# Johnson&Johnson

#### **NEWS RELEASE**

# Johnson & Johnson is transforming solid tumor cancer outcomes with new data at the 2024 World Conference on Lung Cancer and European Society for Medical Oncology Congress

#### 2024-08-27

Four RYBREVANT® (amivantamab-vmjw) studies feature compelling new findings in lung and colorectal cancers

New TAR-200 data reveal the potential of organ-sparing therapy for the treatment of bladder cancer

RARITAN, N.J., Aug. 27, 2024 /PRNewswire/ -- Johnson & Johnson (NYSE: JNJ) announced today that 11 oral presentations from the Company's industry-leading solid tumor portfolio and pipeline will be featured at the 2024 World Conference on Lung Cancer (WCLC) and the European Society for Medical Oncology (ESMO) 2024 Congress. Twenty-seven studies (23 company-sponsored and four investigator-initiated), including four late-breaking abstracts, will feature new data in lung, bladder, prostate, and colorectal cancers.

"Our targeted approach to treating lung, prostate, bladder, and now, colorectal cancers is on full display at this year's WCLC and ESMO conferences, highlighting our ongoing commitment to develop much-needed treatments where high unmet needs remain," said Yusri Elsayed, M.D., M.H.Sc., Ph.D. Global Therapeutic Area Head, Oncology, Johnson & Johnson Innovative Medicine. "With a legacy of more than three decades of oncology innovation, Johnson is uniquely positioned to transform the treatment of solid tumor malignancies."

# Key WCLC Presentations (September 7-10) in San Diego, CA

Presentations build on recent market approvals and showcase RYBREVANT® regimens in EGFR-mutated non-small cell lung cancer (NSCLC) in frontline settings:

- Latest overall survival data from the Phase 3 MARIPOSA study evaluating RYBREVANT<sup>®</sup> plus LAZCLUZE™ (lazertinib) compared to osimertinib as first-line treatment for patients with EGFR-mutated advanced NSCLC (Oral Abstract #1146)
- First presentation from the MARIPOSA study of the randomized, double-blind comparison of LAZCLUZE™ monotherapy versus osimertinib as first-line treatment for patients with EGFR-mutated advanced NSCLC (Oral Abstract #1318)
- Primary results from the Phase 2 SKIPPirr study evaluating prophylactic strategies to prevent and reduce infusion-related reactions (IRR) with intravenous RYBREVANT® in patients with EGFR-mutated advanced NSCLC (Oral Abstract #1785)
- Additional results from the Phase 3 PALOMA study comparing subcutaneous and intravenous RYBREVANT<sup>®</sup> in patients with EGFR-mutated advanced NSCLC reporting on convenience, patient preference, and healthcare resources (Oral Abstract #3305)

# Key ESMO Presentations (September 13-17) in Barcelona, Spain

New data further support RYBREVANT® as an innovative therapy for EGFR-mutated advanced NSCLC; additionally, the first presentation of data for the RYBREVANT® and chemotherapy combination confirms its potential role in metastatic colorectal cancer, where patients do not often respond to existing treatments and have an urgent need for more durable therapies. Updates from the SunRISe program in bladder cancer reinforce J&J's intent and plan to transform treatment through the development of novel targeted drug releasing systems. While in prostate cancer, data illustrate the Company's decade-plus commitment to investigating compounds across all stages of the disease. Key presentations include:

