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# U.S. FDA Approves WELIREG® (belzutifan) Plus LENVIMA® (lenvatinib) for Certain Previously Treated Adult Patients With Advanced Renal Cell Carcinoma With a Clear Cell Component (ccRCC)

*Approval based on results from the Phase 3 LITESPARK-011 trial evaluating WELIREG in combination with LENVIMA compared to cabozantinib for the treatment of patients with advanced ccRCC following treatment with a PD-1/PD-L1 inhibitor*

*WELIREG plus LENVIMA is the first approved combination of a HIF-2 alpha inhibitor and a multi-targeted VEGFR-TKI for these patients*

RAHWAY, N.J., and Tokyo, Sep. 28, 2026 – Merck & Co., Inc., Rahway, NJ, USA (known as MSD outside of the United States and Canada), and Eisai (Headquarters: Tokyo, CEO: Haruo Naito) today announced the U.S. Food and Drug Administration (FDA) has approved the dual oral regimen of WELIREG® (belzutifan), MSD's first-in-class oral hypoxia-inducible factor-2 alpha (HIF-2α) inhibitor, plus LENVIMA® (lenvatinib), the orally available multiple receptor tyrosine kinase inhibitor (TKI) discovered by Eisai, for the treatment of adult patients with advanced renal cell carcinoma with a clear cell component (ccRCC) following a programmed death receptor-1 (PD-1) or programmed death ligand 1 (PD-L1) inhibitor.

The approval is based on data from the Phase 3 LITESPARK-011 trial. Results from a pre-specified interim analysis showed treatment with WELIREG plus LENVIMA led to a statistically significant and clinically meaningful improvement in progression-free survival (PFS), one of the dual primary endpoints, compared to cabozantinib, reducing the risk of disease progression or death by 26% (HR=0.74 [95% CI, 0.61-0.89]; p=0.001) in patients with advanced ccRCC following a PD-1 or PD-L1 inhibitor. WELIREG plus LENVIMA resulted in a median PFS of 14.6 months (95% CI, 11.1-16.6) versus 10.6 months (95% CI, 9.2-11.1) with cabozantinib. WELIREG plus LENVIMA also demonstrated a statistically significant improvement in objective response rate (ORR), a key secondary endpoint, with an ORR of 53% (95% CI, 47-58) versus 40% (95% CI, 35-45) for cabozantinib (p=0.0002). Data for duration of response (DOR), another secondary endpoint, were also reported. At the final analysis, overall survival (OS), the study's other primary endpoint, did not meet statistical significance for patients who received WELIREG plus LENVIMA versus cabozantinib. These results will be presented at the upcoming European Society for Medical Oncology (ESMO) Congress 2026 in Madrid, Spain.

The WELIREG prescribing information contains a boxed warning that exposure to WELIREG during pregnancy can cause embryo-fetal harm. Verify pregnancy status prior to the initiation of WELIREG. Advise patients of these risks and the need for effective non-hormonal contraception. WELIREG can render some hormonal contraceptives ineffective. WELIREG can cause severe anemia that can require a blood transfusion. Monitor for anemia before initiation of and periodically throughout treatment with WELIREG.

WELIREG can cause severe hypoxia that may require discontinuation, supplemental oxygen or hospitalization. Monitor oxygen saturation before initiation of and periodically throughout treatment with WELIREG. Serious cardiac dysfunction, including heart failure with reduced left ventricular ejection fraction (LVEF), and cardiomyopathy, can occur with WELIREG in combination with LENVIMA. The safety of WELIREG in combination with LENVIMA has not been established in patients with LVEF below 50%. Monitor patients for symptoms or signs of heart failure and if present, reassess LVEF. Withhold and resume at a reduced dose upon recovery to baseline or Grade 1 or permanently discontinue WELIREG in combination with LENVIMA based on severity. For more information, see "Selected Safety Information" below.

