Johnson&Johnson

Media contacts:
Suzanne Frost
+1 416 317-0304

Brian Kenney
+1 215 620-0111

Investor contact:
Raychel Kruper
investor-relations@its.jnj.com

U.S. Medical Inquiries
+1 1 800 526-7736

For Immediate Release

Johnson & Johnson Submits Supplemental Biologics License Application and New Drug Application to U.S. FDA Seeking Approval of RYBREVANT® (amivantamab-vmjw) Plus Lazertinib for the Treatment of Patients with EGFR-Mutated Non-Small Cell Lung Cancer (NSCLC)

Submissions supported by data from landmark Phase 3 MARIPOSA study, which showed statistically significant and clinically meaningful improvement in progression-free survival in patients with EGFR-mutated advanced NSCLC treated with RYBREVANT® plus lazertinib versus osimertinib

RARITAN, New Jersey (December 21, 2023) – Johnson & Johnson announced today the submission of a supplemental Biologics License Application (sBLA) to the U.S. Food and Drug Administration (FDA) together with a New Drug Application (NDA) seeking the approval of RYBREVANT® (amivantamab-vmjw) in combination with lazertinib for the first-line treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 19 deletions or L858R substitution mutations, as detected by an FDA-approved test. Based on the Phase 3 MARIPOSA study, this marks the third submission from the RYBREVANT® clinical development program in four months, following sBLA submissions for MARIPOSA-2 and PAPILLON.

“The combination of RYBREVANT® and lazertinib demonstrated statistically significant and clinically meaningful improvement in progression-free survival compared to osimertinib in patients with previously untreated EGFR-mutated NSCLC. This remains an area of high unmet need as patients often experience treatment resistance and disease progression on currently available therapies,” said Kiran Patel, M.D., Vice President, Clinical Development, Solid Tumors, Johnson & Johnson Innovative Medicine. “We believe this targeted, chemotherapy-free regimen may have the potential to transform the treatment of EGFR-mutated NSCLC, and we look forward to working with the FDA in review of these applications.”

These applications are supported by data from the Phase 3 MARIPOSA (NCT04487080) study evaluating the efficacy and safety of RYBREVANT® in combination with lazertinib versus osimertinib and versus lazertinib alone in first-line treatment of patients with locally advanced or metastatic NSCLC with EGFR ex19del or L858R substitution mutations.[1,2] Results from the MARIPOSA study were recently presented in a Presidential Symposium at the European Society of Medical Oncology (ESMO) 2023 Congress (Abstract #LBA14).

About the MARIPOSA Study

MARIPOSA (NCT04487080), which enrolled 1,074 patients, is a randomized, Phase 3 study evaluating RYBREVANT®[1] (amivantamab-vmjw), a bispecific antibody targeting EGFR and mesenchymal-epithelial transition (MET), in combination with lazertinib, an oral, third-generation epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI), versus osimertinib and versus lazertinib alone in first-line treatment of patients with locally advanced or metastatic NSCLC with EGFR ex19del or L858R substitution mutations. The primary endpoint of the study is progression-free survival (PFS) (using RECIST* v1.1 guidelines) as assessed by blinded independent central review (BICR). Secondary endpoints include OS, ORR, DOR, second progression-free survival (PFS2) and intracranial PFS.[1]

The MARIPOSA study required all patients to have serial brain imaging with MRIs in order to detect or monitor brain metastases, a measure not implemented in most prior studies for EGFR-mutated NSCLC. The primary endpoint of PFS in MARIPOSA included these central nervous system (CNS) events detected by serial brain MRIs. Extracranial PFS, which may more closely approximate what would be seen in other trials, was also explored in MARIPOSA.

