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MEMBERS OF THE COVID R&D ALLIANCE AND QUANTUM LEAP HEALTHCARE COLLABORATIVE ENROLL FIRST PATIENTS IN I-SPY COVID TRIAL

- *I-SPY COVID will evaluate the impact of cenicriviroc, Otezla®, and Firazyr® on inflammatory response in COVID-19 patients*
- *Additional candidates from COVID R&D member companies entering platform trials in coming weeks*

SAN FRANCISCO, CA August 3, 2020 – Today, members of the COVID R&D Alliance AbbVie, Inc. (NYSE: ABBV), Amgen Inc. (NASDAQ: AMGN), and Takeda Pharmaceutical Co. Ltd. (NYSE: TAK) announced the first patients enrolled in the I-SPY COVID Trial (Investigation of Serial Studies to Predict Your COVID Therapeutic Response with Biomarker Integration and Adaptive Learning) clinical trial. The I-SPY COVID Trial will evaluate the efficacy of cenicriviroc, a chemokine (CCR2 and CCR5) dual-receptor antagonist, Otezla® (apremilast), a PDE4 inhibitor, and Firazyr® (icatibant injection), a bradykinin B2 receptor antagonist in severely ill, hospitalized COVID-19 patients who require high-flow oxygen.

The I-SPY COVID Trial utilizes Quantum Leap Healthcare Collaborative's adaptive platform trial design, which is intended to increase trial efficiency by minimizing the number of participants and time required to evaluate potential treatments.

"Collaborative research efforts leveraging adaptive platform trials enable faster and more complete learning about what works for patients, and they are especially critical for addressing urgent public health threats like COVID-19," said Dr. Mark McClellan, director of the Robert J. Margolis, Center for Health Policy at Duke University and former commissioner of the U.S. FDA and administrator of the Centers for Medicare and Medicaid Services. "Platform trials bring down the cost and increase the ease of executing well-powered, high quality studies, especially when multiple, potential therapies need to be evaluated quickly. The I-SPY COVID Trial is expanding a timely and effective platform trial strategy to evaluate promising treatments while maintaining an appropriate level of safety and statistical rigor necessary for regulatory evaluation."

The study is a collaboration between members of the COVID R&D Alliance, Quantum Leap, and the U.S. Food and Drug Administration (FDA). AbbVie, Amgen, and Takeda are members of the COVID R&D Alliance (COVID R&D), a group of more than 20 of the world's leading

biopharmaceutical and life science companies working to speed the development of potential therapies, novel antibodies, and anti-viral therapies for COVID-19 and its related symptoms.

“Sick patients in hospitals cannot wait; options are urgently needed. I’m proud to partner with AbbVie and Amgen and the dozens of other companies who have joined the COVID R&D Alliance, to initiate critical platform trials like I-SPY COVID,” remarked Andy Plump, President of R&D at Takeda Pharmaceuticals and co-founder of the COVID R&D Alliance. “The world learned of COVID-19 only six months ago, and the speed at which the scientific community has joined forces to address the critically high unmet need is inspiring. Together, experts across our companies and industry can accelerate trials with promising, well-understood therapies that upon investigation, may show efficacy in this devastating disease.”

The therapies under investigation were selected based on their potential to impact the immune system response of COVID-19 patients who need respiratory support. Approximately 10-15 percent of patients afflicted by COVID-19 develop acute respiratory distress syndrome (ARDS), and up to 60 percent of those patients admitted to an ICU require ventilation for an average of two weeks. It is estimated that half of those patients will not survive. Based on the respective mechanisms of action, Otezla® may suppress inflammation resulting from an immune response, Firazyr® may ameliorate bradykinin-driven pulmonary edema, and cenicriviroc acts by blocking monocytes trafficking to tissues, features that may help to reduce or mitigate the severity of ARDS response in severely ill COVID-19 patients.