Adverse reactions, some of which can be serious or fatal, may occur with LENVIMA, including hypertension, cardiac dysfunction, arterial thromboembolic events, hepatotoxicity, renal failure or impairment, proteinuria, diarrhea, fistula formation and gastrointestinal perforation, QTc interval prolongation, hypocalcemia, reversible posterior leukoencephalopathy syndrome, hemorrhagic events, impairment of thyroid stimulating hormone suppression/thyroid dysfunction, impaired wound healing, osteonecrosis of the jaw and embryo-fetal toxicity. Based on its mechanism of action and data from animal reproduction studies, LENVIMA can cause fetal harm when administered to a pregnant woman. Females of reproductive potential should be advised to use effective contraception, and based on the severity of the adverse reaction, LENVIMA should be interrupted, reduced and/or discontinued. For more information, see "Selected Safety Information" below.

"While there has been much progress in the first-line treatment of advanced kidney cancer, we have limited options to offer patients if the disease progresses after treatment with a PD-1/PD-L1 immunotherapy," said Dr. Robert Motzer, Principal Investigator and Genitourinary Medical Oncologist, Memorial Sloan Kettering Cancer Center. "With this FDA approval of belzutifan plus lenvatinib, we have a new treatment option for patients who progress following treatment with anti-PD-1/PD-L1 therapy – an important development for patients and the physicians who care for them."

"By bringing together two therapies that each target different pathways, WELIREG plus LENVIMA is now the first approved regimen of its kind, offering a new treatment option for certain patients with advanced renal cell carcinoma who have progressed after anti-PD-1/PD-L1 therapy," said Dr. M. Catherine Pietanza, Vice President, Global Clinical Development, MSD Research Laboratories. "This approval represents real progress for patients and further reinforces the importance of a HIF-2α inhibitor plus TKI combination as a new treatment approach for these patients."

"Patients facing advanced renal cell carcinoma need treatment options at every stage of their journey, and the complexity of managing this disease over time makes every treatment decision meaningful," said Dr. Corina Dutcus, Senior Vice President, Oncology Global Clinical Development Lead at Eisai. "Combination approaches with LENVIMA have shaped the treatment landscape for advanced RCC from frontline therapy through later lines, and this FDA approval builds on that legacy by introducing WELIREG plus LENVIMA – the first and only approved combination following a PD-1/PD-L1 inhibitor. At Eisai, our science is driven by the humanity of the patients we serve, and, alongside MSD, we are proud to continue advancing combination treatment options with LENVIMA for the kidney cancer community."

LENVIMA is approved in the U.S., European Union (EU), Japan, and other regions in combination with multiple agents for the treatment of RCC. In the U.S., it is approved for the following indications:

- LENVIMA, in combination with KEYTRUDA® (pembrolizumab) or KEYTRUDA QLEX™ (pembrolizumab and berahyaluronidase alfa-pmph), is approved for the first-line treatment of adult patients with advanced renal cell carcinoma (RCC).

- LENVIMA, in combination with everolimus, is approved for the treatment of adult patients with advanced RCC following one prior anti-angiogenic therapy.

Lenvatinib is approved as KISPLYX for advanced RCC in the EU.

WELIREG is approved in the U.S., EU, Japan, and other regions as a monotherapy and in combination treatment options for the treatment of RCC. In the U.S., it is approved for the following indications:

- WELIREG, as monotherapy, is approved for the treatment of adult patients with advanced ccRCC following a PD-1 or PD-L1 inhibitor and a VEGF-TKI.
- WELIREG, in combination with KEYTRUDA or KEYTRUDA QLEX, is approved for the adjuvant treatment of adult patients with ccRCC at intermediate-high or high risk of recurrence following nephrectomy, or following nephrectomy and resection of metastatic lesions.

