



NEWS RELEASE

2015 ASCO Annual Meeting: New Data in 10 Different Cancers from Merck's Rapidly Expanding Immuno-Oncology Research Program for KEYTRUDA® (pembrolizumab) to be Presented

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New Findings Show Anti-tumor Activity of KEYTRUDA in Five Additional Cancers: Colorectal, Esophageal, Ovarian, Renal Cell Carcinoma and Small-Cell Lung Cancer

First-Time Presentations of DNA Mismatch Repair Deficiency Data in Colorectal and other Cancers and Nanostring RNA Data in Melanoma, Head and Neck and Gastric Cancers

Industry-leading Number of PD-1 Clinical Trials Resulting in Growing Body of Data for KEYTRUDA across 13 Tumor Types

KENILWORTH, N.J.--**(BUSINESS WIRE)**--Merck (NYSE:MRK), known as MSD outside the United States and Canada, today announced that new investigational data in 10 different types of cancer from the company's immuno-oncology development program evaluating its anti-PD-1 therapy, KEYTRUDA® (pembrolizumab), will be presented at the 51st Annual Meeting of the American Society of Clinical Oncology (ASCO) in Chicago, May 29 – June 2, 2015. Merck is advancing a comprehensive clinical development program for KEYTRUDA, a fact reflected in the more than 40 abstracts accepted for this year's ASCO meeting, including 11 oral presentations of which two are late-breakers (Abstract #LBA6008 and #LBA100) selected for the official ASCO press program on Friday, May 29.

"At Merck, we are executing a broad and deep immuno-oncology research program – now in more than 85 studies and 30 different tumor types – to understand the potential for KEYTRUDA in a broad range of cancers, at different

stages, lines of therapy, both alone and in combination," said Dr. Roy Baynes, senior vice president and head of global clinical development, Merck Research Laboratories. "This commitment to breakthrough science has thus far yielded data supporting the potential of KEYTRUDA in 13 different cancers. With our collaborators in the cancer community, we remain focused on pursuing our clinical research program with the goal of advancing therapies with meaningful benefit to patients with cancer."

Merck's Immuno-Oncology Data at 2015 ASCO Annual Meeting

First-time presentation of findings with KEYTRUDA are anticipated in five additional tumor types – colorectal, esophageal, ovarian, renal cell carcinoma (RCC) and small-cell lung cancer (SCLC) – as well as new data in advanced bladder, gastric, head and neck, melanoma and non-small cell lung cancer (NSCLC). These studies will evaluate KEYTRUDA as monotherapy and in combination with other therapies – including across different patient sub-groups, lines of therapy and based on biomarker expression. There will be first-time presentations of data for KEYTRUDA that evaluate nanostring RNA signatures and DNA mismatch repair deficiency as potential biomarkers for improved efficacy across different types of cancer. A select list of sessions, including oral presentations, clinical science symposia and poster discussions, included in the 2015 ASCO program is provided below.

Head and Neck Cancer

New results for KEYTRUDA will be presented in advanced head and neck cancer, including data from an expansion cohort of the KEYNOTE-012 trial as an oral late-breaker presentation. These data are part of the official ASCO press program.

- (Abstract #LBA6008) Late-Breaker Presentation: Antitumor activity and safety of pembrolizumab in patients (pts) with advanced squamous cell carcinoma of the head and neck (SCCHN): Preliminary results from KEYNOTE-012 expansion cohort. T. Seiwert. Monday, June 1, 3:39 PM – 3:51 PM CDT. Location: S100bc. ASCO Press Program, Friday, May 29, 1:00 PM CDT.
- (Abstract #6017) Poster Discussion: Inflamed-phenotype gene expression signatures to predict benefit from the anti-PD-1 antibody pembrolizumab in PD-L1+ head and neck cancer patients. T. Seiwert. Saturday, May 30, 1:15 PM – 4:45 PM CDT (poster session). Location: S Hall A. 4:45 PM – 6:00 PM CDT (discussion). Location: S406.

Melanoma

Merck has a broad development program in melanoma evaluating KEYTRUDA across multiple stages of disease, lines of therapy and in combination with other anti-cancer agents. KEYTRUDA was the first anti-PD-1 therapy approved in the United States and is currently indicated in the United States at a 2 mg/kg dose 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. Please see below for complete indication and selected safety information for KEYTRUDA. At ASCO, data evaluating KEYTRUDA in advanced melanoma will be the subject of three oral presentations and several poster discussions.