About RYBREVANT®

RYBREVANT® (amivantamab-vmjw), a fully-human bispecific antibody targeting EGFR and MET with immune cell-directing activity, received accelerated approval by the U.S. Food and Drug Administration (FDA) in May 2021 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.[2] This indication is approved under accelerated approval based on ORR and DOR. Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trials. RYBREVANT® has also received approval from health authorities in Europe as well as other markets around the world. The supplemental Biologics License Application (sBLA) Johnson & Johnson submitted to the U.S. FDA for RYBREVANT® in combination with chemotherapy (carboplatin-pemetrexed) for the first-line treatment of patients with NSCLC with EGFR exon 20 insertion mutations has been granted priority review. In October 2023, a type II extension of indication application was submitted to the European Medicines Agency (EMA) seeking approval of RYBREVANT® for this indication. In November 2023, Johnson & Johnson submitted an sBLA to the U.S. FDA for RYBREVANT® in combination with

chemotherapy for the treatment of patients with EGFR-mutated NSCLC who progressed on or after osimertinib. A type II extension of indication application was also submitted to the EMA seeking the approval of RYBREVANT® for this indication.

The NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for NSCLC‡ prefer next-generation sequencing–based strategies over polymerase chain reaction–based approaches for the detection of EGFR exon 20 insertion variants and include amivantamab-vmjw (RYBREVANT®) as a subsequent therapy option with a Category 2A recommendation for patients that have progressed on or after platinum-based chemotherapy with or without immunotherapy and have EGFR exon 20 insertion mutation-positive advanced NSCLC.[3§‖]

In addition to the Phase 3 MARIPOSA study, RYBREVANT® is being studied in multiple clinical trials in NSCLC, including:

- The Phase 3 MARIPOSA-2 (NCT04988295) study evaluating the efficacy and safety of RYBREVANT® and chemotherapy in patients with locally advanced or metastatic EGFR ex19del or L858R substitution NSCLC who had disease progression on or after treatment with osimertinib. Data for this randomized Phase 3 study presented at the ESMO 2023 Congress demonstrated statistically significant and clinically meaningful improvement in PFS in patients receiving RYBREVANT® plus chemotherapy with and without lazertinib versus chemotherapy.[4]
- The Phase 3 PAPILLON (NCT04538664) study assessing RYBREVANT® in combination with carboplatin-pemetrexed versus carboplatin-pemetrexed in the first-line treatment of patients with advanced or metastatic NSCLC with EGFR exon 20 insertion mutations. Data for this randomized Phase 3 study presented at the ESMO 2023 Congress demonstrated statistically significant and clinically meaningful improvement in PFS in patients receiving RYBREVANT® versus chemotherapy.[5]
- The Phase 1 CHRYSALIS (NCT02609776) study evaluating RYBREVANT® in participants with advanced NSCLC.[6]
- The Phase 1/1b CHRYSALIS-2 (NCT04077463) study evaluating RYBREVANT® in combination with lazertinib and lazertinib as a monotherapy in patients with advanced NSCLC with EGFR mutations.[7]
- The Phase 1 PALOMA (NCT04606381) study assessing the feasibility of subcutaneous (SC) administration of amivantamab based on safety and pharmacokinetics and to determine a dose, dose regimen and formulation for amivantamab SC delivery.[8]
- The Phase 2 PALOMA-2 (NCT05498428) study assessing subcutaneous amivantamab in participants with advanced or metastatic solid tumors including EGFR-mutated NSCLC.[9]
- The Phase 3 PALOMA-3 (NCT05388669) study assessing lazertinib with subcutaneous amivantamab compared to intravenous amivantamab in participants with EGFR-mutated advanced or metastatic NSCLC.[10]
- The Phase 1/2 METalmark (NCT05488314) study assessing RYBREVANT® and capmatinib combination therapy in locally advanced or metastatic NSCLC.[11]
- The Phase 1/2 PolyDamas (NCT05908734) study assessing RYBREVANT® and cetrelimab combination therapy in locally advanced or metastatic NSCLC.[12]
- The Phase 2 SKIPPirr study (NCT05663866) exploring how to decrease the incidence and/or severity of first-dose infusion-related reactions with RYBREVANT® in combination with lazertinib in relapsed or refractory EGFR-mutated advanced or metastatic NSCLC.[13]
- The Phase 2 COCOON study (NCT06120140) will evaluate enhanced dermatological care to reduce rash and paronychia in patients with EGFR-mutated NSCLC treated first-line with amivantamab plus lazertinib.[14]