*Dr. Motzer has provided consulting and advisory services for Merck & Co., Inc., Rahway, NJ, USA and Eisai.*

## Study design and additional data from LITESPARK-011

LITESPARK-011 is a randomized, open-label Phase 3 trial (ClinicalTrials.gov, NCT04586231) evaluating WELIREG in combination with LENVIMA compared to cabozantinib for the treatment of patients with advanced ccRCC. Eligible patients include participants with locally advanced or metastatic ccRCC who have progressed on or after a PD-1 or PD-L1 inhibitor, or within 6 months of completing adjuvant therapy with a PD-1 inhibitor. The study excluded patients with hypoxia, active CNS metastases and clinically significant cardiac disease within 6 months before first dose of study intervention. The trial enrolled 747 patients who were randomized to receive WELIREG (120 mg orally once daily) plus LENVIMA (20 mg orally once daily) or cabozantinib (60 mg orally once daily). The major efficacy endpoints were PFS per Response Evaluation Criteria in Solid Tumors version 1.1 (RECIST v1.1) as assessed by blinded independent central review (BICR) and OS. Additional efficacy endpoints included ORR by BICR using RECIST v1.1.

The median duration of exposure to WELIREG was 15.8 months (range: 1 day to 50.6 months) and the median duration of exposure to LENVIMA was 14.5 months (range: 1 day to 50.6 months).

Serious adverse reactions occurred in 54% of patients treated with WELIREG in combination with LENVIMA. Serious adverse reactions in >2% of patients included hypoxia (6%), pneumonia (5%), hyponatremia (3.2%), acute kidney injury (3%), hemorrhage (2.7%), anemia (2.7%), cardiac failure (2.4%) and diarrhea (2.4%).

Fatal adverse reactions occurred in 5% of patients who received WELIREG in combination with LENVIMA, including sepsis (0.8%), pneumonia (0.5%), pneumonitis (0.5%), respiratory failure (0.5%) and one case (0.3%) each of acute cholecystitis, acute respiratory distress syndrome, pulmonary edema, embolic cerebral infarction, hemorrhage, postoperative wound complication, thrombotic microangiopathy and upper respiratory tract infection.

Permanent discontinuation of WELIREG due to an adverse reaction occurred in 17% of patients. Adverse reactions which resulted in permanent discontinuation of WELIREG in >0.5% of patients included hypoxia (2.2%), pneumonia (1.1%), fatigue (0.8%), hyponatremia (0.8%), pneumonitis (0.8%) and respiratory failure (0.8%).

Permanent discontinuation of LENVIMA due to an adverse reaction occurred in 23% of patients. Adverse reactions which resulted in permanent discontinuation of LENVIMA in >0.5% of patients included fatigue

(1.6%), cardiac failure (1.1%), hyponatremia (1.1%), pneumonia (1.1%), decreased ejection fraction (0.8%), increased lipase (0.8%), pneumonitis (0.8%), proteinuria (0.8%) and rash (0.8%).

Dosage interruptions of WELIREG due to an adverse reaction occurred in 69% of patients. Adverse reactions which required dosage interruption in >3% of patients included fatigue (14%), diarrhea (12%), anemia (9%), vomiting (9%), hypertension (9%), nausea (8%), decreased appetite (5%), abdominal pain (4.6%), COVID-19 (4.6%), musculoskeletal pain (4.1%), pneumonia (3.5%), hypoxia (3.5%) and hemorrhage (3.5%).

Dosage interruptions of LENVIMA due to an adverse reaction occurred in 72% of patients. The most common adverse reactions resulting in dosage interruption of LENVIMA (>3%) were fatigue (15%), hypertension (14%), diarrhea (13%), nausea (10%), vomiting (10%), anemia (8%), proteinuria (7%), decreased appetite (6%), COVID-19 (5%), musculoskeletal pain (4.3%), abdominal pain (4.3%), rash (4.3%), pneumonia (3.5%), stomatitis (3.5%) and hemorrhage (3.2%).

Dose reductions of WELIREG due to an adverse reaction occurred in 35% of patients. Adverse reactions which required dose reductions of WELIREG in >2% of patients included fatigue (7%), hypoxia (7%), anemia (6%), diarrhea (3%) and dyspnea (2.4%).

