



NEWS RELEASE

Data for KEYTRUDA® (pembrolizumab) Across 16 Types of Cancer from Merck's Industry-Leading Immuno-Oncology Program to Be Presented at the 2017 ASCO Annual Meeting

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Research with KEYTRUDA in Monotherapy and in Combination Includes Findings in Non-Small Cell Lung Cancer (NSCLC), Melanoma, Urothelial Carcinoma, Microsatellite-Instability High (MSI-H) Cancers, Gastric Cancer and Breast Cancer

New Overall Survival Data to be Presented in NSCLC, Melanoma and Urothelial Carcinoma

KENILWORTH, N.J.--(**BUSINESS WIRE**)--Merck (NYSE:MRK), known as MSD outside the United States and Canada, today announced that new and updated data from studies of KEYTRUDA® (pembrolizumab), the company's anti-PD-1 therapy, will be presented at the 53rd Annual Meeting of the American Society of Clinical Oncology (ASCO) in Chicago, June 2 – 6, 2017. At this year's meeting, researchers will present data from more than 50 abstracts investigating the use of KEYTRUDA as monotherapy and in novel combinations across 16 cancers, including non-small cell lung cancer (NSCLC), melanoma, urothelial carcinoma, microsatellite instability-high (MSI-H) cancers, gastric cancer and breast cancer. Additional longer-term progression-free survival (PFS) and overall survival (OS) data for KEYTRUDA in monotherapy and as a combination therapy in first-line NSCLC from KEYNOTE-024 and KEYNOTE-021G will be presented. As noted in the abstracts, in KEYNOTE-024 significant improvement in OS was maintained with KEYTRUDA compared to chemotherapy with a longer follow-up of approximately six months; and in KEYNOTE-021G with more than five months of additional follow-up, a trend for improved OS with KEYTRUDA in combination with pemetrexed and carboplatin (pem/carbo) was observed when compared to pem/carbo alone,

despite high rates of patient cross-over. Additional data on these findings will be presented at the meeting.

“Our data at ASCO bring to life the potential of KEYTRUDA across many different cancer types as both monotherapy and in combination, and underscore the remarkable progress that is being made in the fight against cancer,” said Dr. Roy Baynes, senior vice president and head of global clinical development, Chief Medical Officer, Merck Research Laboratories. “In particular, we continue to show improved survival outcomes in the first-line treatment of both melanoma and non-small cell lung cancer, and we highlight clinical collaboration data that explore the potential of novel immunotherapy combinations as a treatment for patients with cancer.”

In monotherapy, data for KEYTRUDA (pembrolizumab) will be presented in NSCLC, melanoma, urothelial carcinoma, gastric cancer and triple-negative breast cancer (TNBC), among others. In the combination setting, data for KEYTRUDA in NSCLC, TNBC and endometrial cancer, among others, will be presented. Additionally, studies providing insight into the role of biomarkers – such as PD-L1 and microsatellite-instability – across a variety of tumors and treatment settings will be presented. Merck continues to advance the study of genomic markers and signals that can help physicians to identify the treatment regimen that may be best for each patient.

Merck Data at the 2017 ASCO Annual Meeting

A select listing of the more than 50 Merck-sponsored and collaboration abstracts featuring KEYTRUDA is provided below. Data from studies of other oncology medicines in Merck’s portfolio and pipeline will also be presented at the meeting. For more information, including a complete list of abstract titles and presentation days and times, please visit the ASCO website at <https://iplanner.asco.org/am2017/#/>.

Advanced Bladder Cancers: Merck has the largest immuno-oncology development program in bladder cancer. In monotherapy, OS results from KEYNOTE-045, the phase 3 trial of KEYTRUDA compared to chemotherapy for patients with locally advanced or metastatic advanced urothelial carcinoma (a type of bladder cancer) in the second-line setting (Abstract #4501), will be presented. In addition, a biomarker analysis from KEYNOTE-052, the phase 2 trial of patients with advanced urothelial carcinoma in the first-line setting who are not eligible for cisplatin-based chemotherapy (Abstract #4502), will also be presented; data from both studies served as the basis for supplemental Biologics License Applications (sBLAs) for KEYTRUDA that are currently under review with the U.S. Food and Drug Administration (FDA). In the combination setting, new data will be presented from the phase 1/2 ECHO-202/KEYNOTE-037 study of KEYTRUDA (pembrolizumab) and Incyte’s investigational oral selective IDO1 enzyme inhibitor, epacadostat, in patients with advanced urothelial carcinoma (Abstract #4503).