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

About Lazertinib

In 2018, Janssen Biotech, Inc., entered into a license and collaboration agreement with Yuhan Corporation for the development of lazertinib. Lazertinib 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 lazertinib from the Phase 3 LASER301 study was published in *The Journal of Clinical Oncology* in 2023.[15]

About Non-Small Cell Lung Cancer

Worldwide, lung cancer is one of the most common cancers, with NSCLC making up 80 to 85 percent of all lung cancer cases.[16,17] The main subtypes of NSCLC are adenocarcinoma, squamous cell carcinoma, and large cell carcinoma.[18] Among the most common driver mutations in NSCLC are alterations in EGFR, which is a receptor tyrosine kinase controlling cell growth and division.[19] EGFR mutations are present in 10 to 15 percent of Western patients with NSCLC with adenocarcinoma histology and occur in 40 to 50 percent of Asian patients.[18,19,20,21,22,23] EGFR ex19del or EGFR L858R mutations are the most common EGFR mutations.[24] The five-year survival rate for all people with advanced NSCLC and EGFR mutations treated with EGFR TKIs is less than 20 percent.[25,26] Patients with EGFR ex19del or L858R mutations have a real-world five-year OS of 19 percent.[27]

RYBREVANT® IMPORTANT SAFETY INFORMATION[2]

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.

Based on the safety population, 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® as recommended. Administer RYBREVANT® via a peripheral line on Week 1 and Week 2. Monitor patients for any signs and symptoms of infusion reactions during RYBREVANT® 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® based on severity.

Interstitial Lung Disease/Pneumonitis

RYBREVANT® can cause interstitial lung disease (ILD)/pneumonitis. Based on the safety population, 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). Immediately withhold RYBREVANT® in patients with suspected ILD/pneumonitis and permanently discontinue if ILD/pneumonitis is confirmed.

Dermatologic Adverse Reactions

RYBREVANT® can cause rash (including dermatitis acneiform), pruritus and dry skin. Based on the safety population, rash occurred in 74% of patients treated with RYBREVANT®, 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® was permanently discontinued due to rash in 0.7% of patients.

Toxic epidermal necrolysis occurred in one patient (0.3%) treated with RYBREVANT®.

Instruct patients to limit sun exposure during and for 2 months after treatment with RYBREVANT®. Advise patients to wear protective clothing and use broad spectrum UVA/UVB sunscreen. Alcohol-free emollient cream is recommended for dry skin.

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. Withhold, dose reduce or permanently discontinue RYBREVANT® based on severity.

Ocular Toxicity

RYBREVANT® can cause ocular toxicity including keratitis, dry eye symptoms, conjunctival redness, blurred vision, visual impairment, ocular itching, and uveitis. Based on the safety population, 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 presenting with 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® 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 final dose of RYBREVANT®.

Adverse Reactions

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%).

Please read the full Prescribing Information for RYBREVANT®.

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 both 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) and lazertinib. 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 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; competition, including technological advances, new products and patents attained by competitors; challenges to patents; 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 January 1, 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., and Johnson & Johnson undertakes to update any forward-looking statement as a result of new information or future events or developments.

###

*RECIST (v1.1) refers to Response Evaluation Criteria in Solid Tumors, which is a standard way to measure how well solid tumors respond to treatment and is based on whether tumors shrink, stay the same or get bigger.

‡The NCCN Content does not constitute medical advice and should not be used in place of seeking professional medical advice, diagnosis or treatment by licensed practitioners. NCCN makes no representations or warranties and explicitly disclaims the appropriateness or applicability of the NCCN Content to any specific patient's care or treatment.