- First results from the Phase 3 MARIPOSA study reporting on the impact of the multi-targeted approach of RYBREVANT® inhibiting epidermal growth factor receptor (EGFR) and mesenchymal-epithelial transition factor (MET) combined with LAZCLUZE™ and the emergence of acquired resistance versus osimertinib as first-line treatment for patients with EGFR-mutated advanced NSCLC (Oral Abstract #LBA1682)
- Longer follow-up data including overall survival results from the Phase 3 MARIPOSA-2 study evaluating RYBREVANT® plus chemotherapy compared to chemotherapy alone in EGFR-mutated advanced NSCLC after disease progression on osimertinib (Oral Abstract #6888)
- Additional results from the SKIPPirr study with oral dexamethasone pre-medication regimen and its prevention and reduction of infusion-related reactions (IRR) with intravenous RYBREVANT® in patients with EGFR-mutated advanced NSCLC (Poster Abstract #5546)
- First results from the Phase 1b/2 OrigAMI-1 study evaluating RYBREVANT® plus chemotherapy in patients with metastatic colorectal cancer (Oral Abstract #2915)
- Late-breaking first interim analysis results from the Phase 2 SunRISe-4 study evaluating neoadjuvant TAR-200 plus cetrelimab or cetrelimab alone in patients with muscle-invasive bladder cancer who are ineligible for or

- refuse neoadjuvant platinum-based chemotherapy (Oral Abstract #LBA84)
- Longer follow-up of TAR-200 alone and first report of TAR-200 in combination with cetrelimab and cetrelimab alone from the pivotal Phase 2b SunRISe-1 in patients with Bacillus Calmette-Guérin-unresponsive, high-risk non–muscle-invasive bladder cancer with carcinoma in situ, with or without papillary disease (Oral Abstract #LBA85)
- First presentation of a trial in progress from the first-in-human Phase 1 study evaluating JNJ-87189401, a prostate-specific membrane antigen (PSMA)-CD28 bispecific antibody, in combination with JNJ-78278343, a kallikrein 2 (KLK2)-CD3 bispecific antibody, in patients with advanced prostate cancer (Poster Abstract #1214)

A table detailing all Johnson & Johnson sponsored abstracts is available on JNJ.com.

# About RYBREVANT®

RYBREVANT® (amivantamab-vmjw), a fully-human bispecific antibody targeting EGFR and MET with immune cell-directing activity, is approved in the **U.S.**, **Europe**, and in other markets around the world as monotherapy for the treatment of adult patients with locally advanced or metastatic NSCLC with EGFR exon 20 insertion mutations, as detected by an FDA-approved test, whose disease has progressed on or after platinum-based chemotherapy. It is also approved in the U.S. in combination with chemotherapy (carboplatin and pemetrexed) for the first-line treatment of adult patients with locally advanced or metastatic NSCLC with EGFR exon 20 insertion mutations, as detected by an FDA-approved test. Additional supplemental reviews in multiple regions around the world for additional indications are ongoing.

For more information, visit: https://www.RYBREVANT.com.

#### About LAZCLUZE™

In 2018, Janssen Biotech, Inc., entered into a license and collaboration agreement with Yuhan Corporation for the development of LAZCLUZE™ (lazertinib, marketed as LACLAZA in Korea). LAZCLUZE™ is an oral, third-generation, brain-penetrant EGFR TKI that targets both the T790M mutation and activating EGFR mutations while sparing wild-type EGFR. An analysis of the efficacy and safety of LAZCLUZE™ from the Phase 3 LASER301 study was published in **The Journal of Clinical Oncology** in 2023.<sup>2</sup>

#### About TAR-200

TAR-200 is an investigational targeted releasing system enabling controlled release of gemcitabine into the bladder, providing sustained local drug exposure over several weeks. The safety and efficacy of TAR-200, as monotherapy or in combination with cetrelimab, are being evaluated in Phase 2 and Phase 3 studies in patients with muscle-invasive bladder cancer in **SunRise-2** and **SunRise-4** and with non-muscle invasive bladder cancer in **SunRise-1**, **SunRise-**

#### 3, and SunRISe-5.

#### **About Cetrelimab**

Administered intravenously, cetrelimab is an investigational programmed cell death receptor-1 (PD-1) monoclonal antibody being studied for the treatment of bladder cancer, prostate cancer, melanoma, and multiple myeloma as part of a combination treatment. Cetrelimab is also being evaluated in multiple other combination regimens across the Janssen Oncology portfolio.

