NEWS RELEASE

Data Investigating KEYTRUDA® (pembrolizumab), Merck's Anti-PD-1 Therapy, in Patients with Advanced Triple-Negative Breast Cancer Presented at 2014 San Antonio Breast Cancer Symposium

12/10/2014

18.5 Percent Overall Response Rate Observed in KEYTRUDA-Treated Patients with This Aggressive Form of Breast Cancer

Phase 2 Study Planned for the First Half of 2015 (KEYNOTE-086)

SAN ANTONIO--(**BUSINESS WIRE**)--Merck (NYSE: MRK), known as MSD outside the United States and Canada, announced today early study findings demonstrating an overall response rate of 18.5 percent with KEYTRUDA, the company's anti-PD-1 therapy, as assessed by RECIST v1.1, central review (n=5/27), in PD-L1 positive, advanced triple-negative breast cancer – one of the most aggressive forms of breast cancer. At the time of analysis, the median duration of response had not been reached with three of five responders on therapy for 11 months or more (range, 15 to 40+ weeks). These early findings, from the ongoing Phase 1b KEYNOTE-012 study, were shared today for the first time as part of the official press program at the 2014 San Antonio Breast Cancer Symposium (SABCS) (ABSTRACT #S1-09) and will be presented in an oral session at 10:45 a.m. CST by Dr. Rita Nanda, the University of Chicago.

"Metastatic, triple-negative breast cancer is an aggressive and often difficult to treat disease," said Dr. Rita Nanda, associate director, breast medical oncology, the University of Chicago and principal investigator for the KEYTRUDA triple-negative breast cancer Phase 1b study cohort. "The results presented at this year's SABCS, while early, show encouraging anti-tumor activity in these patients, most of whom had received multiple prior chemotherapies."

“This year, Merck has significantly advanced our immuno-oncology development program and new data for KEYTRUDA have been presented in seven different cancers, including these first findings in triple-negative breast cancer,” said Dr. Alise Reicin, vice president, global clinical development, oncology, Merck Research Laboratories. “These early data with KEYTRUDA show responses in patients with one of the most aggressive forms of breast cancer and further our understanding of the PD-1 pathway’s role in this disease. Our Phase 2 study planned for the first half of 2015 will be an important next step for our breast cancer clinical program.”

Early Findings Evaluating KEYTRUDA in Advanced Triple-Negative Breast Cancer

Data presented were from a cohort of the ongoing Phase 1b KEYNOTE-012 study which evaluated KEYTRUDA monotherapy at 10 mg/kg every two weeks in patients with advanced TNBC whose tumors were determined to be positive for PD-L1 expression (n=32). As measured by Merck’s proprietary PD-L1 immunohistochemistry (IHC) clinical trial assay, tumors were considered to be PD-L1 positive if staining was present in the stroma or in greater than or equal to one percent of tumor cells. In the study, 58 percent of patients screened had tumors determined to be positive for PD-L1 expression. Most patients enrolled in this study had received two or more prior chemotherapies for metastatic disease and 87.5 percent had received prior neo-adjuvant or adjuvant therapy.

Antitumor Activity with KEYTRUDA by Response Evaluation Criteria in Solid Tumors (RECIST) v1.1, Central Review*

	Patients Evaluable for Response (n=27)(a)
Overall Response Rate (ORR), n (%)	5 (18.5%)
Best Overall Response, n (%)	
Complete Responseb	1 (3.7%)
Partial Responseb	4 (14.8%)
Stable Disease	7 (25.9%)
Progressive Disease	12 (44.4%)
No Assessmentc	3 (11.1%)

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*Analysis cut-off as of: November 10, 2014.

aIncludes patients with measurable disease at baseline who received ≥1 pembrolizumab dose and who had ≥1 post-baseline scan or discontinued therapy before the first scan due to progressive disease or a treatment-related AE. Five patients were excluded because they did not have any assessments per central review (n=2) or because they did not have measurable disease per central review at baseline (n=3).

bConfirmed responses only.

c"No assessment" signifies patients who discontinued therapy before the first post-baseline scan due to progressive disease or a treatment-related AE.

The median time to response was 18 weeks (range, 7-32 weeks). In the study, 33 percent of patients with KEYTRUDA achieved tumor shrinkage. At six months, the progression-free survival rate with KEYTRUDA was 23.3 percent.

Adverse events were consistent with previously reported safety data for KEYTRUDA. The most common treatment-related adverse events (occurring in greater than or equal to five percent of patients) included arthralgia (n=6), fatigue (n=6), myalgia (n=5), nausea (n=5), ALT increased (n=2), AST increased (n=2), diarrhea (n=2), erythema (n=2) and headache (n=2). Grade 3-5 treatment-related adverse events occurred in a total of five patients and included anemia, disseminated intravascular coagulation (DIC), headache, meningitis aseptic, decreased blood fibrinogen, and pyrexia. Two patients discontinued KEYTRUDA due to adverse events. One treatment-related death was reported in a patient with rapidly progressive disease and was due to DIC with thrombocytopenia and decreased blood fibrinogen.

About the KEYNOTE-012 Study

KEYNOTE-012 is an ongoing multi-center, non-randomized Phase 1b trial evaluating the safety, tolerability, and anti-tumor activity of KEYTRUDA monotherapy in patients with advanced triple-negative breast cancer (TNBC), advanced head and neck cancer, advanced urothelial (bladder) cancer, or advanced gastric cancer. The primary endpoints of the study include overall safety, tolerability and anti-tumor activity (as measured by RECIST v1.1 assessed by independent radiology review) in PD-L1 positive tumors; secondary endpoints include progression-free survival (PFS), overall survival (OS) and duration of response. In 2014, early findings were presented for all four cohorts of the Phase 1b KEYNOTE-012 study.

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.

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.

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.

About Breast Cancer

Breast cancer is a malignant tumor that begins in the cells of the breast.1 Worldwide, breast cancer is most common cancer among women, with an estimated 1.67 million new cases diagnosed in 2012.2 Breast cancer ranks as the fifth most common cause of cancer death worldwide.2 Triple-negative breast cancer (TNBC) is an aggressive type of breast cancer where the cancer cells do not have estrogen or progesterone receptors and do not have too much HER2, a growth-promoting protein.3 Approximately 15 to 20 percent of breast cancer patients are diagnosed with triple-negative breast cancer.4

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**).

KEYTRUDA® is a registered trademark of Merck & Co., Inc., Whitehouse Station, N.J., USA

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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