News Release

FOR IMMEDIATE RELEASE

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FDA Approves Merck's KEYTRUDA® (pembrolizumab) as First-Line Combination Therapy with Pemetrexed and Carboplatin for Patients with Metastatic Nonsquamous Non-Small Cell Lung Cancer (NSCLC), Irrespective of PD-L1 Expression

First Approval for an Anti-PD-1 Therapy as a Combination in Metastatic Nonsquamous NSCLC

KENILWORTH, N.J., May 10, 2017 – Merck (NYSE: MRK), known as MSD outside the United States and Canada, today announced that the U.S. Food and Drug Administration (FDA) has approved KEYTRUDA® (pembrolizumab), the company's anti-PD-1 therapy, in combination with pemetrexed (brand name Alimta®) and carboplatin (pem/carbo), a commonly used chemotherapy regimen, for the first-line treatment of metastatic nonsquamous NSCLC, irrespective of PD-L1 expression. Under the FDA's accelerated approval regulations, this indication is approved based on tumor response rate and progression-free survival (PFS). Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trials.

The approval was based on data from KEYNOTE-021, Cohort G1, in 123 previously untreated patients with metastatic nonsquamous NSCLC with no EGFR or ALK genomic tumor aberrations and irrespective of PD-L1 expression. In this trial, KEYTRUDA + pem/carbo demonstrated an objective response rate (ORR) that was nearly double the ORR of pem/carbo alone (55 percent [95% CI: 42, 68] compared to 29 percent [95% CI: 18, 41], respectively; all responses were partial responses). Among patients who received KEYTRUDA + pem/carbo, 93 percent had a duration of response of six months or more (range 1.4+ to 13.0+ months) compared to 81 percent who received pem/carbo alone (range 1.4+ to 15.2+ months). In addition, findings demonstrated an improvement in PFS (HR 0.53 [95% CI, 0.31-0.91; p=0.0205]), with a median PFS of 13.0 months (95% CI, 8.3-not estimable) for patients treated with KEYTRUDA + pem/carbo compared to 8.9 months (95% CI, 4.4-10.3) with pem/carbo alone.

Immune-mediated adverse reactions occurred with KEYTRUDA including pneumonitis, colitis, hepatitis, endocrinopathies, and nephritis. Based on the severity of the adverse reaction, KEYTRUDA should be withheld or discontinued and corticosteroids administered when appropriate. KEYTRUDA can also cause severe or life-threatening infusion-related reactions. Monitor patients for signs and symptoms of infusion-related reactions; for Grade 3 or 4 reactions, stop infusion and permanently

discontinue KEYTRUDA (pembrolizumab). Based on its mechanism of action, KEYTRUDA can cause fetal harm when administered to a pregnant woman. Female patients of reproductive potential should be advised of the potential hazard to a fetus. For more information regarding immune-mediated and infusion-related adverse reactions and use in pregnancy, see “Selected Important Safety Information” below.

“The improved responses seen with the KEYTRUDA plus pemetrexed/carboplatin regimen are significant, and highlight the importance of finding new approaches that address the unmet needs of patients with metastatic nonsquamous non-small cell lung cancer,” said Dr. Roger M. Perlmutter, president, Merck Research Laboratories. “Today’s approval further supports our commitment to improve the lives of people with cancer.”

“This approval marks an important milestone in the treatment of lung cancer. Now, pembrolizumab in combination with pemetrexed and carboplatin can be prescribed in the first-line setting for patients with metastatic nonsquamous non-small cell lung cancer, irrespective of PD-L1 expression,” said Dr. Corey Langer, director of thoracic oncology and professor of medicine at the Hospital of the University of Pennsylvania. “Physicians should continue to use each patient’s individual characteristics – including biomarker status, histology, and other clinical factors – to determine the best treatment plan for each person.”

The combination therapy indication makes KEYTRUDA an option for more patients. KEYTRUDA is the only anti-PD-1 approved in the first-line setting as both monotherapy and combination therapy for appropriate patients with metastatic NSCLC. KEYTRUDA is approved as monotherapy in the first-line setting for patients with metastatic 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 as monotherapy is also indicated for the second-line or greater 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.

“The combination of this immunotherapy with pemetrexed and carboplatin is more good news for patients,” said Bonnie J. Addario, a lung cancer survivor and founder of the Bonnie J. Addario Lung Cancer Foundation. “Congratulations to Merck and the FDA for moving so swiftly on this important addition to our patients’ options for treatment. With this approval, hope for lung cancer patients continues to improve.”