#### IMPORTANT SAFETY INFORMATION

#### WARNINGS AND PRECAUTIONS

#### Infusion-Related Reactions

RYBREVANT® can cause infusion-related reactions (IRR); signs and symptoms of IRR include dyspnea, flushing, fever, chills, nausea, chest discomfort, hypotension, and vomiting. The median time to IRR onset is approximately 1 hour.

RYBREVANT® with LAZCLUZE $^{\text{\tiny{M}}}$ 

RYBREVANT<sup>®</sup> in combination with LAZCLUZE<sup>™</sup> can cause infusion-related reactions. In MARIPOSA (n=421), IRRs occurred in 63% of patients treated with RYBREVANT<sup>®</sup> in combination with LAZCLUZE<sup>™</sup>, including Grade 3 in 5% and Grade 4 in 1% of patients. The incidence of infusion modifications due to IRR was 54% of patients, and IRRs leading to dose reduction of RYBREVANT<sup>®</sup> occurred in 0.7% of patients. Infusion-related reactions leading to permanent discontinuation of RYBREVANT<sup>®</sup> occurred in 4.5% of patients receiving RYBREVANT<sup>®</sup> in combination with LAZCLUZE<sup>™</sup>.

RYBREVANT® with Carboplatin and Pemetrexed

In PAPILLON (n=151), infusion-related reactions occurred in 42% of patients treated with RYBREVANT<sup>®</sup> in combination with carboplatin and pemetrexed, including Grade 3 (1.3%) adverse reactions. The incidence of infusion modifications due to IRR was 40%, and 0.7% of patients permanently discontinued RYBREVANT<sup>®</sup>.

RYBREVANT® as a Single Agent

In CHRYSALIS (n=302), IRR occurred in 66% of patients treated with RYBREVANT®. Among patients receiving treatment on Week 1 Day 1, 65% experienced an IRR, while the incidence of IRR was 3.4% with the Day 2 infusion,

0.4% with the Week 2 infusion, and cumulatively 1.1% with subsequent infusions. Of the reported IRRs, 97% were Grade 1-2, 2.2% were Grade 3, and 0.4% were Grade 4. The median time to onset was 1 hour (range 0.1 to 18 hours) after start of infusion. The incidence of infusion modifications due to IRR was 62% and 1.3% of patients permanently discontinued RYBREVANT® due to IRR.

Premedicate with antihistamines, antipyretics, and glucocorticoids and infuse RYBREVANT<sup>®</sup> as recommended. Administer RYBREVANT<sup>®</sup> via a peripheral line on Week1 and Week2 to reduce the risk of infusion-related reactions. Monitor patients for signs and symptoms of infusion reactions during RYBREVANT<sup>®</sup> infusion in a setting where cardiopulmonary resuscitation medication and equipment are available. Interrupt infusion if IRR is suspected. Reduce the infusion rate or permanently discontinue RYBREVANT<sup>®</sup> based on severity.

# Interstitial Lung Disease/Pneumonitis

RYBREVANT® can cause severe and fatal interstitial lung disease (ILD)/pneumonitis.

RYBREVANT<sup>®</sup> with LAZCLUZE™

In MARIPOSA, ILD/pneumonitis occurred in 3.1% of patients treated with RYBREVANT® in combination with LAZCLUZE™, including Grade 3 in 1.0% and Grade 4 in 0.2% of patients. There was one fatal case (0.2%) of ILD/pneumonitis and 2.9% of patients permanently discontinued RYBREVANT® and LAZCLUZE™ due to ILD/pneumonitis.

RYBREVANT® with Carboplatin and Pemetrexed

In PAPILLON, Grade 3 ILD/pneumonitis occurred in 2.6% of patients treated with RYBREVANT® in combination with carboplatin and pemetrexed, all patients required permanent discontinuation.