Dose reductions of LENVIMA due to an adverse reaction occurred in 67% of patients. Adverse reactions which required dose reductions of LENVIMA in >2%of patients included fatigue (20%), diarrhea (13%), hypertension (12%), proteinuria (9%), decreased appetite (8%), nausea (6%), rash (6%), vomiting (4.1%), anemia (3.5%), decreased weight (3.5%), abdominal pain (3%), increased alanine aminotransferase (ALT) (2.7%), stomatitis (2.7%), musculoskeletal pain (2.4%) and hypothyroidism (2.2%).

The most common (≥25%) adverse reactions, including laboratory abnormalities, that occurred in patients who received WELIREG in combination with LENVIMA were decreased hemoglobin, fatigue, increased AST, hypertension, increased ALT, musculoskeletal pain, diarrhea, decreased lymphocytes, decreased sodium, increased creatinine, nausea, hypothyroidism, decreased appetite, decreased platelets, increased potassium, increased lipase, proteinuria, decreased magnesium, decreased calcium, increased activated partial thromboplastin time, rash, vomiting, decreased weight, constipation, abdominal pain and stomatitis.

Clinically relevant adverse reactions occurring in <15% of patients who received WELIREG in combination with LENVIMA included COVID-19 (14%), dysphonia (14%), dysgeusia (14%), urinary tract infection (14%), pruritus (12%), pyrexia (11%) and arrhythmia (9%).

**About renal cell carcinoma**

Renal cell carcinoma is the most common type of kidney cancer, with about nine out of 10 kidney cancer diagnoses being RCC. In 2024, there were an estimated 442,570 new cases of kidney cancer and 144,871 deaths from the disease worldwide. Renal cell carcinoma is about twice as common in men as in women. Cases of RCC might be discovered incidentally during imaging tests for other reasons. Approximately 32% of patients with kidney cancer are diagnosed at a regional or metastatic stage. Clear cell renal cell carcinoma, which accounts for about 70% of RCC diagnoses, is the most common subtype.

**About LENVIMA® (lenvatinib); available as 10 mg and 4 mg capsules**

LENVIMA, discovered and developed by Eisai, is an orally available multiple receptor tyrosine kinase inhibitor that inhibits the kinase activities of vascular endothelial growth factor (VEGF) receptors VEGFR1 (FLT1), VEGFR2 (KDR), and VEGFR3 (FLT4). LENVIMA inhibits other kinases that have been implicated in pathogenic angiogenesis, tumor growth, and cancer progression in addition to their normal cellular

functions, including fibroblast growth factor (FGF) receptors FGFR1-4, the platelet derived growth factor receptor alpha (PDGFRα), KIT, and RET. In syngeneic mouse tumor models, LENVIMA decreased tumor-associated macrophages, increased activated cytotoxic T cells, and demonstrated greater antitumor activity in combination with an anti-PD-1 monoclonal antibody compared to either treatment alone. The combination of LENVIMA and everolimus showed increased antiangiogenic and antitumor activity as demonstrated by decreased human endothelial cell proliferation, tube formation, and VEGF signaling in vitro and tumor volume in mouse xenograft models of human renal cell cancer greater than each drug alone. LENVIMA has been approved for the indications below.

*Thyroid cancer*

- Indication as monotherapy

(Approved mainly in Japan, the United States, Europe, China and Asia)

Japan: Unresectable thyroid cancer

The United States: The treatment of adult patients with locally recurrent or metastatic, progressive, radioiodine-refractory differentiated thyroid cancer (DTC)

Europe: The treatment of adult patients with progressive, locally advanced or metastatic, differentiated (papillary/follicular/Hürthle cell) thyroid carcinoma (DTC), refractory to radioactive iodine (RAI)

*Hepatocellular carcinoma*

- Indication as monotherapy

(Approved mainly in Japan, the United States, Europe, China and Asia)