Data Supporting the Approval

The efficacy of KEYTRUDA (pembrolizumab) was investigated in patients enrolled in the open-label, multicenter, multi-cohort KEYNOTE-021 study; the efficacy data are limited to patients with metastatic nonsquamous NSCLC randomized within the single cohort (Cohort G1). The KEYNOTE-021G1 trial was conducted in collaboration with Eli Lilly and Company, the maker of pemetrexed. The key eligibility criteria for this cohort were locally advanced or metastatic nonsquamous NSCLC, regardless of tumor PD-L1 expression status, and no prior systemic treatment for metastatic disease. Patients with autoimmune disease that required systemic therapy within two years of treatment; a medical condition that required immunosuppression; or who had received more than 30 Gy of thoracic radiation within the prior 26 weeks were ineligible. Patients in KEYNOTE-021G1 were randomized to receive KEYTRUDA + pem/carbo (n=60) or pem/carbo alone (n=63). Patients in the KEYTRUDA combination arm received KEYTRUDA (200 mg), pemetrexed (500 mg/m^2), and carboplatin (AUC 5 mg/mL/min) every three weeks for four cycles followed by KEYTRUDA every three weeks. In the control arm, patients received pemetrexed (500 mg/m^2) and carboplatin (AUC 5 mg/mL/min) alone for four cycles. At the investigator's discretion, maintenance pemetrexed (500 mg/m^2) every three weeks was permitted in both treatment arms. Treatment with KEYTRUDA continued until Response Evaluation Criteria in Solid Tumors (RECIST) 1.1-defined progression of disease as determined by blinded independent central review (BICR), unacceptable toxicity, or a maximum of 24 months. Administration of KEYTRUDA was permitted beyond RECIST-defined disease progression if the patient was clinically stable and deriving clinical benefit as determined by the investigator.

The major efficacy outcome measure was ORR as assessed by BICR using RECIST 1.1. Additional efficacy outcome measures were PFS as assessed by BICR using RECIST 1.1, duration of response, and overall survival (OS).

Findings from this cohort demonstrated an ORR with KEYTRUDA + pem/carbo of 55 percent (95% CI: 42, 68) compared to 29 percent (95% CI: 18, 41) for pem/carbo alone. KEYTRUDA in this combination also reduced the risk of disease progression or death by 47 percent (HR, 0.53 [95% CI, 0.31, 0.91]; p=0.0205).

Exploratory analyses found similar results in patients with or without PD-L1 expression, with an ORR in patients whose tumors did not express PD-L1 (TPS <1%) of 57 percent with KEYTRUDA + pem/carbo compared to 13.0 percent with pem/carbo alone; in patients with PD-L1 TPS ≥1%, the ORR was 54 percent with KEYTRUDA + pem/carbo compared to 38 percent with pem/carbo alone.

Efficacy Results from KEYNOTE-021, Cohort G1

Endpoint	KEYTRUDA + Pem/Carbo (n=60)	Pem/Carbo (n=63)
Overall Response Rate		
Overall Response Rate	55%	29%
(95% CI)	(42, 68)	(18, 41)
Complete Response	0%	0%
Partial Response	55%	29%
p-value*	0.0032	
Duration of Response		
% with duration ≥6-months†	93%	81%
Range (months)	1.4+ to 13.0+	1.4+ to 15.2+
PFS		
Number of events (%)	23 (38%)	33 (52%)
Progressive Disease	15 (25%)	27 (43%)
Death	8 (13%)	6 (10%)
Median in months (95% CI)	13.0 (8.3, NE)	8.9 (4.4, 10.3)
Hazard ratio‡ (95% CI)	0.53 (0.31, 0.91)	
p-value§	0.0205	

* Based on Miettinen-Nurminen method stratified by PD-L1 status (TPS < 1% vs. TPS ≥ 1%)
† Based on Kaplan-Meier estimation
‡ Based on the Cox proportional hazard model stratified by PD-L1 status (TPS < 1% vs. TPS ≥ 1%)
§ Based on the log-rank test stratified by PD-L1 status (TPS < 1% vs. TPS ≥ 1%)
NE = not estimable

In the KEYNOTE-021G1 trial, safety was evaluated in 59 patients who received KEYTRUDA (pembrolizumab) + pem/carbo and 62 patients who received pem/carbo alone. KEYNOTE-021 was not designed to demonstrate a statistically significant difference in adverse reaction rates for KEYTRUDA plus chemotherapy, as compared to chemotherapy alone, for any specified adverse reaction listed in the chart below.

