New Studies Investigating the Use of KEYTRUDA® (pembrolizumab) Across Solid and Hematological Cancers to Be Presented at Upcoming Congresses

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First-Time Presentation of KEYTRUDA Compared to Chemotherapy in Advanced Non-Small Cell Lung Cancer From KEYNOTE-010 Study

New Findings of KEYTRUDA in Novel Combinations with Other Immunotherapies in Advanced Melanoma

First-Time Findings in Multiple Myeloma and ER-Positive/HER2-Negative Breast Cancer as Well as New Findings in Classical Hodgkin Lymphoma

KENILWORTH, N.J.--(BUSINESS WIRE)--Merck (NYSE:MRK), known as MSD outside the United States and Canada, today announced that data investigating the use of KEYTRUDA® (pembrolizumab), the company’s anti-PD-1 therapy, in advanced non-small cell lung cancer, melanoma, classical Hodgkin lymphoma, multiple myeloma, and ER-positive/HER2-negative breast cancer will be presented at four medical congresses through the end of this year. In total, data from more than 30 abstracts will be presented at the Society for Melanoma Research (SMR) 2015 Congress in San Francisco, Nov. 18 – 21; the 57th American Society of Hematology (ASH) Annual Meeting in Orlando, Florida, Dec. 5 – 8; the San Antonio Breast Cancer Symposium (SABCS), Dec. 8 – 12; and the European Society for Medical Oncology (ESMO) Asia 2015 Congress in Singapore, Dec. 18 – 21. By the end of 2015, data on the anti-tumor activity of KEYTRUDA will have been presented across more than 20 tumor types.

“The field of immuno-oncology holds great potential across a broad spectrum of cancers,” said Dr. Roy Baynes, senior vice president and head of global clinical development, Merck Research Laboratories. “Data for KEYTRUDA being presented at these scientific meetings include a first-time comparison to chemotherapy in advanced non-small cell lung cancer, novel combination data in advanced melanoma, as well as first-time data in two additional tumor types, namely multiple myeloma and hormone receptor positive breast cancer, further demonstrating our deep commitment to advancing cancer treatment.”

The KEYTRUDA clinical development program to date includes patients with more than 30 tumor types in more than 160 clinical trials, including more than 80 trials that combine KEYTRUDA with other cancer treatments.

A select list of KEYTRUDA data to be presented at these meetings includes:

SMR (data to be presented include three late breaking oral presentations and multiple posters on KEYTRUDA monotherapy)

- **Late Breaker Oral Presentation**: Preliminary Data From a Phase 1/2 Study of Epacadostat (INCB024360) with Pembrolizumab as First-Line Treatment in Patients with Advanced/Metastatic Melanoma. O. Hamid. Saturday, Nov. 21, 2:50 p.m. PST. Location: Salon 9-15 (San Francisco Marriott Marquis).

- **Late Breaker Oral Presentation**: Primary Analysis of MASTERKEY-265 Phase 1b Study of Talimogene Laherparepvec (T-VEC) and Pembrolizumab (pembro) for Unresectable Stage IIIB-IV Melanoma. G. Long. Saturday, Nov. 21, 3:20 p.m. PST. Location: Salon 9-15 (San Francisco Marriott Marquis).

- **Late Breaker Oral Presentation**: KEYNOTE-029: Pembrolizumab (pembro) + Low-Dose Ipilimumab (ipi) For Advanced Melanoma. G. Long. Saturday, Nov. 21, 2:00 p.m. PST. Location: Salon 9-15 (San Francisco Marriott Marquis).
ASH (data to be presented include four oral presentations and one poster presentation, including updated findings in classical Hodgkin lymphoma and first-time findings in multiple myeloma)

- **(Abstract #505) Oral Presentation:** Pembrolizumab in Combination with Lenalidomide and Low-Dose Dexamethasone for Relapsed/Refractory Multiple Myeloma (RRMM): Keynote-023. J. San Miguel. Monday, Dec. 7, 7:00 a.m. EST. Location: Hall E1 (Orange County Convention Center).


For more information about this congress, including a complete list of abstract titles, please visit the ASH Annual Meeting website at [www.hematology.org/Annual-Meeting](http://www.hematology.org/Annual-Meeting).

SABCS (data to be presented include one oral presentation and three poster presentations, including first-time findings in ER-positive/HER2-negative breast cancer)

- **(Abstract #S5-07) Oral Presentation:** Preliminary Efficacy and Safety of Pembrolizumab (MK-3475) in Patients with PD-L1-positive, Estrogen Receptor-positive (ER+)/HER2-negative Advanced Breast Cancer Enrolled in KEYNOTE-028. H. Rugo. Friday, Dec. 11, 11:00 a.m. CST. Location: Hall D (Henry B. Gonzalez Convention Center).

For more information about this congress, including a complete list of abstract titles, please visit the SABCS website at [www.sabcs.org](http://www.sabcs.org).

ESMO Asia (data to be presented include one oral presentation featured in the Presidential Symposium, one proffered paper presentation and seven poster presentations, including data comparing KEYTRUDA to chemotherapy in advanced non-small cell lung cancer)

- **(Abstract #LBA3) Presidential Symposium:** KEYNOTE-010: Phase 2/3 Study of Pembrolizumab (MK-3475) vs Docetaxel for PD-L1-Positive NSCLC After Platinum-Based Therapy. R. Herbst. Sunday, Dec. 20, 5:00 p.m. SGT. Location: Hall 406 (Suntec Convention & Exhibition Centre).

