Data Investigating KEYTRUDA® (pembrolizumab), Merck’s Anti-PD-1 Therapy, in Patients with Classical Hodgkin Lymphoma Presented at ASH Annual Meeting

12/6/2014

Overall Response Rate of 66 Percent Observed in KEYTRUDA-treated Patients Whose Cancer Progressed on Brentuximab Vedotin

Phase 2 Study Planned for the First Half of 2015 (KEYNOTE-087)

SAN FRANCISCO--(BUSINESS WIRE)--Merck (NYSE:MRK), known as MSD outside the United States and Canada, announced today early study findings demonstrating that KEYTRUDA® (pembrolizumab), the company’s anti-PD-1 therapy, achieved an overall response rate of 66 percent, as assessed by International Harmonization Project response criteria (n=19/29: 95% CI, 46-82), in transplant-ineligible and failure patients with relapsed/refractory classical Hodgkin Lymphoma (cHL) whose disease progressed on or after treatment with brentuximab vedotin. Complete remission was achieved in 21 percent of patients (n=6/29) in the study. At the time of analysis, 89 percent of responses were ongoing (n=17/19) with the median duration of response not yet reached (range 1+ to 185+ days). These early findings, from the ongoing Phase 1b KEYNOTE-013 study, were described for the first time as part of the official press program at the 56th American Society of Hematology (ASH) Annual Meeting in San Francisco (ABSTRACT #290) and will be presented in an oral session on December 8th by Dr. Craig Moskowitz, Memorial Sloan Kettering Cancer Center.

“These early data presented at ASH 2014 are very promising and show response rates of 66 percent with pembrolizumab in patients with classical Hodgkin Lymphoma,” said Dr. Craig Moskowitz, clinical director, division of
hematologic oncology, Memorial Sloan Kettering Cancer Center. “There are few options for patients with multiple relapsed or refractory, classical Hodgkin Lymphoma, and pembrolizumab should continue to be studied for the treatment of this cancer.”

“Merck’s immuno-oncology development program spans more than 30 different types of cancer including a focus on blood cancers like classical Hodgkin Lymphoma,” said Dr. Alise Reicin, vice president, global clinical development, oncology, Merck Research Laboratories. “Response rates being observed with KEYTRUDA in these patients support the potential role of the PD-1 pathway in blood cancers. We look forward to initiating additional studies including a Phase 2 trial in classical Hodgkin Lymphoma in the first half of 2015.”

Early Findings for Investigational Use of KEYTRUDA in Relapsed/Refractory cHL

Data from a cohort of the ongoing Phase 1b KEYNOTE-013 study evaluated KEYTRUDA monotherapy at 10 mg/kg every two weeks in patients with relapsed/refractory classical Hodgkin Lymphoma who had progressed on or after treatment with brentuximab vedotin after failure of autologous stem-cell transplant, or who were transplant-ineligible (n=29).

| Antitumor Activity by International Harmonization Project Response Criteria* |
|-----------------------------------|-----------------|-----------------|-----------------|
| Overall Response Rate             | Transplant Ineligible or Refused n=9 (%) | Transplant Failure n=20 (%) | Total n=29 (%) |
| Complete Remission                | 4 (44)          | 15 (75)         | 19 (66)         |
| Partial Remission                 | 2 (22)          | 4 (20)          | 6 (21)          |
| Stable Disease                    | 2 (22)          | 11 (55)         | 13 (45)         |
| Clinical Benefit Rate             | 3 (33)          | 3 (15)          | 6 (21)          |
| Progressive Disease               | 7 (78)          | 18 (90)         | 25 (86)         |

*Analysis cut-off date: November 17, 2014

Median time to response was 12 weeks. In the transplant ineligible/refusal patient group, eight patients were ineligible and one patient refused transplant, respectively. The patient who refused transplant achieved a complete remission.

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 two patients) included hypothyroidism (n=3), pneumonitis (n=3), constipation (n=2), diarrhea (n=2), nausea (n=2), hypercholesterolemia (n=2),
hypertriglyceridemia (n=2) and hematuria (n=2). Sixteen patients (55%) experienced at least one treatment-related adverse event of any grade. Grade 3 treatment-related adverse events occurred in a total of three patients and included axillary pain, hypoxia, joint swelling, and pneumonitis. No Grade 4 treatment-related adverse events or treatment-related deaths were reported.

About the KEYNOTE-013 Study

KEYNOTE-013 is an ongoing multi-center, non-randomized Phase 1b trial of approximately 106 patients evaluating the safety, tolerability, and efficacy of KEYTRUDA monotherapy in patients with blood cancers, including myelodysplastic syndromes, multiple myeloma, Hodgkin lymphoma, mediastinal large B cell lymphoma and non-Hodgkin’s lymphoma. The primary endpoints of the study include overall safety, tolerability, and complete remission rate (as measured by International Harmonization Project Response Criteria); secondary endpoints include overall response rate (ORR), progression-free survival (PFS), overall survival (OS) and duration of response.

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 Lymphoma

Lymphoma is a type of blood cancer that affects the lymphatic system, which removes excess fluids from the body and produces immune cells. Abnormal lymphocytes, a type of white blood cell that fight infection, become lymphoma cells, which multiply and collect in the lymph nodes and other tissues. Over time, these cancerous cells impair the immune system.1 In 2012, more than 450,000 people were estimated to have been diagnosed with lymphoma (Hodgkin lymphoma and non-Hodgkin lymphoma); more than 225,000 people died from the condition.2 Hodgkin lymphoma is different from other lymphomas because it contains Reed-Sternberg cells, a specific type of large cancer cells.3

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.

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.

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


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