§See the NCCN Guidelines for detailed recommendations, including other treatment options.

‖The NCCN Guidelines for NSCLC provide recommendations for certain individual biomarkers that should be tested and recommend testing techniques but do not endorse any specific commercially available biomarker assays or commercial laboratories.

---

[1]ClinicalTrials.gov. A Study of Amivantamab and Lazertinib Combination Therapy Versus Osimertinib in Locally Advanced or Metastatic Non-Small Cell Lung Cancer (MARIPOSA). Accessed October 2023. Available at: https://classic.clinicaltrials.gov/ct2/show/NCT04487080.
[2] RYBREVANT® Prescribing Information. Horsham, PA: Johnson & Johnson Innovative Medicine.
[3] Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Non-Small Cell Lung Cancer V.3.2022.© National Comprehensive Cancer Network, Inc. 2022. All rights reserved. Accessed September 2023. To view the most recent and complete version of the guideline, go online to NCCN.org.
[4] ClinicalTrials.gov. A Study of Amivantamab and Lazertinib in Combination With Platinum-Based Chemotherapy Compared With Platinum-Based Chemotherapy in Patients With Epidermal Growth Factor Receptor (EGFR)-Mutated Locally Advanced or Metastatic Non-Small Cell Lung Cancer After Osimertinib Failure (MARIPOSA-2). Accessed October 2023. Available at: https://clinicaltrials.gov/ct2/show/NCT04988295.
[5] ClinicalTrials.gov. A Study of Combination Amivantamab and Carboplatin-Pemetrexed Therapy, Compared With Carboplatin-Pemetrexed, in Participants With Advanced or Metastatic Non-Small Cell Lung Cancer Characterized by Epidermal Growth Factor Receptor (EGFR) Exon 20 Insertions (PAPILLON). Accessed September 2023. Available at: https://clinicaltrials.gov/ct2/show/NCT04538664.
[6] ClinicalTrials.gov. A Study of Amivantamab, a Human Bispecific EGFR and cMet Antibody, in Participants With Advanced Non-Small Cell Lung Cancer (CHRYSALIS). Accessed September 2023.Available at: https://clinicaltrials.gov/ct2/show/NCT02609776.
[7] ClinicalTrials.gov. A Study of Lazertinib as Monotherapy or in Combination With Amivantamab in Participants With Advanced Non-small Cell Lung Cancer (CHRYSALIS-2). Accessed September 2023. Available at: https://clinicaltrials.gov/ct2/show/NCT04077463.
[8] ClinicalTrials.gov. A Study of Amivantamab Subcutaneous (SC) Administration for the Treatment of Advanced Solid Malignancies (PALOMA). Accessed September 2023. Available at: https://clinicaltrials.gov/ct2/show/NCT04606381.
[9] ClinicalTrials.gov. A Study of Amivantamab in Participants With Advanced or Metastatic Solid Tumors Including Epidermal Growth Factor Receptor (EGFR)-Mutated Non-Small Cell Lung Cancer (PALOMA-2). Accessed September 2023. Available at: https://clinicaltrials.gov/ct2/show/NCT05498428.
[10] ClinicalTrials.gov. A Study of Lazertinib With Subcutaneous Amivantamab Compared With Intravenous Amivantamab in Participants With Epidermal Growth Factor Receptor (EGFR)-Mutated Advanced or Metastatic Non-small Cell Lung Cancer (PALOMA-3). Available at: https://clinicaltrials.gov/ct2/show/NCT05388669. Accessed September 2023.
[11] ClinicalTrials.gov. A Study of Amivantamab and Capmatinib Combination Therapy in Unresectable Metastatic Non-small Cell Lung Cancer (METalmark). Accessed September 2023.Available at: https://clinicaltrials.gov/ct2/show/NCT05488314.
