NEWS RELEASE

KEYTRUDA® (pembrolizumab) Treatment Results in Patients with Relapsed or Refractory Classical Hodgkin Lymphoma (cHL) Presented at 58th Annual Meeting of the American Society of Hematology

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Data from Pivotal KEYNOTE-087 Trial Show Overall Response Rate (ORR) of 69.0 Percent and Complete Remission Rate (CRR) of 22.4 Percent

With More than Two Years of Follow-up, Findings from KEYNOTE-013 Show ORR of 58 Percent and CRR of 19 Percent with Responses of 12 Months or Greater in 70 Percent of Responding Patients

KENILWORTH, N.J.--(**BUSINESS WIRE**)--Merck (NYSE:MRK), known as MSD outside the United States and Canada, announced today updated findings evaluating KEYTRUDA® (pembrolizumab), the company's anti-PD-1 therapy, in two trials of patients with relapsed or refractory classical Hodgkin lymphoma (cHL). In the KEYNOTE-087 and KEYNOTE-013 trials, KEYTRUDA demonstrated overall response rates (ORR) of 69.0 percent and 58 percent, respectively. KEYNOTE-013, which had a median follow up of 29 months, showed responses of 12 months or greater in 70 percent of patients who responded to therapy. These findings will be presented today at the 58th Annual Meeting of the American Society of Hematology (ASH). Additionally, data from these trials supported the recently announced regulatory filing with the U.S. Food and Drug Administration.

"As the data mature from these two studies, we continue to be encouraged by the response rates, including complete remission and durable responses, in patients with relapsed or refractory classical Hodgkin lymphoma," said Dr. Roger Dansey, senior vice president and therapeutic area head, oncology late-stage development, Merck Research Laboratories.

The KEYTRUDA clinical development program includes more than 30 tumor types in nearly 400 clinical trials, including more than 200 trials that combine KEYTRUDA with other cancer treatments. For hematologic malignancies specifically, Merck is conducting broad immuno-oncology research assessing the role of monotherapy and combination regimens with KEYTRUDA (pembrolizumab). The hematology program includes nearly 40 ongoing studies – including company sponsored, investigator sponsored and collaborative studies; several of these are registration-enabling trials.

"When patients with classical Hodgkin lymphoma do not respond to standard of care chemotherapy or autologous stem cell transplantation, the cancer is difficult to successfully treat. For these patients, who are often in their 20s and 30s, the need to identify new treatment options is urgent," said Dr. Craig Moskowitz, clinical director, division of hematologic oncology, Memorial Sloan Kettering Cancer Center. "These data are promising and show that pembrolizumab may provide meaningful clinical benefit to patients with this disease."

Results from KEYNOTE-087

Results from the KEYNOTE-087 trial will be presented in an oral presentation by Dr. Moskowitz at 5 p.m. PST (Location: San Diego Convention Center, Room 6B) (Abstract #1107).

KEYNOTE-087 is a multicenter, open-label, multi-cohort, activity-estimating phase 2 trial evaluating KEYTRUDA (200 mg fixed dose every three weeks) monotherapy in patients with relapsed or refractory cHL across three cohorts. The primary endpoints include overall safety, tolerability, and ORR (per blinded independent central review, BICR); secondary endpoints include ORR (per investigator review), duration of response (DOR), progression-free survival (PFS) and overall survival (OS). The patient cohorts are intended to assess the outcome measures in: patients whose disease progressed following an autologous stem cell transplantation and subsequent treatment with brentuximab vedotin, an antibody drug conjugate (Cohort 1); patients who failed salvage chemotherapy and were ineligible for a transplant and whose disease progressed following treatment with brentuximab vedotin (Cohort 2); and patients whose disease progressed after transplant and who did not receive brentuximab vedotin after transplant (Cohort 3).

Across all 210 enrolled patients, the ORR was 69.0 percent (n=145; 95% CI, 62.3-75.2) by BICR, and the complete remission rate was 22.4 percent (n=47; 95% CI, 16.9-28.6). Across all cohorts, 93 percent of patients experienced a decrease in tumor burden (n=192).