RYBREVANT® as a Single Agent

In CHRYSALIS, ILD/pneumonitis occurred in 3.3% of patients treated with RYBREVANT $^{\$}$ , with 0.7% of patients experiencing Grade 3 ILD/pneumonitis. Three patients (1%) discontinued RYBREVANT $^{\$}$  due to ILD/pneumonitis.

Monitor patients for new or worsening symptoms indicative of ILD/pneumonitis (e.g., dyspnea, cough, fever). For patients receiving RYBREVANT® in combination with LAZCLUZE™, immediately withhold both drugs in patients with suspected ILD/pneumonitis and permanently discontinue if ILD/pneumonitis is confirmed. For patients receiving RYBREVANT® as a single agent or in combination with carboplatin and pemetrexed, immediately withhold RYBREVANT® in patients with suspected ILD/pneumonitis and permanently discontinue if ILD/pneumonitis is

confirmed.

# Venous Thromboembolic (VTE) Events with Concomitant Use of RYBREVANT® and LAZCLUZE™

RYBREVANT<sup>®</sup> in combination with LAZCLUZE<sup>™</sup> can cause serious and fatal venous thromboembolic (VTEs) events, including deep vein thrombosis and pulmonary embolism. The majority of these events occurred during the first four months of therapy.

In MARIPOSA, VTEs occurred in 36% of patients receiving RYBREVANT® in combination with LAZCLUZE™, including Grade 3 in 10% and Grade 4 in 0.5% of patients. On-study VTEs occurred in 1.2% of patients (n=5) while receiving anticoagulation therapy. There were two fatal cases of VTE (0.5%), 9% of patients had VTE leading to dose interruptions of RYBREVANT®, and 7% of patients had VTE leading to dose interruptions of LAZCLUZE™; 1% of patients had VTE leading to dose reductions of RYBREVANT®, and 0.5% of patients had VTE leading to dose reductions of LAZCLUZE™; 3.1% of patients had VTE leading to permanent discontinuation of RYBREVANT®, and 1.9% of patients had VTE leading to permanent discontinuation of LAZCLUZE™. The median time to onset of VTEs was 84 days (range: 6 to 777).

Administer prophylactic anticoagulation for the first four months of treatment. The use of Vitamin K antagonists is not recommended. Monitor for signs and symptoms of VTE events and treat as medically appropriate.

Withhold RYBREVANT<sup>®</sup> and LAZCLUZE<sup>™</sup> based on severity. Once anticoagulant treatment has been initiated, resume RYBREVANT<sup>®</sup> and LAZCLUZE<sup>™</sup> at the same dose level at the discretion of the healthcare provider. In the event of VTE recurrence despite therapeutic anticoagulation, permanently discontinue RYBREVANT<sup>®</sup> and continue treatment with LAZCLUZE<sup>™</sup> at the same dose level at the discretion of the healthcare provider.

# **Dermatologic Adverse Reactions**

RYBREVANT® can cause severe rash including toxic epidermal necrolysis (TEN), dermatitis acneiform, pruritus, and dry skin.

RYBREVANT® with LAZCLUZE $^{\text{\tiny{M}}}$ 

In MARIPOSA, rash occurred in 86% of patients treated with RYBREVANT® in combination with LAZCLUZE™, including Grade 3 in 26% of patients. The median time to onset of rash was 14 days (range: 1 to 556 days). Rash leading to dose interruptions occurred in 37% of patients for RYBREVANT® and 30% for LAZCLUZE™, rash leading to dose reductions occurred in 23% of patients for RYBREVANT® and 19% for LAZCLUZE™, and rash leading to

permanent discontinuation occurred in 5% of patients for RYBREVANT® and 1.7% for LAZCLUZE™.

RYBREVANT® with Carboplatin and Pemetrexed

In PAPILLON, rash occurred in 89% of patients treated with RYBREVANT<sup>®</sup> in combination with carboplatin and pemetrexed, including Grade 3 (19%) adverse reactions. Rash leading to dose reductions occurred in 19% of patients, and 2% permanently discontinued RYBREVANT<sup>®</sup> and 1.3% discontinued pemetrexed.