[12] ClinicalTrials.gov. A Study of Combination Therapy With Amivantamab and Cetrelimab in Participants With Metastatic Non-small Cell Lung Cancer (PolyDamas). Accessed September 2023. Available at: https://www.clinicaltrials.gov/study/NCT05908734?term=polydamas&rank=1.
[13] ClinicalTrials.gov. Premedication to Reduce Amivantamab Associated Infusion Related Reactions (SKIPPirr). Accessed September 2023. Available at: https://classic.clinicaltrials.gov/ct2/show/NCT05663866.
[14] ClinicalTrials.gov. Enhanced Dermatological Care to Reduce Rash and Paronychia in Epidermal Growth Factor Receptor (EGRF)-Mutated Non-Small Cell Lung Cancer (NSCLC) Treated First-line With Amivantamab Plus Lazertinib (COCOON). Accessed December 2023. Available at: https://clinicaltrials.gov/study/NCT06120140?term=COCOON&intr=Amivantamab&checkSpell=false&rank=1.
[15] 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. https://c212.net/c/link/?t=0&l=en&o=3957815-1&h=1674621843&u=https://doi.org/10.1200/JCO.23.00515&a=https://doi.org/10.1200/JCO.23.00515
[16] The World Health Organization. Cancer. Accessed September 2023. https://www.who.int/news-room/fact-sheets/detail/cancer.
[17] American Cancer Society. What is Lung Cancer? Accessed September 2023. https://www.cancer.org/content/cancer/en/cancer/lung-cancer/about/what-is.html.
[18] Oxnard JR, et al. Natural history and molecular characteristics of lung cancers harboring EGFR exon 20 insertions. *J Thorac Oncol*. 2013 Feb;8(2):179-84. doi: 10.1097/JTO.0b013e3182779d18.
[19] Bauml JM, et al. Underdiagnosis of EGFR Exon 20 Insertion Mutation Variants: Estimates from NGS-based Real World Datasets. Abstract presented at: World Conference on Lung Cancer Annual Meeting; January 29, 2021; Singapore.
[20] Pennell NA, et al. A phase II trial of adjuvant erlotinib in patients with resected epidermal growth factor receptor-mutant non-small cell lung cancer. *J Clin Oncol*. 37:97-104.
[21] Burnett H, et al. Epidemiological and clinical burden of EGFR exon 20 insertion in advanced non-small cell lung cancer: a systematic literature review. Abstract presented at: World Conference on Lung Cancer Annual Meeting; January 29, 2021; Singapore.
[22] Zhang YL, et al. The prevalence of EGFR mutation in patients with non-small cell lung cancer: a systematic review and meta-analysis. *Oncotarget*. 2016;7(48):78985-78993.
[23] Midha A, et al. EGFR mutation incidence in non-small-cell lung cancer of adenocarcinoma histology: a systematic review and global map by ethnicity. *Am J Cancer Res*. 2015;5(9):2892-2911.
[24] American Lung Association. EGFR and Lung Cancer. Accessed September 2023. https://www.lung.org/lung-health-diseases/lung-disease-lookup/lung-cancer/symptoms-diagnosis/biomarker-testing/egfr.
[25] Howlader N, et al. SEER Cancer Statistics Review, 1975-2016, National Cancer Institute. Bethesda, MD, https://seer.cancer.gov/csr/1975_2016/, based on November 2018 SEER data submission, posted to the SEER web site.
[26] Lin JJ, et al. Five-Year Survival in EGFR-Mutant Metastatic Lung Adenocarcinoma Treated with EGFR-TKIs. *J Thorac Oncol*. 2016 Apr;11(4):556-65.
[27] Girard N, et al. Comparative clinical outcomes for patients with NSCLC harboring EGFR exon 20 insertion mutations and common EGFR mutations. Abstract presented at: World Conference on Lung Cancer Annual Meeting; January 29, 2021; Singapore.