- **(Abstract #315O) Proffered Paper Presentation:** Antitumor Activity and Safety of Pembrolizumab in Patients with PD-L1-positive Nasopharyngeal Carcinoma: Interim Results From a Phase 1b Study. C. Hsu. Friday, Dec. 18, 2:50 p.m. SGT. Location: Hall 332 (Suntec Convention & Exhibition Centre).

For more information about this congress, including a complete list of abstract titles, please visit the ESMO Asia 2015 congress website at [http://www.esmo.org/Conferences/ESMO-Asia-2015-Congress](http://www.esmo.org/Conferences/ESMO-Asia-2015-Congress).

**About KEYTRUDA® (pembrolizumab) Injection 100 mg**

KEYTRUDA is a humanized monoclonal antibody that works by increasing the ability of the body’s immune system to help detect and fight tumor cells. KEYTRUDA blocks the interaction between PD-1 and its ligands, PD-L1 and PD-L2, thereby activating T lymphocytes which may affect both tumor cells and healthy cells.

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. KEYTRUDA is also indicated at the same dosing 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 durability of response. An improvement in survival or disease-related symptoms has not yet been established. Continued approval for these indications may be contingent upon verification and description of clinical benefit in the confirmatory trials.

**Selected Important Safety Information for KEYTRUDA (pembrolizumab)**

Pneumonitis, including fatal cases, occurred in patients receiving KEYTRUDA. Pneumonitis occurred in 12 (2.9%) of 411 melanoma patients, including Grade 2 or 3 cases in 8 (1.9%) and 1 (0.2%) patients, respectively, receiving KEYTRUDA. Pneumonitis occurred in 19 (3.5%) of 550 patients with NSCLC, 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 or recurrent Grade 2 pneumonitis.

Colitis (including microscopic colitis) occurred in 4 (1%) of 411 patients with melanoma, including Grade 2 or 3 cases in 1 (0.2%) and 2 (0.5%) patients, respectively, receiving KEYTRUDA. Colitis occurred in 4 (0.7%) of 550 patients with NSCLC, 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. Hepatitis (including autoimmune hepatitis) occurred in 2 (0.5%) of 411 patients with melanoma, 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 with melanoma, including a Grade 2 case in 1 and a Grade 4 case in 1 (0.2%...
States and Canada.

About Merck

Our Focus on Cancer

Safety and effectiveness of KEYTRUDA have not been established in pediatric patients.

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 health care 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 each patient, receiving KEYTRUDA. Hypophysitis occurred in 1 (0.2 %) of 550 patients with NSCLC, 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 5 (1.2%) of 411 patients with melanoma, including Grade 2 or 3 cases in 2 (0.5%) and 1 (0.2%) patients, respectively, receiving KEYTRUDA. Hyperthyroidism occurred in 34 (8.3%) of 411 patients with melanoma, including a Grade 3 case in 1 (0.2%) patient, receiving KEYTRUDA. Hyperthyroidism occurred in 10 (1.8%) of 550 patients with NSCLC, including Grade 2 (0.7%) or 3 (0.3%). Hyperthyroidism occurred in 38 (6.9%) of 550 patients with NSCLC, 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 administer anti-i-hyperglycemics in patients with severe hyperglycemia.

Nephritis occurred in patients receiving KEYTRUDA. Nephritis occurred in 3 (0.7%) patients with melanoma, 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.

Other clinically important immune-mediated adverse reactions can occur. 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.

Across clinical studies with KEYTRUDA, the following clinically significant, immune-mediated adverse reactions have occurred: bullous pemphigoid and Guillain-Barré syndrome. The following clinically significant, immune-mediated adverse reactions occurred in less than 1% of patients with melanoma treated with KEYTRUDA: exfoliative dermatitis, uveitis, arthritis, myositis, pancreatitis, hemolytic anemia, and partial seizures arising in a patient with inflammatory foci in brain parenchyma. The following clinically significant, immune-mediated adverse reactions occurred in less than 1% of 550 patients with NSCLC treated with KEYTRUDA: rash, vasculitis, hemolytic anemia, serum sickness, and myasthenia gravis.

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.

Among the 411 patients with metastatic melanoma, KEYTRUDA was discontinued for adverse reactions in 9% of 411 patients. Adverse reactions, reported in at least two patients, that led to discontinuation of KEYTRUDA were: pneumonitis, renal failure, and pain. Serious adverse reactions occurred in 36% of patients. The most frequent serious adverse reactions, reported in 2% or more of patients, were renal failure, dyspnea, pneumonia, and cellulitis. The most common adverse reactions (reported in at least 20% of patients) were fatigue (47%), cough (30%), nausea (30%), pruritus (30%), rash (29%), decreased appetite (26%), constipation (21%), arthralgia (20%), and diarrhea (20%).

Among the 550 patients with metastatic NSCLC, 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.

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 health care 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 health care through far-reaching policies, programs and partnerships. For more information, visit www.merck.com and connect with us on Twitter, Facebook, YouTube and LinkedIn.

Forward-Looking Statement of Merck & Co., Inc., Kenilworth, N.J., USA

This news release of Merck & Co., Inc., Kenilworth, N.J., USA (the “company”) includes “forward-looking statements” within the meaning of the safe harbor provisions of the U.S. 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 health care legislation in the United States and internationally; global trends toward health care 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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