Japan: Unresectable hepatocellular carcinoma

The United States: The first-line treatment of patients with unresectable hepatocellular carcinoma (HCC)

Europe: The treatment of adult patients with advanced or unresectable hepatocellular carcinoma (HCC) who have received no prior systemic therapy

- Indication in combination with KEYTRUDA (generic name: pembrolizumab) and transarterial chemoembolization (Approved in China)

*Thymic carcinoma*

- Indication as monotherapy (Approved mainly in Japan and Asia)

Japan: Unresectable thymic carcinoma

*Renal cell carcinoma* (In Europe other than the United Kingdom, the agent was launched under the brand name KISPLYX®)

- Indication in combination with everolimus

(Approved mainly in the United States, Europe and Asia)

The United States: The treatment of adult patients with advanced renal cell carcinoma (RCC) following one prior anti-angiogenic therapy

Europe: The treatment of adult patients with advanced renal cell carcinoma following one prior vascular endothelial growth factor (VEGF) targeted therapy

- Indication in combination with KEYTRUDA or KEYTRUDA QLEX (In Japan, KEYTRUDA QLEX was launched under the brand name KEYJECT®)

(Approved mainly in Japan, the United States, Europe and Asia)

Japan: Radically unresectable or metastatic renal cell carcinoma

The United States: The first-line treatment of adult patients with advanced renal cell carcinoma
Europe: The first-line treatment of adult patients with advanced renal cell carcinoma

*Endometrial carcinoma*

- Indication in combination with KEYTRUDA or KEYTRUDA QLEX (In Japan, KEYTRUDA QLEX was launched under the brand name KEYJECT®)

(Approved mainly in Japan, the United States, Europe and Asia)

Japan: Unresectable, advanced or recurrent endometrial carcinoma that progressed after cancer chemotherapy

The United States: The treatment of patients with advanced endometrial carcinoma that is mismatch repair proficient (pMMR) or not microsatellite instability-high (MSI-H), as determined by an FDA-approved test, who have disease progression following prior systemic therapy in any setting and are not candidates for curative surgery or radiation

Europe: The treatment of adult patients with advanced or recurrent endometrial carcinoma (EC) who have disease progression on or following prior treatment with a platinum-containing therapy in any setting and are not candidates for curative surgery or radiation therapy.

**Indications for LENVIMA® (lenvatinib) in the U.S.**

For detailed information on the approved indications in the United States, please refer to the U.S. Prescribing Information provided at the end of this document.

**Selected Safety Information for LENVIMA**

For detailed safety information, please refer to the U.S. Prescribing Information provided at the end of this document.

**About Merck & Co., Inc., Rahway, NJ, USA's research in genitourinary cancers**

Merck & Co., Inc., Rahway, NJ, USA is advancing research aimed at helping transform the treatment landscape and broaden options for people with genitourinary (GU) cancers, including bladder, kidney and prostate cancers. Globally, GU cancers account for an estimated 2.6 million new cancer diagnoses each year, equaling over 1 in 8 of all cancer incidences. Through a robust clinical development program with more than 50 ongoing clinical trials evaluating more than 22,000 patients around the world, Merck & Co., Inc., Rahway, NJ, USA is investigating the potential of several portfolio medicines and pipeline assets, leveraging multiple novel combination strategies, across various stages of disease, to help address unmet needs in GU cancers.

**About WELIREG® (belzutifan) 40 mg tablets, for oral use**

WELIREG, Merck & Co., Inc., Rahway, NJ, USA's first-in-class hypoxia-inducible factor 2 alpha (HIF-2α) inhibitor, is an orally administered small-molecule that in conditions of hypoxia or impairment of VHL protein function, blocks HIF-2alpha and HIF-1beta interaction, which may reduce the transcription and expression of HIF-2α target genes associated with cellular proliferation, angiogenesis and tumor growth. By inhibiting HIF-2α signaling, WELIREG may disrupt key pathways certain tumors may use to adapt to low-oxygen conditions, including those that help promote abnormal blood vessel formation and support tumor survival.