- Abstract #4501 Oral Session: Planned survival analysis from KEYNOTE-045: Phase 3, open-label study of pembrolizumab (pembro) versus paclitaxel, docetaxel, or vinflunine in recurrent, advanced urothelial cancer (UC). D. Bajorin. Monday, June 5. 8:12 a.m. - 8:24 a.m. CDT. Location: Arie Crown Theater.

- Abstract #4502 Oral Session: Biomarker findings and mature clinical results from KEYNOTE-052: First-line pembrolizumab (pembro) in cisplatin-ineligible advanced urothelial cancer (UC). P. O'Donnell. Monday, June 5. 8:24 a.m. - 8:36 a.m. CDT. Location: Arie Crown Theater.
- Abstract #4503 Oral Session: Epcadostat plus pembrolizumab in patients with advanced urothelial carcinoma: Preliminary phase I/II results of ECHO-202/KEYNOTE-037. D. Smith. Monday, June 5. 8:36 a.m. - 8:48 a.m. CDT. Location: Arie Crown Theater.

Advanced Breast Cancer and Other Women's Cancers: Merck is currently conducting several studies investigating the potential for KEYTRUDA as a monotherapy and as a combination therapy in breast cancer, and in endometrial, ovarian and cervical cancers. Monotherapy data to be presented include two of the phase 2 KEYNOTE-086 study cohorts (A & B) of KEYTRUDA in patients with metastatic TNBC with varying levels of PD-L1 expression (Abstract #1008 and Abstract #1088, respectively). In the combination setting, findings will be presented investigating KEYTRUDA with chemotherapy in the neoadjuvant treatment setting for high-risk breast cancer (or TNBC) (Abstract #556 and Abstract #506, respectively), including results from the phase 2 I-SPY 2 TRIAL.

- Abstract #1008 Oral Session: Phase 2 study of pembrolizumab (pembro) monotherapy for previously treated metastatic triple-negative breast cancer (mTNBC): KEYNOTE-086 cohort A. S. Adams. Saturday, June 3. 3:39 p.m. - 3:51 p.m. CDT. Location: Hall D1.
- Abstract #1088 Poster Session: Phase 2 study of pembrolizumab as first-line therapy for PD-L1-positive metastatic triple-negative breast cancer (mTNBC): Preliminary data from KEYNOTE-086 cohort B. S. Adams. Sunday, June 4. 8:00 a.m. - 11:30 a.m. CDT. Location: Hall A.
- Abstract #506 Oral Session: Pembrolizumab plus standard neoadjuvant therapy for high-risk breast cancer (BC): Results from I-SPY 2. R. Nanda. Monday, June 5. 11:45 a.m. - 11:57 a.m. CDT. Location: Hall D2.
- Abstract #556 Poster Session: Pembrolizumab (pembro) + chemotherapy (chemo) as neoadjuvant treatment for triple negative breast cancer (TNBC): Preliminary results from KEYNOTE-173. P. Schmid. Sunday, June 4. 8:00 a.m. - 11:30 a.m. CDT. Location: Hall A.

Advanced Gastrointestinal (GI) Cancers: Data will be presented from the phase 2 registrational KEYNOTE-059 study of KEYTRUDA (pembrolizumab) in patients with advanced gastric cancer – the monotherapy cohort (Abstract #4003) and the combination cohort (Abstract #4012). Additionally, combination data from the clinical collaboration with Eli Lilly and Company investigating KEYTRUDA with ramucirumab will be presented (Abstract #4046).

- Abstract #4003 Oral Session: KEYNOTE-059 cohort 1: Efficacy and safety of pembrolizumab (pembro) monotherapy in patients with previously treated advanced gastric cancer. C. Fuchs. Sunday, June 4. 9:00 a.m. - 9:12 a.m. CDT. Location: Hall D2.
- Abstract #4012 Poster Session/Discussion: KEYNOTE-059 cohort 2: Safety and efficacy of pembrolizumab

(pembro) plus 5-fluorouracil (5-FU) and cisplatin for first-line (1L) treatment of advanced gastric cancer. YJ. Bang. Saturday, June 3. Poster: 8:00 a.m. - 11:30 a.m. CDT. Location: Hall A. Discussion: 4:45 p.m. - 6:00 p.m. CDT. Location: Hall D2.