By cohort, the data showed:

- In Cohort 1, (n=69), ORR was 73.9 percent (n=51; 95% CI, 61.9-83.7) – with complete remissions in 21.7 percent

(n=15; 95% CI, 12.7-33.3) and partial remissions in 52.2 percent (n=36; 95% CI, 39.8-64.4) of patients. An additional 15.9 percent of patients had stable disease (n=11; 95% CI, 8.2-26.7) and 7.2 percent of patients had progressive disease (n=5; 95% CI, 2.4-16.1). Additionally, 82.2 percent of responding patients had a response of six months or greater.

- In Cohort 2 (n=81), ORR was 64.2 percent (n=52; 95% CI, 52.8-74.6) – with complete remissions in 24.7 percent (n=20; 95% CI, 15.8-35.5) and partial remissions in 39.5 percent (n=32; 95% CI, 28.8-51.0) of patients. An additional 12.3 percent of patients had stable disease (n=10; 95% CI, 6.1-21.5) and 21.0 percent of patients had progressive disease (n=17; 95% CI, 12.7-31.5). Additionally, 70 percent of responding patients had a response of six months or greater.
- In Cohort 3 (n=60), ORR was 70.0 percent (n=42; 95% CI, 56.8-81.2) – with complete remissions in 20.0 percent (n=12; 95% CI, 10.8-32.3) and partial remissions in 50.0 percent (n=30; 95% CI, 36.8-63.2) of patients. An additional 16.7 percent of patients had stable disease (n=10; 95% CI, 8.3-28.5) and 13.3 percent of patients had progressive disease (n=8; 95% CI, 5.9-24.6). Additionally, 75.6 percent of responding patients had a response of six months or greater.

Results also included an analysis of patients with primary refractory disease (n=73), defined as failure to achieve complete or partial response to first-line treatment. In this patient population, the ORR (per BICR) was 79.5 percent (n=58; 95% CI, 68.4-88.0). Additionally, an ORR of 67.8 percent (95% CI, 59.6-75.3) was reported in patients who relapsed after three or more lines of prior therapy (n=99/146).

The safety profile of KEYTRUDA (pembrolizumab) was consistent with that observed in previously reported studies. The most common treatment-related adverse events were hypothyroidism (12.4%), pyrexia (10.5%), fatigue (9.0%), rash (7.6%), diarrhea (7.1%), headache (6.2%), nausea (5.7%), cough (5.7%) and neutropenia (5.2%). The most common grade 3 or 4 treatment-related adverse events were neutropenia (2.4%), diarrhea (1.0%) and dyspnea (1.0%). Immune-mediated adverse events included pneumonitis (2.9%), hyperthyroidism (2.9%), colitis (1.0%) and myositis (1.0%). There were nine discontinuations because of treatment-related adverse events and no treatment-related deaths.

Results from KEYNOTE-013

Results from the KEYNOTE-013 trial will be presented in an oral presentation by Dr. Philippe Armand, medical oncologist, Dana-Farber Cancer Institute at 5:15 p.m. PST (Location: San Diego Convention Center, Room 6B) (Abstract #1108).

KEYNOTE-013 is an ongoing, multicenter, non-randomized, phase 1b trial of approximately 200 patients evaluating the safety, tolerability, and efficacy of KEYTRUDA (pembrolizumab) monotherapy in patients with blood cancers, including myelodysplastic syndromes, multiple myeloma, classical Hodgkin lymphoma, mediastinal large B cell

lymphoma and certain other non-Hodgkin's lymphoma (or lymphomata). 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 ORR, DOR, PFS, and OS.

Data from a cohort of the study evaluated KEYTRUDA monotherapy at 10 mg/kg every two weeks in patients with relapsed or refractory cHL who had progressed on or after treatment with brentuximab vedotin after failure of autologous stem cell transplant, or who were transplant-ineligible. Response was assessed at week 12 and every 8 weeks thereafter according to the International Harmonization Project 2007 criteria.