WELIREG has received prior regulatory approvals in certain patients with advanced renal cell carcinoma with a clear cell component (ccRCC) and adjuvant ccRCC in combination with KEYTRUDA, von Hippel-Lindau (VHL) disease-associated tumors and pheochromocytoma or paraganglioma (PPGL). As part of a

broader clinical program, Merck & Co., Inc., Rahway, NJ, USA continues to research WELIREG for people with RCC and selected solid tumors across different treatment settings, to further understand where WELIREG may provide clinical benefit.

**Indications for WELIREG® (belzutifan) in the U.S.**
For detailed information on the approved indications in the United States, please see the U.S. Prescribing Information and Medication Guide attached at the end of this document.

**Selected Safety Information for WELIREG**
For detailed safety information, including the Boxed Warning regarding embryo-fetal toxicity associated with exposure during pregnancy, please refer to the U.S. Prescribing Information provided at the end of this document.

**About KEYTRUDA® (pembrolizumab) injection for intravenous use, 100 mg**
KEYTRUDA is an anti-programmed death receptor-1 (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.

Merck & Co., Inc., Rahway, NJ, USA has the industry's largest immuno-oncology clinical research program. There are currently more than 2,800 trials studying KEYTRUDA across a wide variety of cancers and treatment settings. The KEYTRUDA clinical program seeks to understand the role of KEYTRUDA across cancers and the factors that may predict a patient's likelihood of benefitting from treatment with KEYTRUDA, including exploring several different biomarkers.

**About KEYTRUDA QLEX™ (pembrolizumab and berahyaluronidase alfa-pmph) injection for subcutaneous use, 165 mg + 2,000 units/mL**
KEYTRUDA QLEX is a fixed-combination drug product of pembrolizumab and berahyaluronidase alfa. Pembrolizumab is a programmed death receptor-1 (PD-1) blocking antibody and berahyaluronidase alfa enhances dispersion and permeability to enable subcutaneous administration of pembrolizumab. KEYTRUDA QLEX is administered as a subcutaneous injection into the thigh or abdomen, avoiding the 5 cm area around the navel, over one minute every three weeks (2.4 mL) or over two minutes every six weeks (4.8 mL).

**Indications for KEYTRUDA® (pembrolizumab) and KEYTRUDA QLEX™ (pembrolizumab and berahyaluronidase alfa-pmph) in the U.S.**
For detailed information on the approved indications in the United States, please refer to the U.S. Prescribing Information provided at the end of this document.

**Selected Safety Information for KEYTRUDA and KEYTRUDA QLEX**
For detailed safety information, please refer to the U.S. Prescribing Information provided at the end of this document.

**About the Eisai and Merck & Co., Inc., Rahway, NJ, USA strategic collaboration**
In March 2018, Eisai and Merck & Co., Inc., Rahway, NJ, USA, known as MSD outside of the United States and Canada, through an affiliate, entered into a strategic collaboration for the worldwide co-development and co-commercialization of LENVIMA. Under the agreement, the companies jointly develop, manufacture and commercialize LENVIMA, both as monotherapy and in combination with Merck & Co., Inc., Rahway, NJ, USA's anti-PD-1 therapy, KEYTRUDA, and HIF-2α inhibitor, WELIREG.

**Eisai's focus on cancer**
Eisai positions Oncology as one of its key strategic areas, and aims to contribute to the cure of cancers through the discovery of innovative new drugs with new targets and mechanisms of action under the Deep Human Biology Learning (DHBL) drug discovery and development organization.
By utilizing biomarker data obtained from our products to elucidate the mechanisms of the incidence and root causes of cancer, as well as drug resistance, and using Eisai Group's precision chemistry technology to turn undruggable intracellular therapeutic targets into druggable ones, we will create new backbone therapeutic drugs.