Dr. Laura Esserman, co-founder of Quantum Leap Healthcare Collaborative and lead investigator of the I-SPY Trials stated, “The level of cooperation among pharma companies in response to the pandemic is unprecedented. The COVID R&D Alliance stepped forward to streamline the process of identifying safe, scalable and potentially effective agents and joined with the I-SPY consortium to propel our efforts forward at record speed. We are excited to open the trial and work to reduce the devastating effects of the virus in severely ill COVID patients, and to do it now, when we need it most.”

I-SPY COVID is one of several platform studies being pursued by members of COVID R&D to test promising therapeutic candidates faster than any single company could do operating alone. Members are investigating marketed and late-stage therapies indicated for other disease states, which, based on their mechanisms of action may have a potential treatment effect in COVID-19 patients. The group is employing adaptive platform trial methodologies that enable the ability to test multiple therapies simultaneously and modify protocols in real-time based on outcomes observed.

In addition to designing and sponsoring several platform trials, the COVID R&D Alliance is:

- Evaluating more than 1,900 preclinical candidates against active controls to uncover which hold the greatest promise for COVID-19.
- Reviewing promising early-stage candidates that may show potential efficacy against COVID-19, and connecting them with potential funders from venture capital or pharmaceutical developers to enable rapid advancement.
- Working with TransCelerate’s DataCelerate® platform to enable real-time data sharing and real-world evidence to inform ongoing and future studies in COVID-19, so research communities benefit from learnings and avoid duplication.
- Operating as an interlocutor with governments, regulators, and non-governmental organizations to share insights and engage in other platform trials.

About the I-SPY COVID Trial
The I-SPY COVID Trial (Investigation of Serial Studies to Predict Your COVID Therapeutic Response with Biomarker Integration and Adaptive Learning) is an adaptive platform trial designed to increase trial efficiency by minimizing the number of participants and time required to evaluate experimental and/or repurposed drugs. The focus of the trial is to improve outcomes for severely-ill COVID-19 patients—those who require at least 6L of high-flow oxygen either by mask or nasal cannula, known as level 5 on the World Health Organization (WHO) COVID scale, an 8 point ordinal scale of clinical severity status. The primary endpoint of I-SPY COVID is time to achieve level 4 (or less) for at least 48 hours on the WHO COVID scale. Key secondary endpoints include duration of time on ventilator and mortality.

The I-SPY COVID Trial is sponsored and managed by Quantum Leap Healthcare Collaborative. For more information, visit www.quantumleaphealth.org or www.ispytrials.org.

About the COVID R&D Alliance
Organized in March 2020, the COVID R&D Alliance is operating unconstrained by past models of development and is accelerating study candidates without regard to company affiliation. Members are sharing clinical trial data and real-world evidence, as well as crowd-sourcing early stage candidates to identify mechanisms and treatments that may be effective against COVID-19. Initial efforts by the group focus on advancing well understood therapies and late-stage investigational medicines for severely ill patients who need options. Future activities will expand to testing re-purposed molecules, early stage candidates, and therapeutic drug combinations.

Additional information on the COVID R&D Alliance is available at www.CovidRDAlliance.com.

About Cenicriviroc (CVC)
CVC is an oral, once-daily, potent immunomodulator that blocks two chemokine receptors, CCR2 and CCR5, which are intricately involved in the inflammatory and fibrogenic pathways in nonalcoholic steatohepatitis (NASH) known to cause liver damage including cirrhosis, liver cancer, or liver failure. These pathways have also been shown to be closely involved with the respiratory sequelae of COVID-19 and of related viral infections. Because of CVC's unique mechanisms of action, the drug has been viewed as having a potential role in the treatment of COVID-19 patients, in addition to its potential in the management liver fibrosis due to NASH, including as a part of combination-treatment strategies. CVC has been studied in both NASH patients and in HIV+ patients, and is in Phase 3 development for NASH. CVC has been granted Fast Track status in adults with liver fibrosis due to NASH, the population at highest risk of progression to cirrhosis.

About Otezla® (apremilast)
OTEZLA® (apremilast) is an oral small-molecule inhibitor of phosphodiesterase 4 (PDE4) specific for cyclic adenosine monophosphate (cAMP). PDE4 inhibition results in increased intracellular cAMP levels, which is thought to indirectly modulate the production of inflammatory mediators. The specific mechanism(s) by which Otezla exerts its therapeutic action in patients is not well defined.