Across all 31 patients enrolled in the KEYNOTE-013 classical Hodgkin lymphoma cohort, the ORR was 58 percent (n=18; 95% CI, 39-76) by BICR, and the complete remission rate was 19 percent (n=6; 95% CI, 8-38). Thirty-nine percent of patients achieved partial remission (n=12; 95% CI, 22-58) and 23 percent had stable disease (n=7; 95% CI, 10-41). The median duration of response was not yet reached (range 0.0+ to 26.1+ months) and 70 percent of responding patients had a response of 12 months or greater. The median duration of follow-up was 29 months.

Measured by BICR, median PFS was 11.4 months (4.9-27.8). The six-month PFS rate was 66 percent and the 12-month rate was 48 percent. Median OS was not reached. Six-month and 12-month OS rates were 100 percent and 87 percent, respectively.

The safety profile of KEYTRUDA was consistent with that observed in previously reported studies. The most common treatment-related adverse events were diarrhea (19%), hypothyroidism (13%), pneumonitis (13%), nausea (13%), fatigue (10%) and dyspnea (10%). The most common grade 3 or 4 treatment-related adverse events were colitis (3%), axillary pain (3%), AST increased (3%), joint swelling (3%), nephrotic syndrome back pain (3%) and dyspnea (3%). Adverse events leading to discontinuation were nephrotic syndrome (grade 3), interstitial lung disease (grade 2) and pneumonitis (grade 2). There were no treatment-related deaths.

About Hodgkin Lymphoma

Hodgkin lymphoma is a type of lymphoma that develops in the white blood cells, called lymphocytes, which are part of the immune system. Hodgkin lymphoma can start almost anywhere – most often in lymph nodes in the upper part of the body, with the most common sites being in the chest, neck or under the arms. In 2016, it is estimated that more than 8,500 people will be diagnosed with Hodgkin lymphoma in the U.S.; cHL accounts for about 95 percent of all cases of Hodgkin lymphoma in developed countries.

About KEYTRUDA ® (pembrolizumab)

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 administered as an intravenous infusion over 30 minutes every three weeks for the approved indications. KEYTRUDA for injection is supplied in a 100 mg single use vial.

KEYTRUDA Indications and Dosing

Melanoma

KEYTRUDA is indicated for the treatment of patients with unresectable or metastatic melanoma at a dose of 2 mg/kg every three weeks until disease progression or unacceptable toxicity.

Lung Cancer

KEYTRUDA is indicated for the first-line treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have high PD-L1 expression [tumor proportion score (TPS) ≥50%] as determined by an FDA-approved test, with no EGFR or ALK genomic tumor aberrations.

KEYTRUDA is also indicated for the treatment of patients with metastatic NSCLC whose tumors express PD-L1 (TPS ≥1%) 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.

In metastatic NSCLC, KEYTRUDA is administered at a fixed dose of 200 mg every three weeks until disease progression, unacceptable toxicity, or up to 24 months in patients without disease progression.

Head and Neck Cancer

KEYTRUDA (pembrolizumab) is indicated for the treatment of patients with recurrent or metastatic head and neck squamous cell carcinoma (HNSCC) with disease progression on or after platinum-containing chemotherapy. This indication is approved under accelerated approval based on tumor response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trials. In HNSCC, KEYTRUDA is administered at a fixed dose of 200 mg every three weeks until disease progression, unacceptable toxicity, or up to 24 months in patients without disease progression.

Selected Important Safety Information for KEYTRUDA ® (pembrolizumab)

KEYTRUDA can cause immune-mediated pneumonitis, including fatal cases. Pneumonitis occurred in 94 (3.4%) of 2799 patients receiving KEYTRUDA, including Grade 1 (0.8%), 2 (1.3%), 3 (0.9%), 4 (0.3%), and 5 (0.1%) pneumonitis, and occurred more frequently in patients with a history of prior thoracic radiation (6.9%) compared to those without (2.9%). 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.