**About Eisai**
Eisai's Corporate Concept is "to give first thought to patients and people in the daily living domain, and to increase the benefits that health care provides." Under this Concept [also known as our *human health care* (*hhc*) Concept], we aim to effectively achieve social good in the form of relieving anxiety over health and reducing health disparities. With a global network of R&D facilities, manufacturing sites and marketing subsidiaries, we strive to create and deliver innovative products to target diseases with high unmet medical needs, with a particular focus in our strategic areas of Neurology and Oncology.

In addition, our continued commitment to the elimination of neglected tropical diseases (NTDs), which is a target (3.3) of the United Nations Sustainable Development Goals (SDGs), is demonstrated by our work on various activities together with global partners.

For more information about Eisai, please visit www.eisai.com (for global headquarters: Eisai Co., Ltd.), us.eisai.com (for U.S. headquarters: Eisai Inc.) or www.eisai.eu (for Europe, Middle East, Africa, Russia, Australia, and New Zealand headquarters: Eisai Europe Ltd.), and connect with us on Twitter (U.S. and global) and LinkedIn (for U.S. and EMEA).

**Merck & Co., Inc., Rahway, NJ, USA's focus on cancer**
Every day, we follow the science as we work to discover innovations that can help patients, no matter what stage of cancer they have. As a leading oncology company, we are pursuing research where scientific opportunity and medical need converge, underpinned by our diverse pipeline of more than 20 novel mechanisms. With one of the largest clinical development programs across more than 25 tumor types, we strive to advance breakthrough science that will shape the future of oncology. By addressing barriers to clinical trial participation, screening and treatment, we work with urgency to reduce disparities and help ensure patients have access to high-quality cancer care. Our unwavering commitment is what will bring us closer to our goal of bringing life to more patients with cancer. For more information, visit https://www.merck.com/research/oncology.

**About Merck & Co., Inc., Rahway, NJ, USA**
At Merck & Co., Inc., Rahway, N.J., USA, known as MSD outside of the United States and Canada, we are unified around our purpose: We use the power of leading-edge science to save and improve lives around the world. For more than 130 years, we have brought hope to humanity through the development of important medicines and vaccines. We aspire to be the premier research-intensive biopharmaceutical company in the world – and today, we are at the forefront of research to deliver innovative health solutions that advance the prevention and treatment of diseases in people and animals. We foster a diverse and inclusive global workforce and operate responsibly every day to enable a safe, sustainable and healthy future for all people and communities. For more information, visit www.merck.com and connect with us on X (formerly Twitter), Facebook, Instagram, YouTube and LinkedIn.

**Forward-Looking Statement of Merck & Co., Inc., Rahway, N.J., USA**
This news release of Merck & Co., Inc., Rahway, 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 candidates that the candidates 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 Annual Report on Form 10-K for the year ended December 31, 2025 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, including information for the Boxed Warning about embryo-fetal toxicity, for WELIREG (belzutifan) at https://www.merck.com/product/usa/pi_circulars/w/welireg/welireg_pi.pdf and Medication Guide for WELIREG at https://www.merck.com/product/usa/pi_circulars/w/welireg/welireg_mg.pdf.**

**Please see Prescribing Information for LENVIMA (lenvatinib) at https://www.lenvima.com/pdfs/prescribing-information.pdf.**

**Please see Prescribing Information for KEYTRUDA (pembrolizumab) at https://www.merck.com/product/usa/pi_circulars/k/keytruda/keytruda_pi.pdf and Medication Guide for KEYTRUDA at https://www.merck.com/product/usa/pi_circulars/k/keytruda/keytruda_mg.pdf.**

**Please see Prescribing Information for KEYTRUDA QLEX™ (pembrolizumab and berahyaluronidase alfa-pmph) at https://www.merck.com/product/usa/pi_circulars/k/keytruda_qlex/keytruda_qlex_pi.pdf and Medication Guide for KEYTRUDA QLEX™ at https://www.merck.com/product/usa/pi_circulars/k/keytruda_qlex/keytruda_qlex_mg.pdf.**

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