Otezla is currently approved for use in more than 45 countries as an oral treatment for inflammatory diseases including psoriasis, psoriatic arthritis and Behçet's disease. By inhibiting PDE4, Otezla is thought to modulate the production of inflammatory cytokines and other mediators, which may prove helpful in inhibiting the inflammatory response associated with the signs, symptoms and pulmonary involvements observed in some COVID-19 patients. Amgen

plans to collaborate with platform trials to investigate Otezla's ability to prevent clinical deterioration in patients with COVID-19.

Otezla® (apremilast) U.S. INDICATIONS
Otezla® (apremilast) is indicated for the treatment of adult patients with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy.

Otezla is indicated for the treatment of adult patients with active psoriatic arthritis.

Otezla is indicated for the treatment of adult patients with oral ulcers associated with Behçet's Disease.

Otezla® (apremilast) U.S. IMPORTANT SAFETY INFORMATION

Contraindications

- Otezla® (apremilast) is contraindicated in patients with a known hypersensitivity to apremilast or to any of the excipients in the formulation

Warnings and Precautions

- Diarrhea, Nausea, and Vomiting: Cases of severe diarrhea, nausea, and vomiting were associated with the use of Otezla. Most events occurred within the first few weeks of treatment. In some cases, patients were hospitalized. Patients 65 years of age or older and patients taking medications that can lead to volume depletion or hypotension may be at a higher risk of complications from severe diarrhea, nausea, or vomiting. Monitor patients who are more susceptible to complications of diarrhea or vomiting; advise patients to contact their healthcare provider. Consider Otezla dose reduction or suspension if patients develop severe diarrhea, nausea, or vomiting

- Depression: Carefully weigh the risks and benefits of treatment with Otezla for patients with a history of depression and/or suicidal thoughts/behavior, or in patients who develop such symptoms while on Otezla. Patients, caregivers, and families should be advised of the need to be alert for the emergence or worsening of depression, suicidal thoughts, or other mood changes, and they should contact their healthcare provider if such changes occur
    - Psoriasis: Treatment with Otezla is associated with an increase in depression. During clinical trials, 1.3% (12/920) of patients reported depression compared to 0.4% (2/506) on placebo. Depression was reported as serious in 0.1% (1/1308) of patients exposed to Otezla, compared to none in placebo-treated patients (0/506). Suicidal behavior was observed in 0.1% (1/1308) of patients on Otezla, compared to 0.2% (1/506) on placebo. One patient treated with Otezla attempted suicide; one patient on placebo committed suicide
    - Psoriatic Arthritis: Treatment with Otezla is associated with an increase in depression. During clinical trials, 1.0% (10/998) reported depression or depressed mood compared to 0.8% (4/495) treated with placebo. Suicidal ideation and behavior was observed in 0.2% (3/1441) of patients on Otezla, compared to none in placebo-treated patients. Depression was reported as serious in 0.2% (3/1441) of patients exposed to Otezla, compared to none in placebo-treated patients (0/495). Two patients who received placebo committed suicide compared to none on Otezla

    - Behçet's Disease: Treatment with Otezla is associated with an increase in depression. During the phase 3 clinical trial, 1% (1/104) reported depression or depressed mood compared to 1% (1/103) treated with placebo. No instances of suicidal ideation or behavior were reported in patients treated with Otezla or treated with placebo

- Weight Decrease: Monitor body weight regularly; evaluate unexplained or clinically significant weight loss, and consider discontinuation of Otezla
    - Psoriasis: During clinical trials, body weight loss of 5-10% occurred in 12% (96/784) of patients treated with Otezla and in 5% (19/382) of patients treated with placebo. Body weight loss of ≥10% occurred in 2% (16/784) of patients treated with Otezla compared to 1% (3/382) of patients treated with placebo
    - Psoriatic Arthritis: During clinical trials, body weight loss of 5-10% was reported in 10% (49/497) of patients taking Otezla and in 3.3% (16/495) of patients taking placebo
    - Behçet's Disease: During the phase 3 clinical trial, body weight loss of >5% was reported in 4.9% (5/103) of patients taking Otezla and in 3.9% (4/102) of patients taking placebo