RYBREVANT® as a Single Agent

In CHRYSALIS, rash occurred in 74% of patients treated with RYBREVANT<sup>®</sup> as a single agent, including Grade 3 rash in 3.3% of patients. The median time to onset of rash was 14 days (range: 1 to 276 days). Rash leading to dose reduction occurred in 5% of patients, and RYBREVANT<sup>®</sup> was permanently discontinued due to rash in 0.7% of patients.

Toxic epidermal necrolysis occurred in one patient (0.3%) treated with RYBREVANT<sup>®</sup> as a single agent.

Instruct patients to limit sun exposure during and for 2 months after treatment with RYBREVANT<sup>®</sup> or LAZCLUZE™ in combination with RYBREVANT<sup>®</sup>. Advise patients to wear protective clothing and use broad-spectrum UVA/UVB sunscreen. Alcohol-free (e.g., isopropanol-free, ethanol-free) emollient cream is recommended for dry skin.

When initiating RYBREVANT<sup>®</sup> treatment with or without LAZCLUZE<sup>™</sup>, administer alcohol-free emollient cream to reduce the risk of dermatologic adverse reactions. Consider prophylactic measures (e.g. use of oral antibiotics) to reduce the risk of dermatologic reactions. If skin reactions develop, start topical corticosteroids and topical and/or oral antibiotics. For Grade 3 reactions, add oral steroids and consider dermatologic consultation. Promptly refer patients presenting with severe rash, atypical appearance or distribution, or lack of improvement within 2 weeks to a dermatologist. For patients receiving RYBREVANT<sup>®</sup> in combination with LAZCLUZE<sup>™</sup>, withhold, dose reduce or permanently discontinue both drugs based on severity. For patients receiving RYBREVANT<sup>®</sup> as a single agent or in combination with carboplatin and pemetrexed, withhold, dose reduce or permanently discontinue RYBREVANT<sup>®</sup> based on severity.

# **Ocular Toxicity**

RYBREVANT® can cause ocular toxicity including keratitis, blepharitis, dry eye symptoms, conjunctival redness, blurred vision, visual impairment, ocular itching, eye pruritus, and uveitis.

RYBREVANT® with LAZCLU7F™

In MARIPOSA, ocular toxicity occurred in 16% of patients treated with RYBREVANT<sup>®</sup> in combination with LAZCLUZE<sup>™</sup>, including Grade 3 or 4 ocular toxicity in 0.7% of patients. Withhold, reduce the dose, or permanently discontinue RYBREVANT<sup>®</sup> and continue LAZCLUZE<sup>™</sup> based on severity.

RYBREVANT® with Carboplatin and Pemetrexed

In PAPILLON, ocular toxicity including blepharitis, dry eye, conjunctival redness, blurred vision, and eye pruritus occurred in 9%. All events were Grade 1-2.

RYBREVANT® as a Single Agent

In CHRYSALIS, keratitis occurred in 0.7% and uveitis occurred in 0.3% of patients treated with RYBREVANT®. All events were Grade 1-2.

Promptly refer patients with new or worsening eye symptoms to an ophthalmologist. Withhold, dose reduce or permanently discontinue RYBREVANT® based on severity.

# **Embryo-Fetal Toxicity**

Based on its mechanism of action and findings from animal models, RYBREVANT<sup>®</sup> and LAZCLUZE™ can cause fetal harm when administered to a pregnant woman. Advise females of reproductive potential of the potential risk to the fetus.

Advise female patients of reproductive potential to use effective contraception during treatment and for 3 months after the last dose of RYBREVANT<sup>®</sup>.

Advise females of reproductive potential to use effective contraception during treatment with LAZCLUZE™ and for 3 weeks after the last dose. Advise male patients with female partners of reproductive potential to use effective contraception during treatment with LAZCLUZE™ and for 3 weeks after the last dose.