KEYTRUDA can cause immune-mediated colitis. Colitis occurred in 48 (1.7%) of 2799 patients receiving KEYTRUDA, including Grade 2 (0.4%), 3 (1.1%), and 4 (<0.1%) colitis. 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.

KEYTRUDA can cause immune-mediated hepatitis. Hepatitis occurred in 19 (0.7%) of 2799 patients receiving KEYTRUDA, including Grade 2 (0.1%), 3 (0.4%), and 4 (<0.1%) hepatitis. 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.

KEYTRUDA can cause hypophysitis. Hypophysitis occurred in 17 (0.6%) of 2799 patients receiving KEYTRUDA, including Grade 2 (0.2%), 3 (0.3%), and 4 (<0.1%) hypophysitis. Monitor patients for signs and symptoms of hypophysitis (including hypopituitarism and adrenal insufficiency). Administer corticosteroids and hormone replacement as clinically indicated. Withhold KEYTRUDA for Grade 2; withhold or discontinue for Grade 3 or 4 hypophysitis.

KEYTRUDA (pembrolizumab) can cause thyroid disorders, including hyperthyroidism, hypothyroidism, and thyroiditis. Hyperthyroidism occurred in 96 (3.4%) of 2799 patients receiving KEYTRUDA, including Grade 2 (0.8%) and 3 (0.1%) hyperthyroidism. Hypothyroidism occurred in 237 (8.5%) of 2799 patients receiving KEYTRUDA, including Grade 2 (6.2%) and 3 (0.1%) hypothyroidism. The incidence of new or worsening hypothyroidism was higher in patients with HNSCC occurring in 28 (15%) of 192 patients with HNSCC, including Grade 3 (0.5%) hypothyroidism. Thyroiditis occurred in 16 (0.6%) of 2799 patients receiving KEYTRUDA, including Grade 2 (0.3%) thyroiditis. 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 4 hyperthyroidism.

KEYTRUDA can cause type 1 diabetes mellitus, including diabetic ketoacidosis, which have been reported in 6 (0.2%) of 2799 patients. Monitor patients for hyperglycemia or other signs and symptoms of diabetes. Administer insulin

for type 1 diabetes, and withhold KEYTRUDA and administer antihyperglycemics in patients with severe hyperglycemia.

KEYTRUDA can cause immune-mediated nephritis. Nephritis occurred in 9 (0.3%) of 2799 patients receiving KEYTRUDA, including Grade 2 (0.1%), 3 (0.1%), and 4 (<0.1%) nephritis. 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.

KEYTRUDA can cause other clinically important immune-mediated adverse reactions. 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 to Grade 1 or less, initiate corticosteroid taper and continue to taper over at least 1 month. Based on limited data from clinical studies in patients whose immune-related adverse reactions could not be controlled with corticosteroid use, administration of other systemic immunosuppressants can be considered. Resume KEYTRUDA when the adverse reaction remains at Grade 1 or less following corticosteroid taper. Permanently discontinue KEYTRUDA for any Grade 3 immune-mediated adverse reaction that recurs and for any life-threatening immune-mediated adverse reaction.

The following clinically significant immune-mediated adverse reactions occurred in less than 1% (unless otherwise indicated) of 2799 patients: arthritis (1.5%), exfoliative dermatitis, bullous pemphigoid, rash (1.4%), uveitis, myositis, Guillain-Barré syndrome, myasthenia gravis, vasculitis, pancreatitis, hemolytic anemia, and partial seizures arising in a patient with inflammatory foci in brain parenchyma.

KEYTRUDA (pembrolizumab) can cause severe or life-threatening infusion-related reactions, which have been reported in 6 (0.2%) of 2799 patients. Monitor patients for signs and symptoms of infusion-related reactions, including rigors, chills, wheezing, pruritus, flushing, rash, hypotension, hypoxemia, and fever. For Grade 3 or 4 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.