- Drug Interactions: Apremilast exposure was decreased when Otezla was co-administered with rifampin, a strong CYP450 enzyme inducer; loss of Otezla efficacy may occur. Concomitant use of Otezla with CYP450 enzyme inducers (e.g., rifampin, phenobarbital, carbamazepine, phenytoin) is not recommended

Adverse Reactions

- Psoriasis: Adverse reactions reported in ≥5% of patients were (Otezla%, placebo%): diarrhea (17, 6), nausea (17, 7), upper respiratory tract infection (9, 6), tension headache (8, 4), and headache (6, 4)
- Psoriatic Arthritis: Adverse reactions reported in at least 2% of patients taking Otezla, that occurred at a frequency at least 1% higher than that observed in patients taking placebo, for up to 16 weeks (after the initial 5-day titration), were (Otezla%, placebo%): diarrhea (7.7, 1.6); nausea (8.9, 3.1); headache (5.9, 2.2); upper respiratory tract infection (3.9, 1.8); vomiting (3.2, 0.4); nasopharyngitis (2.6, 1.6); upper abdominal pain (2.0, 0.2)
- Behçet's Disease: Adverse reactions reported in at least ≥5% of patients taking Otezla, that occurred at a frequency at least 1% higher than that observed in patients taking placebo, for up to 12 weeks, were (Otezla%, placebo%): diarrhea (41.3, 20.4); nausea (19.2, 10.7); headache (14.4, 10.7); upper respiratory tract infection (11.5, 4.9); upper abdominal pain (8.7, 1.9); vomiting (8.7, 1.9); back pain (7.7, 5.8); viral upper respiratory tract infection (6.7, 4.9); arthralgia (5.8, 2.9)

Use in Specific Populations

- Pregnancy: Otezla has not been studied in pregnant women. Advise pregnant women of the potential risk of fetal loss. Consider pregnancy planning and prevention for females of reproductive potential. There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to Otezla during pregnancy. Information about the registry can be obtained by calling 1-877-311-8972 or visiting https://mothertobaby.org/ongoing-study/otezla/
- Lactation: There are no data on the presence of apremilast or its metabolites in human milk, the effects of apremilast on the breastfed infant, or the effects of the drug on milk

production. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for Otezla and any potential adverse effects on the breastfed child from Otezla or from the underlying maternal condition
- Renal Impairment: Otezla dosage should be reduced in patients with severe renal impairment (creatinine clearance less than 30 mL/min) for details, see Dosage and Administration, Section 2, in the Full Prescribing Information

Please click here for Otezla® Full Prescribing Information.

About Firazyr® (icatibant injection)
FIRAZYR® (icatibant injection) is a bradykinin B2 receptor antagonist indicated for the treatment of acute attacks of hereditary angioedema (HAE) in adults 18 years of age and older. Indication may vary by country. It is administered by subcutaneous injection. It is thought that icatibant may ameliorate bradykinin-driven pulmonary edema by blocking the bradykinin-2 receptors.

Firazyr® (icatibant injection) IMPORTANT SAFETY INFORMATION

Laryngeal attacks can become life threatening. **If you have an HAE attack of the throat (laryngeal attack)**, inject icatibant injection and then go to the nearest hospital emergency room right away.

The most common side effects of icatibant injection include:
- redness, bruising, swelling, warmth, burning, itching, irritation, hives, numbness, pressure, or pain at the injection site
- fever
- too much of an enzyme called transaminase in your blood
- dizziness
- nausea
- headache
- rash

These are not all of the possible side effects of icatibant injection. Tell your healthcare provider if you have any side effect that bothers you or that does not go away. You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

Tell your healthcare provider if you have any other medical conditions, if you are breastfeeding or plan to breastfeed, or if you are pregnant or planning to become pregnant. Icatibant injection has not been evaluated in pregnant or nursing women. You and your healthcare provider will decide if icatibant injection is right for you.