- Abstract #4046 Poster Session: Ramucirumab (R) plus pembrolizumab (P) in treatment naive and previously treated advanced gastric or gastroesophageal junction (G/GEJ) adenocarcinoma: A multi-disease phase I study. I. Chau. Saturday, June 3. 8:00 a.m. - 11:30 a.m. CDT. Location: Hall A.

Advanced Head and Neck Cancer: In advanced head and neck squamous cell carcinoma (HNSCC), a study evaluating the role of genomic determinants of response to KEYTRUDA monotherapy (Abstract #6009) will be presented. In the combination setting, researchers will present data from the ECHO-202/KEYNOTE-037 trial, which is studying KEYTRUDA in combination with Incyte's epacadostat (Abstract #6010).

- Abstract #6009 Clinical Science Symposium: Genomic determinants of response to pembrolizumab in head and neck squamous cell carcinoma (HNSCC). R. Haddad. Tuesday, June 6. 8:00 a.m. - 8:12 a.m. CDT. Location: S100a.
- Abstract #6010 Clinical Science Symposium: Epacadostat plus pembrolizumab in patients with SCCHN: Preliminary phase I/II results from ECHO-202/KEYNOTE-037. O. Hamid. Tuesday, June 6. 8:12 a.m. - 8:24 a.m. CDT. Location: S100a.

Advanced Lung Cancer: Merck is continuing to advance understanding of the important role of KEYTRUDA (pembrolizumab) in metastatic lung cancer both as monotherapy and in combination with other therapies. In monotherapy, PFS and updated OS data from the phase 3 KEYNOTE-024 trial of patients with advanced NSCLC whose tumors have high PD-L1 expression [tumor proportion score (TPS) $\geq 50\%$] (Abstract #9000) will be presented. In the combination setting, additional follow-up will be presented from the phase 1/2 KEYNOTE-021G study (Abstract #9094), including OS. KEYNOTE-021G was the basis of the recent approval of KEYTRUDA in combination with pemetrexed and carboplatin for the first-line treatment of metastatic nonsquamous NSCLC, irrespective of PD-L1 expression. In addition, data will be presented from ECHO-202/KEYNOTE-037 investigating KEYTRUDA with epacadostat in patients with NSCLC (Abstract #9014).

- Abstract #9000 Oral Session: Progression after the next line of therapy (PFS2) and updated OS among patients (pts) with advanced NSCLC and PD-L1 tumor proportion score (TPS) $\geq 50\%$ enrolled in KEYNOTE-024. J. Brahmer. Tuesday, June 6. 9:45 a.m. - 9:57 a.m. CDT. Location: Hall D1.
- Abstract #9094 Poster Session: First-line carboplatin and pemetrexed (CP) with or without pembrolizumab (pembro) for advanced nonsquamous NSCLC: Updated results of KEYNOTE-021 cohort G. V. Papadimitrakopoulou. Saturday, June 3. 8:00 a.m. - 11:30 a.m. CDT. Location: Hall A.
- Abstract #9014 Poster Session/Discussion: Efficacy and safety of epacadostat plus pembrolizumab treatment of NSCLC: Preliminary phase I/II results of ECHO-202/KEYNOTE-037. T. Gangadhar. Saturday, June 3. Poster:

8:00 a.m. - 11:30 a.m. CDT. Location: Hall A. Discussion: 3:00 p.m. - 4:15 p.m. CDT. Location: Hall D2.

Advanced Melanoma: In monotherapy, longer-term OS data from the phase 3 KEYNOTE-006 trial (Abstract #9504) of KEYTRUDA will be presented. In combination studies, early findings from the phase 1b/2 KEYNOTE-184 study of Dynavax's intratumoral SD-101 in combination with KEYTRUDA in anti-PD-1 naïve and experienced metastatic melanoma patients (Abstract #9550) will be presented, as will updated data from the KEYNOTE-029 study of KEYTRUDA with ipilimumab (Abstract #9545). In addition, data from the phase 2 KEYNOTE-142 study of Syndax's entinostat in combination with KEYTRUDA (pembrolizumab) in patients with advanced melanoma (Abstract #9529) will be presented for the first time.