KEYTRUDA was discontinued for adverse reactions in 10 percent of patients. The most common adverse reaction resulting in discontinuation of KEYTRUDA (≥2%) was acute kidney injury (3.4%). Adverse reactions leading to interruption of KEYTRUDA occurred in 39% of patients; the most common (≥2%) were fatigue (8%), neutrophil count decreased (8%), anemia (5%), dyspnea (3.4%), and pneumonitis (3.4%).

Adverse Reactions Occurring in ≥20% of Patients in KEYNOTE-021, Cohort G1

	KEYTRUDA + Pem/Carbo n=59		Pem/Carbo n=62	
Adverse Reaction	**All Grades* (%)**	**Grade 3-4 (%)**	**All Grades (%)**	**Grade 3-4 (%)**
General Disorders and Administration Site Conditions				
Fatigue	71	3.4	50	0
Peripheral Edema	22	0	18	0
Gastrointestinal Disorders				
Nausea	68	1.7	56	0

Constipation	51	0	37	1.6
Vomiting	39	1.7	27	0
Diarrhea	37	1.7	23	1.6
Skin and Subcutaneous Tissue Disorders				
Rash†	42	1.7	21	1.6
Pruritus	24	0	4.8	0
Alopecia	20	0	3.2	0
Respiratory, Thoracic and Mediastinal Disorders				
Dyspnea	39	3.4	21	0
Cough	24	0	18	0
Metabolism and Nutrition Disorders				
Decreased Appetite	31	0	23	0
Nervous System Disorders				
Headache	31	0	16	1.6
Dizziness	24	0	16	0
Dysgeusia	20	0	11	0
Psychiatric Disorders				
Insomnia	24	0	15	0
Infections and Infestations				
Upper respiratory tract infection	20	0	3.2	0
Musculoskeletal and Connective Tissue Disorders				
Arthralgia	15	0	24	1.6

* Graded per NCI CTCAE v4.0
† Includes rash, rash generalized, rash macular, rash maculo-papular, and rash pruritic.

When administering KEYTRUDA in combination with pem/carbo, KEYTRUDA should be administered first prior to chemotherapy when given on the same day. In metastatic NSCLC, KEYTRUDA is approved at a fixed dose of 200 mg administered as an intravenous infusion over 30 minutes every three weeks until disease progression, unacceptable toxicity, or up to 24 months in patients without disease progression; pemetrexed and carboplatin should be administered according to their FDA-approved labels.

About KEYTRUDA® (pembrolizumab) Injection

KEYTRUDA is an anti-PD-1 therapy that works by increasing the ability of the body's immune system to help detect and fight tumor cells. KEYTRUDA is a humanized monoclonal antibody that 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.

Studies of KEYTRUDA – from the largest immuno-oncology program in the industry with more than 450 trials – include a wide variety of cancers and treatment settings. The KEYTRUDA clinical program seeks to understand factors that predict a patient's likelihood of benefitting from treatment with KEYTRUDA, including the exploration of several different biomarkers across a broad range of tumors.

KEYTRUDA® (pembrolizumab) 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, as a single agent, 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, as a single agent, 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.

KEYTRUDA, in combination with pemetrexed and carboplatin, is indicated for the first-line treatment of patients with metastatic nonsquamous NSCLC. This indication is approved under accelerated approval based on tumor response rate and progression-free survival. Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trials.

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.

When administering KEYTRUDA in combination with chemotherapy, KEYTRUDA should be administered prior to chemotherapy when given on the same day. See also the Prescribing Information for pemetrexed and carboplatin.

Head and Neck Cancer

KEYTRUDA 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.

Classical Hodgkin Lymphoma

KEYTRUDA (pembrolizumab) is indicated for the treatment of adult and pediatric patients with refractory classical Hodgkin lymphoma (cHL), or who have relapsed after three or more prior lines of therapy. 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 adults with cHL, KEYTRUDA is administered at a fixed dose of 200 mg every three weeks until disease progression or unacceptable toxicity, or up to 24 months in patients without disease progression. In pediatric patients with cHL, KEYTRUDA is administered at a dose of 2 mg/kg (up to a maximum of 200 mg) every three weeks until disease progression or 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 (pembrolizumab) for Grade 2; withhold or discontinue for Grade 3 or 4 hypophysitis.