If your symptoms continue or come back, you may repeat your icatibant injection at least 6 hours apart. Do not use more than 3 doses of icatibant injection in a 24-hour period. Tiredness, drowsiness, and dizziness have been reported following the use of icatibant injection. If this occurs, do not drive a car, use machinery, or do anything that needs you to be alert.

Please see the full Prescribing Information**.**

About AbbVie

AbbVie's mission is to discover and deliver innovative medicines that solve serious health issues today and address the medical challenges of tomorrow. We strive to have a remarkable impact on people's lives across several key therapeutic areas: immunology, oncology, neuroscience, eye care, virology, women's health, and gastroenterology, in addition to products and services across its Allergan Aesthetics portfolio. For more information about AbbVie, please visit us at www.abbvie.com. Follow @abbvie on Twitter, Facebook, Instagram, YouTube, and LinkedIn.

Forward-Looking Statements
Some statements in this news release are, or may be considered, forward-looking statements for purposes of the Private Securities Litigation Reform Act of 1995. The words "believe," "expect," "anticipate," "project" and similar expressions, among others, generally identify forward-looking statements. AbbVie cautions that these forward-looking statements are subject to risks and uncertainties that may cause actual results to differ materially from those indicated in the forward-looking statements. Such risks and uncertainties include, but are not limited to, competition from other products, challenges to intellectual property, difficulties inherent in the research and development process, adverse litigation or government action, and changes to laws and regulations applicable to our industry. Additional information about the economic, competitive, governmental, technological and other factors that may affect AbbVie's operations is set forth in Item 1A, "Risk Factors," of AbbVie's 2019 Annual Report on Form 10-K, which has been filed with the Securities and Exchange Commission. AbbVie undertakes no obligation to release publicly any revisions to forward-looking statements as a result of subsequent events or developments, except as required by law.

About Amgen
Amgen is committed to unlocking the potential of biology for patients suffering from serious illnesses by discovering, developing, manufacturing, and delivering innovative human therapeutics. This approach begins by using tools like advanced human genetics to unravel the complexities of disease and understand the fundamentals of human biology.

Amgen focuses on areas of high unmet medical need and leverages its biologics manufacturing expertise to strive for solutions that improve health outcomes and dramatically improve people's lives. A biotechnology pioneer since 1980, Amgen has grown to be the world's largest independent biotechnology company, has reached millions of patients around the world and is developing a pipeline of medicines with breakaway potential.

For more information, visit www.amgen.com and follow us on www.twitter.com/amgen.

Amgen Forward-Looking Statements
This news release contains forward-looking statements that are based on the current expectations and beliefs of Amgen. All statements, other than statements of historical fact, are statements that could be deemed forward-looking statements, including any statements on the outcome, benefits and synergies of collaborations, or potential collaborations, with any other company, including Adaptive Biotechnologies (including statements regarding such collaboration’s, or our own, ability to discover and develop fully-human neutralizing antibodies targeting SARS-CoV-2 to potentially prevent or treat COVID-19), or the Otezla® (apremilast) acquisition, including anticipated Otezla sales growth and the timing of non-GAAP EPS accretion, as well as estimates of revenues, operating margins, capital expenditures, cash, other financial metrics, expected legal, arbitration, political, regulatory or clinical results or practices, customer and prescriber patterns or practices, reimbursement activities and outcomes, effects of pandemics or other widespread health problems such as the ongoing

COVID-19 pandemic on Amgen's business, outcomes, progress, or effects relating to studies of Otezla as a potential treatment for COVID-19, and other such estimates and results. Forward-looking statements involve significant risks and uncertainties, including those discussed below and more fully described in the Securities and Exchange Commission reports filed by Amgen, including its most recent annual report on Form 10-K and any subsequent periodic reports on Form 10-Q and current reports on Form 8-K. Unless otherwise noted, Amgen is providing this information as of the date of this news release and does not undertake any obligation to update any forward-looking statements contained in this document as a result of new information, future events or otherwise.