In KEYNOTE-006, KEYTRUDA was discontinued due to adverse reactions in 9% of 555 patients with advanced melanoma; adverse reactions leading to discontinuation in more than one patient were colitis (1.4%), autoimmune hepatitis (0.7%), allergic reaction (0.4%), polyneuropathy (0.4%), and cardiac failure (0.4%). Adverse reactions leading to interruption of KEYTRUDA occurred in 21% of patients; the most common (≥1%) was diarrhea (2.5%). The most

common adverse reactions with KEYTRUDA vs ipilimumab were fatigue (28% vs 28%), diarrhea (26% with KEYTRUDA), rash (24% vs 23%), and nausea (21% with KEYTRUDA). Corresponding incidence rates are listed for ipilimumab only for those adverse reactions that occurred at the same or lower rate than with KEYTRUDA.

In KEYNOTE-002, KEYTRUDA was discontinued due to adverse reactions in 12% of 357 patients with advanced melanoma; the most common (≥1%) were general physical health deterioration (1%), asthenia (1%), dyspnea (1%), pneumonitis (1%), and generalized edema (1%). Adverse reactions leading to interruption of KEYTRUDA occurred in 14% of patients; the most common (≥1%) were dyspnea (1%), diarrhea (1%), and maculopapular rash (1%). The most common adverse reactions with KEYTRUDA vs chemotherapy were fatigue (43% with KEYTRUDA), pruritus (28% vs 8%), rash (24% vs 8%), constipation (22% vs 20%), nausea (22% with KEYTRUDA), diarrhea (20% vs 20%), and decreased appetite (20% with KEYTRUDA). Corresponding incidence rates are listed for chemotherapy only for those adverse reactions that occurred at the same or lower rate than with KEYTRUDA.

KEYTRUDA was discontinued due to adverse reactions in 8% of 682 patients with metastatic NSCLC. The most common adverse event resulting in permanent discontinuation of KEYTRUDA (pembrolizumab) was pneumonitis (1.8%). Adverse reactions leading to interruption of KEYTRUDA occurred in 23% of patients; the most common (≥1%) were diarrhea (1%), fatigue (1.3%), pneumonia (1%), liver enzyme elevation (1.2%), decreased appetite (1.3%), and pneumonitis (1%). The most common adverse reactions (occurring in at least 20% of patients and at a higher incidence than with docetaxel) were decreased appetite (25% vs 23%), dyspnea (23% vs 20%), and nausea (20% vs 18%).

KEYTRUDA was discontinued due to adverse reactions in 17% of 192 patients with HNSCC. Serious adverse reactions occurred in 45% of patients. The most frequent serious adverse reactions reported in at least 2% of patients were pneumonia, dyspnea, confusional state, vomiting, pleural effusion, and respiratory failure. The most common adverse reactions (reported in at least 20% of patients) were fatigue, decreased appetite, and dyspnea. Adverse reactions occurring in patients with HNSCC were generally similar to those occurring in patients with melanoma or NSCLC, with the exception of increased incidences of facial edema (10% all Grades; 2.1% Grades 3 or 4) and new or worsening hypothyroidism.

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, 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.

As part of our focus on cancer, Merck is committed to exploring the potential of immuno-oncology with one of the fastest-growing development programs in the industry. We are currently executing an expansive research program that includes nearly 400 clinical trials evaluating our anti-PD-1 therapy across more than 30 tumor types. We also continue to strengthen our immuno-oncology portfolio through strategic acquisitions and are prioritizing the development of several promising immunotherapeutic candidates with the potential to improve the treatment of advanced cancers.

For more information about our oncology clinical trials, visit **www.merck.com/clinicaltrials**.

About Merck

For 125 years, Merck has been 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 2015 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

Patient Information/Medication Guide for KEYTRUDA at **http://www.merck.com/product/usa/pi_circulars/k/keytruda/keytruda_mg.pdf** .

Merck
Media:
Pamela Eisele, 267-305-3558
or
Kim Hamilton, 908-740-1863
or
Investors:
Teri Loxam, 908-740-1986
or
Amy Klug, 908-740-1898