KEYTRUDA 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. 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. In addition, myelitis and myocarditis were reported in other clinical trials, including classical Hodgkin lymphoma, and postmarketing use.

Solid organ transplant rejection has been reported in postmarketing use of KEYTRUDA (pembrolizumab). Treatment with KEYTRUDA may increase the risk of rejection in solid organ transplant recipients. Consider benefit of treatment with KEYTRUDA vs the risk of possible organ rejection in these patients.

KEYTRUDA 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.

Immune-mediated complications, including fatal events, occurred in patients who underwent allogeneic hematopoietic stem cell transplantation (HSCT) after being treated with KEYTRUDA. Of 23 patients with cHL who proceeded to allogeneic HSCT after treatment with KEYTRUDA on any trial, 6 patients (26%) developed graft-versus-host-disease (GVHD), one of which was fatal, and 2 patients (9%) developed severe hepatic veno-occlusive disease (VOD) after reduced-intensity conditioning, one of which was fatal. Cases of fatal hyperacute GVHD after allogeneic HSCT have also been reported in patients with lymphoma who received a PD-1 receptor blocking antibody before transplantation. These complications may occur despite intervening therapy between PD-1 blockade and allogeneic HSCT. Follow patients closely for early evidence of transplant-related complications such as hyperacute GVHD, severe (Grade 3 to 4) acute GVHD, steroid-requiring febrile syndrome, hepatic VOD, and other immune-mediated adverse reactions, and intervene promptly.

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.

KEYTRUDA monotherapy 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 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%).

When KEYTRUDA (pembrolizumab) was administered in combination with pemetrexed and carboplatin, KEYTRUDA was discontinued in 10% of 59 patients. The most common adverse reaction resulting in discontinuation of KEYTRUDA (≥2%) was acute kidney injury (3.4%). Adverse reactions leading to interruption of KEYTRUDA occurred in 39% of patients; the most common (≥2%) were fatigue (8%), neutrophil count decreased (8%), anemia (5%), dyspnea (3.4%), and pneumonitis (3.4%).The most common adverse reactions (≥20%) with KEYTRUDA compared to carbo/pem alone were fatigue (71% vs 50%), nausea (68% vs 56%), constipation (51% vs 37%), rash (42% vs 21%), vomiting (39% vs 27%), dyspnea (39% vs 21%), diarrhea (37% vs 23%), decreased appetite (31% vs. 23%), headache (31% vs 16%), cough (24% vs 18%), dizziness (24%vs 16%), insomnia (24% vs 15%), pruritus (24% vs 4.8%), peripheral edema (22% vs 18%), dysgeusia (20% vs 11%), alopecia (20% vs 3.2%), upper respiratory tract infection (20% vs 3.2%), and arthralgia (15% vs 24%). The study was not designed to demonstrate a statistically significant difference in adverse reaction rates for KEYTRUDA plus chemotherapy, as compared to chemotherapy alone, for any specified adverse reaction.

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.

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 more than 450 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 Access Program for KEYTRUDA

At Merck, we are committed to supporting accessibility to our cancer medicines. Merck provides multiple programs to help ensure that appropriate patients who are prescribed KEYTRUDA (pembrolizumab) have access to our anti-PD-1 therapy. The Merck Access Program provides reimbursement support for patients receiving KEYTRUDA, including information to help with out-of-pocket costs and co-pay assistance for eligible patients. Merck also offers free product through our patient assistance program to eligible patients, primarily the uninsured, who, without our assistance, could not afford their medicine. More information is available by calling 1-855-257-3932 or visiting www.merckaccessprogram-keytruda.com.

About Merck's Patient Support Program for KEYTRUDA

Merck is committed to helping provide patients and their caregivers support throughout their treatment with KEYTRUDA. The KEY+YOU Patient Support Program provides a range of resources and services. For further information and to sign up, patients and physicians may call 85-KEYTRUDA (855-398-7832) or visit www.keytruda.com.

About Merck

For more than a century, Merck, a leading global biopharmaceutical company known as MSD outside of the United States and Canada, has been bringing forward medicines and vaccines for many of the world's most challenging diseases. 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. Today, Merck continues to be at the forefront of research to advance the prevention and treatment of diseases that threaten people and communities around the world - including cancer, cardio-metabolic diseases, emerging animal diseases, Alzheimer's disease and infectious diseases including HIV and Ebola. For more information, visit www.merck.com and connect with us on Twitter, Facebook, Instagram, 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 2016 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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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.

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