No forward-looking statement can be guaranteed and actual results may differ materially from those Amgen projects. Discovery or identification of new product candidates or development of new indications for existing products cannot be guaranteed and movement from concept to product is uncertain; consequently, there can be no guarantee that any particular product candidate or development of a new indication for an existing product will be successful and become a commercial product.

The scientific information discussed in this news release related to Amgen's product candidates is preliminary and investigative. Such product candidates are not approved by the U.S. Food and Drug Administration, and no conclusions can or should be drawn regarding the safety or effectiveness of the product candidates. Further, any scientific information discussed in this news release relating to new indications for Amgen's products is preliminary and investigative and is not part of the labeling approved by the U.S. Food and Drug Administration for the products. The products are not approved for the investigational use(s) discussed in this news release, and no conclusions can or should be drawn regarding the safety or effectiveness of the products for these uses.

About Takeda Pharmaceutical Company Limited
Takeda Pharmaceutical Company Limited (TSE:4502/NYSE:TAK) is a global, values-based, R&D-driven biopharmaceutical leader headquartered in Japan, committed to bringing better health and a brighter future to patients by translating science into highly-innovative medicines. Takeda focuses its R&D efforts on four therapeutic areas: Oncology, Rare Diseases, Neuroscience, and Gastroenterology (GI). We also make targeted R&D investments in Plasma-Derived Therapies and Vaccines. We are focusing on developing highly innovative medicines that contribute to making a difference in people's lives by advancing the frontier of new treatment options and leveraging our enhanced collaborative R&D engine and capabilities to create a robust, modality-diverse pipeline. Our employees are committed to improving quality of life for patients and to working with our partners in health care in approximately 80 countries.

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

Takeda Forward-Looking Statements
This press release and any materials distributed in connection with this press release may contain forward-looking statements, beliefs or opinions regarding Takeda's future business, future position and results of operations, including estimates, forecasts, targets and plans for Takeda. Without limitation, forward-looking statements often include words such as "targets", "plans", "believes", "hopes", "continues", "expects", "aims", "intends", "ensures", "will", "may", "should", "would", "could" "anticipates", "estimates", "projects" or similar expressions or the negative thereof. These forward-looking statements are based on assumptions about many important factors, including the following, which could cause actual results to differ materially from those expressed or implied by the forward-looking statements: the economic

circumstances surrounding Takeda's global business, including general economic conditions in Japan and the United States; competitive pressures and developments; changes to applicable laws and regulations; the success of or failure of product development programs; decisions of regulatory authorities and the timing thereof; fluctuations in interest and currency exchange rates; claims or concerns regarding the safety or efficacy of marketed products or product candidates; the impact of health crises, like the novel coronavirus pandemic, on Takeda and its customers and suppliers, including foreign governments in countries in which Takeda operates, or on other facets of its business; the timing and impact of post-merger integration efforts with acquired companies; the ability to divest assets that are not core to Takeda's operations and the timing of any such divestment(s); and other factors identified in Takeda's most recent Annual Report on Form 20-F and Takeda's other reports filed with the U.S. Securities and Exchange Commission, available on Takeda's website at: https://www.takeda.com/investors/reports/sec-filings/ or at www.sec.gov. Takeda does not undertake to update any of the forward-looking statements contained in this press release or any other forward-looking statements it may make, except as required by law or stock exchange rule. Past performance is not an indicator of future results and the results or statements of Takeda in this press release may not be indicative of, and are not an estimate, forecast, guarantee or projection of Takeda's future results.

About Quantum Leap Healthcare Collaborative

Quantum Leap Healthcare Collaborative is a 501(C)(3) charitable organization established in 2005 as a collaboration between medical researchers at University of California, San Francisco and Silicon Valley entrepreneurs. Our mission is to integrate high-impact research with clinical processes and systems technology, resulting in improved data management and information systems, greater access to clinical trial matching and sponsorship, and greater benefit to providers, patients, and researchers. Our goal is to improve and save lives. Quantum Leap provides operational, financial, and regulatory oversight to the I-SPY Trials. For more information, visit www.QuantumLeapHealth.org.

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