- Abstract #9504 Oral Session: Long-term outcomes in patients (pts) with ipilimumab (ipi)-naïve advanced melanoma in the phase 3 KEYNOTE-006 study who completed pembrolizumab (pembro) treatment. C. Robert. Sunday, June 4. 9:12 a.m. - 9:24 a.m. CDT. Location: Arie Crown Theater.
- Abstract #9550 Poster Session: Phase 1b/2, open label, multicenter, study of intratumoral SD-101 in combination with pembrolizumab in anti-PD1 naïve & experienced metastatic melanoma patients. A. Leung. Saturday, June 3. 1:15 p.m. - 4:45 p.m. CDT. Location: Hall A.
- Abstract #9545 Poster Session: KEYNOTE-029: Efficacy and safety of pembrolizumab (pembro) plus ipilimumab (ipi) for advanced melanoma. M. Carlino. Saturday, June 3. 1:15 p.m. - 4:45 p.m. CDT. Location: Hall A.
- Abstract #9529 Poster Session: Melanoma/Skin Cancers, ENCORE 601: A phase II study of entinostat (ENT) in combination with pembrolizumab (PEMBRO) in patients with melanoma. M. Johnson. Saturday, June 3. 1:15 p.m. - 4:45 p.m. CDT. Location: Hall A.

Advanced Microsatellite-Instability (MSI) High Cancers: Merck is advancing the use of biomarkers to guide clinical decision making, including for patients with MSI-High advanced malignancies. At ASCO, monotherapy data from KEYNOTE-164 and KEYNOTE-158 will be presented in patients with high levels of MSI (Abstract #3071).

- Abstract #3071 Poster Session: Pembrolizumab therapy for microsatellite instability high (MSI-H) colorectal cancer (CRC) and non-CRC. L. Diaz. Monday, June 5. 8:00 a.m. - 11:30 a.m. CDT. Location: Hall A.

Advanced Renal Cell Carcinoma (RCC): New data from studies of KEYTRUDA in combination in patients with advanced RCC will also be presented, including preliminary data for KEYTRUDA combined with epacadostat from the ECHO-202/KEYNOTE-037 trial (Abstract #4515) and for KEYTRUDA combined with Novartis' pazopanib (Abstract #4506).

- Abstract #4515 Poster Session/Discussion: Epacadostat plus pembrolizumab in patients with advanced RCC: Preliminary phase I/II results from ECHO-202/KEYNOTE-037. P. Lara. Sunday, June 4. Poster: 8:00 a.m. - 11:30 a.m. CDT. Location: Hall A. Discussion: 11:30 a.m. - 12:45 a.m. CDT. Location: Arie Crown Theater.

- Abstract #4506 Oral Session: A phase I/II study to assess the safety and efficacy of pazopanib (PAZ) and pembrolizumab (PEM) in patients (pts) with advanced renal cell carcinoma (aRCC). S. Chowdhury. Monday, June 5. 9:36 a.m. - 9:48 a.m. CDT. Location: Arie Crown Theater.

Merck Investor Event: Merck will hold an investor event in conjunction with the 2017 ASCO Annual Meeting on Monday, June 5 at 5:45 p.m. CDT (6:45 p.m. EDT). Investors, analysts, members of the media and the general public are invited to listen to a live audio webcast of the presentation at <http://investors.merck.com/events-and-presentations/default.aspx> or by dialing (866) 486-2604 – and using ID code number 3314336.

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 500 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 fixed dose of 200 mg 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) $\geq 50\%$] as determined by an FDA-approved test, with no EGFR or ALK genomic tumor aberrations.

KEYTRUDA (pembrolizumab), as a single agent, is also indicated for the treatment of patients with metastatic NSCLC whose tumors express PD-L1 (TPS $\geq 1\%$) 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 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 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 (pembrolizumab) 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. 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 (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.

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 ($\geq 1\%$) 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 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 ($\geq 2\%$) was acute kidney injury (3.4%). Adverse reactions leading to interruption of KEYTRUDA occurred in 39% of patients; the most common ($\geq 2\%$) were fatigue (8%), neutrophil count decreased (8%), anemia (5%), dyspnea (3.4%), and pneumonitis (3.4%). The most common adverse reactions ($\geq 20\%$) with KEYTRUDA (pembrolizumab) 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 500 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 more than a century, Merck, a leading global biopharmaceutical company known as MSD outside of the United States and Canada, has been inventing for life, 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).

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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