# **Adverse Reactions**

RYBREVANT<sup>®</sup> with LAZCLUZE™

For the 421 patients in the MARIPOSA clinical trial who received RYBREVANT<sup>®</sup> in combination with LAZCLUZE<sup>TM</sup>, the most common adverse reactions ( $\geq$ 20%) were rash (86%), nail toxicity (71%), infusion-related reactions (RYBREVANT<sup>®</sup>, 63%), musculoskeletal pain (47%), stomatitis (43%), edema (43%), VTE (36%), paresthesia (35%),

fatigue (32%), diarrhea (31%), constipation (29%), COVID-19 (26%), hemorrhage (25%), dry skin (25%), decreased appetite (24%), pruritus (24%), nausea (21%), and ocular toxicity (16%). The most common Grade 3 or 4 laboratory abnormalities (≥2%) were decreased albumin (8%), decreased sodium (7%), increased ALT (7%), decreased potassium (5%), decreased hemoglobin (3.8%), increased AST (3.8%), increased GGT (2.6%), and increased magnesium (2.6%).

Serious adverse reactions occurred in 49% of patients who received RYBREVANT<sup>®</sup> in combination with LAZCLUZE<sup> $\mathrm{TM}$ </sup>. Serious adverse reactions occurring in  $\geq$ 2% of patients included VTE (11%), pneumonia (4%), ILD/pneumonitis and rash (2.9% each), COVID-19 (2.4%), and pleural effusion and infusion-related reaction (RYBREVANT<sup>®</sup>) (2.1% each). Fatal adverse reactions occurred in 7% of patients who received RYBREVANT<sup>®</sup> in combination with LAZCLUZE<sup> $\mathrm{TM}$ </sup> due to death not otherwise specified (1.2%); sepsis and respiratory failure (1% each); pneumonia, myocardial infarction, and sudden death (0.7% each); cerebral infarction, pulmonary embolism (PE), and COVID-19 infection (0.5% each); and ILD/pneumonitis, acute respiratory distress syndrome (ARDS), and cardiopulmonary arrest (0.2% each).

#### RYBREVANT® with Carboplatin and Pemetrexed

For the 151 patients in the PAPILLON clinical trial who received RYBREVANT® in combination with carboplatin and pemetrexed, the most common adverse reactions (≥20%) were rash (90%), nail toxicity (62%), stomatitis (43%), infusion-related reaction (42%), fatigue (42%), edema (40%), constipation (40%), decreased appetite (36%), nausea (36%), COVID-19 (24%), diarrhea (21%), and vomiting (21%). The most common Grade 3 to 4 laboratory abnormalities (≥2%) were decreased albumin (7%), increased alanine aminotransferase (4%), increased gammaglutamyl transferase (4%), decreased sodium (7%), decreased potassium (11%), decreased magnesium (2%), and decreases in white blood cells (17%), hemoglobin (11%), neutrophils (36%), platelets (10%), and lymphocytes (11%).

Serious adverse reactions occurred in 37% of patients who received RYBREVANT<sup>®</sup> in combination with carboplatin and pemetrexed. Serious adverse reactions in ≥2% of patients included rash, pneumonia, ILD, pulmonary embolism, vomiting, and COVID-19. Fatal adverse reactions occurred in 7 patients (4.6%) due to pneumonia, cerebrovascular accident, cardio-respiratory arrest, COVID-19, sepsis, and death not otherwise specified.

### RYBREVANT® as a Single Agent

For the 129 patients in the CHRYSALIS clinical trial who received RYBREVANT® as a single agent, the most common adverse reactions (≥20%) were rash (84%), IRR (64%), paronychia (50%), musculoskeletal pain (47%), dyspnea (37%), nausea (36%), fatigue (33%), edema (27%), stomatitis (26%), cough (25%), constipation (23%), and vomiting (22%). The most common Grade 3 to 4 laboratory abnormalities (≥2%) were decreased lymphocytes (8%), decreased albumin (8%), decreased phosphate (8%), decreased potassium (6%), increased alkaline phosphatase (4.8%), increased glucose (4%), increased gamma-glutamyl transferase (4%), and decreased sodium (4%).