- (Abstract #9005) Oral Presentation: Long-term efficacy of pembrolizumab (pembro; MK-3475) in a pooled analysis of 655 patients (pts) with advanced melanoma (MEL) enrolled in KEYNOTE-001. A. Daud. Saturday, May 30, 2:39 PM – 2:51 PM CDT. Location: E354b.
- (Abstract #3000) Oral Presentation: Atypical patterns of response in patients (pts) with metastatic melanoma treated with pembrolizumab (MK-3475) in KEYNOTE-001. J. Wolchok. Monday, June 1, 1:15 PM – 1:27 PM CDT. Location: S406.
- (Abstract #3001) Oral Presentation: Association of response to programmed death receptor 1 (PD-1) blockade with pembrolizumab (MK-3475) with an interferon-inflammatory immune gene signature. A. Ribas. Monday, June 1, 1:27 PM – 1:39 PM CDT. Location: S406.
- (Abstract #3009) Poster Discussion: Pembrolizumab (MK-3475) plus low-dose ipilimumab (IPI) in patients (pts) with advanced melanoma (MEL) or renal cell carcinoma (RCC): Data from the KEYNOTE-029 phase 1 study. M. Atkins. Saturday, May 30, 8:00 AM – 11:30 AM CDT (poster session). Location: S Hall A. 3:00 PM – 4:15 PM CDT (discussion). Location: S406.

Lung Cancer

Merck has a broad lung cancer development program for KEYTRUDA across all histologies, multiple lines of therapy and in combination, and based on tumor characteristics such as PD-L1 expression. At ASCO, first-time presentations include early findings with KEYTRUDA monotherapy in SCLC and as combination therapy in NSCLC.

- (Abstract #8011) Clinical Science Symposium: Phase I study of pembrolizumab (pembro; MK-3475) plus ipilimumab (IPI) as second-line therapy for advanced non-small cell lung cancer (NSCLC): KEYNOTE-021 cohort D. A. Patnaik. Sunday, May 31, 4:54 PM – 5:06 PM CDT. Location: E Hall D1.
- (Abstract #7502) Oral Presentation: Pembrolizumab (MK-3475) in patients (pts) with extensive-stage small cell lung cancer (SCLC): Preliminary safety and efficacy results from KEYNOTE-028. P. Ott. Saturday, May 30, 3:48 PM – 4:00 PM CDT. Location: E Hall D1.

Additional Cancers

Early data for KEYTRUDA from Merck's immuno-oncology development program will also be presented in a number of difficult-to-treat cancers. For the first time, data will be presented exploring the potential of an anti-PD-1 therapy in colorectal cancer and other solid tumors based on DNA mismatch repair deficiency, which is evident in different cancers. These data are part of the official ASCO press program.

- (Abstract #LBA100) Late-Breaker Presentation: PD-1 blockade in tumors with mismatch repair deficiency. D. Le. Saturday, May 30, 8:05 AM – 8:17 AM CDT. Location: E Hall D1. ASCO Press Program, Friday, May 29, 1:00 PM CDT.
- (Abstract #4001) Oral Presentation: Relationship between PD-L1 expression and clinical outcomes in patients with advanced gastric cancer treated with the anti-PD-1 monoclonal antibody pembrolizumab (MK-3475) in KEYNOTE-012. Y. Bang. Sunday, May 31, 8:12 AM – 8:24 AM CDT. Location: E Hall D2.
- (Abstract #4010) Clinical Science Symposium: Pembrolizumab (MK-3475) for patients (pts) with advanced esophageal carcinoma: Preliminary results from KEYNOTE-028. T. Doi. Sunday, May 31, 4:54 PM – 5:06 PM CDT. Location: E Hall D2.
- (Abstract #4502) Oral Presentation: Pembrolizumab (MK-3475) for advanced urothelial cancer: Updated results and biomarker analysis from KEYNOTE-012. E. Plimack. Monday, June 1, 10:09 AM – 10:21 AM CDT. Location: E Arie Crown Theater.
- (Abstract #5510) Clinical Science Symposium: Antitumor activity and safety of pembrolizumab in patients (pts) with PD-L1 positive advanced ovarian cancer: Interim results from a phase Ib study. A. Varga. Monday, June 1, 3:12 PM – 3:24 PM CDT. Location: E354b.

Additional Data

Data from studies of other Merck approved medicines and pipeline candidates will also be presented at the meeting. For more information, including a complete list of abstract titles, please visit the ASCO website at <https://iplanner.asco.org/AM2015>.

Merck Oncology Briefing Webcast

Merck will hold a webcast in conjunction with the 2015 ASCO Annual Meeting on June 1 at 7:30 p.m. CDT. Investors and journalists may access the live audio webcast of the event on Merck's website at www.merck.com. Software needed to listen to the webcast is available on the corporate website and should be downloaded prior to the beginning of the webcast. Institutional investors, analysts and members of the media can also listen to the event by dialing (866) 486-2604 or (706) 634-1286 and using ID code number 45855476.

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 administered as an intravenous infusion over 30 minutes 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.

Merck is advancing a broad and fast-growing clinical development program for KEYTRUDA with more than 85 clinical trials – across more than 30 tumor types and over 14,000 patients – both as a monotherapy and in combination with other therapies.

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 $\geq 20\%$ 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 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.

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).

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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