in combination with approved agents in preclinical tumor models. E. Pinheiro. Sunday, April 19, 1:00 PM-5:00 PM EDT. Location: Section 12.

• (Abstract #570) Poster Presentation: PD-L1 expression in paired non-small cell lung cancer tumor samples. J. Kim. Sunday, April 19, 1:00 PM-5:00 PM EDT. Location: Section 24.

• (Abstract #1307) Poster Presentation: Assessment of gene expression in peripheral blood from patients with advanced melanoma using RNA-seq before and after treatment with anti-PD-1 therapy with pembrolizumab (MK-3475). M. Ayers. Monday, April 20, 8:00 AM-12:00 PM EDT. Location: Section 12.
MK-8628 (OTX015)

MK-8628 (OTX015) is an investigational, novel oral BET (bromodomain) inhibitor, which is currently in Phase 1b studies for the treatment of hematological malignancies and advanced solid tumors. BET proteins are considered potential therapeutic targets in cancer, as they play a pivotal role in regulating the transcription of key regulators of cancer cell growth and survival, including c-Myc. Interim data from ongoing Phase 1 clinical studies of MK-8628 have demonstrated meaningful clinical activity in patients with hematological malignancies. An international, open-label Phase 1 study evaluating MK-8628 in five different solid tumors was initiated in November 2014.

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; 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, immuno-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 and other areas of breakthrough science 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 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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Ticker Slug:
Ticker: MRK
Exchange: NYSE