Serious adverse reactions occurred in 30% of patients who received RYBREVANT<sup>®</sup>. Serious adverse reactions in ≥2% of patients included pulmonary embolism, pneumonitis/ILD, dyspnea, musculoskeletal pain, pneumonia, and muscular weakness. Fatal adverse reactions occurred in 2 patients (1.5%) due to pneumonia and 1 patient (0.8%) due to sudden death.

# LAZCLUZE™ Drug Interactions

Avoid concomitant use of LAZCLUZE™ with strong and moderate CYP3A4 inducers. Consider an alternate concomitant medication with no potential to induce CYP3A4.

Monitor for adverse reactions associated with a CYP3A4 or BCRP substrate where minimal concentration changes may lead to serious adverse reactions, as recommended in the approved product labeling for the CYP3A4 or BCRP substrate.

Please read full **Prescribing Information** for RYBREVANT<sup>®</sup>.

Please read full **Prescribing Information** for LAZCLUZE™.

# About Johnson & Johnson

At Johnson & Johnson, we believe health is everything. Our strength in healthcare innovation empowers us to build a world where complex diseases are prevented, treated, and cured, where treatments are smarter and less invasive, and solutions are personal. Through our expertise in Innovative Medicine and MedTech, we are uniquely positioned to innovate across the full spectrum of healthcare solutions today to deliver the breakthroughs of tomorrow, and profoundly impact health for humanity. Learn more at https://www.jnj.com/ or at www.janssen.com/johnson-johnson-innovative-medicine. Follow us at @JanssenUS and @JNJInnovMed. Janssen Research & Development, LLC, and Janssen Biotech, Inc. are Johnson & Johnson companies.

# Cautions Concerning Forward-Looking Statements

This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 regarding product development and the potential benefits and treatment impact of RYBREVANT® (amivantamab-vmjw), LAZCLUZE™ (lazertinib), and TAR-200. The reader is cautioned not to rely on these forward-looking statements. These statements are based on current expectations of future events. If underlying assumptions prove inaccurate or known or unknown risks or uncertainties materialize, actual results could vary materially from the expectations and projections of Janssen Research & Development, LLC, Janssen Biotech, Inc.

and/or Johnson & Johnson. Risks and uncertainties include, but are not limited to: challenges and uncertainties inherent in product research and development, including the uncertainty of clinical success and of obtaining regulatory approvals; uncertainty of commercial success; manufacturing difficulties and delays; competition, including technological advances, new products and patents attained by competitors; challenges to patents; product efficacy or safety concerns resulting in product recalls or regulatory action; changes in behavior and spending patterns of purchasers of health care products and services; changes to applicable laws and regulations, including global health care reforms; and trends toward health care cost containment. A further list and descriptions of these risks, uncertainties and other factors can be found in Johnson & Johnson's Annual Report on Form 10-K for the fiscal year ended December 31, 2023, including in the sections captioned "Cautionary Note Regarding Forward-Looking Statements" and "Item 1A. Risk Factors," and in Johnson & Johnson's subsequent Quarterly Reports on Form 10-Q and other filings with the Securities and Exchange Commission. Copies of these filings are available online at www.sec.gov, www.jnj.com or on request from Johnson & Johnson. None of Janssen Research & Development, LLC, Janssen Biotech, Inc. nor Johnson & Johnson undertakes to update any forwardlooking statement as a result of new information or future events or developments.

<sup>1</sup> RYBREVANT® Prescribing Information. Horsham, PA: Janssen Biotech, Inc.
<sup>2</sup> Cho BC, et al. (2023). Lazertinib versus gefitinib as first-line treatment in patients with EGFR-mutated advanced non-small-cell lung cancer: Results From LASER301. J Clin Oncol. JCO2300515. Advance online publication. https://doi.org/10.1200/JCO.23.00515.

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