World's Leading Life Science Companies Now Enrolling COMMUNITY, A Global, Platform Trial For Hospitalized Patients With COVID-19

November 30, 2020

- A range of therapeutics will be evaluated for their potential efficacy and safety relative to the condition severity of patients hospitalized with COVID-19

- Trial sites are being established in hospitals around the world to support enrollment in communities where the virus is present

- This is the first time that industry has come together to launch an adaptive clinical trial

THOUSAND OAKS, Calif., Nov. 30, 2020 /PRNewswire/ -- Three members of the COVID R&D Alliance - Amgen Inc. (NASDAQ: AMGN), Takeda Pharmaceutical Co. Ltd. (NYSE: TAK), and UCB (Euronext BR: UCB) - today announced the first patient enrolled in the COMMUNITY Trial (COVID-19 Multiple Agents and Modulators Unified Industry Members). COMMUNITY is a randomized, double-blind, placebo-controlled, adaptive platform trial that enables an array of therapeutic candidates to be studied in hospitalized COVID-19 patients.

With worldwide COVID-19 deaths exceeding one million and a resurgence of cases globally, life science companies are working urgently to identify treatments that can potentially reduce clinical severity of COVID-19 in hospitalized patients. COMMUNITY is the first platform trial designed and launched by members of the COVID R&D Alliance, a group of more than 20 leading pharmaceutical and biotech companies who are devoting significant time, insights and company resources to speed the development of potential therapies, novel antibodies, and anti-viral therapies for COVID-19 and its related symptoms.

"As this insidious virus rapidly spreads around the globe, doctors need options to treat hospitalized patients who are actively sick and experiencing a range of symptoms as the disease progresses," said David M. Reese, M.D., Executive Vice President Research & Development, Amgen. "Working hand-in-hand with our peers, we hope to find options that could potentially save lives of the patients who will need treatments for COVID-19 before widespread availability of a vaccine."

COMMUNITY uses an adaptive design which allows for the addition, removal and simultaneous study of multiple therapeutic candidates during the course of the trial. Multiple candidates will be tested against a shared placebo-controlled arm. The design allows for a streamlined approach which may accelerate execution of the study and save time as we search for therapeutics in the fight against the pandemic. Immunomodulating therapies will be the first candidates to enter COMMUNITY. Other therapies may join in the future, such as antivirals.

The trial's design and global footprint were selected to address potential barriers in the study of COVID-19 therapeutics. This includes anticipating and activating trial sites to align with the rise and fall of COVID cases across geographic regions as well as streamlining an influx in trial-related inquiries faced by some hospitals and health systems. COMMUNITY will onboard global sites in the United States, Brazil, Mexico, Russia, South Africa and other countries. This geographic diversity will allow the trial sites to be active when cases spike locally. COMMUNITY aims to simplify the study of investigational therapies that may result in potential treatment options and address the needs of hospitals in treating patients.

"COVID is not confined to one country, making it imperative that we share the challenges, successes and insights in real-time," said Dhavalkumar Patel, Executive Vice President and Chief Scientific Officer, UCB. "By sharing our expertise and resources, we hope to arm care teams with promising investigational therapies to help patients who cannot wait."

Uncontrolled vascular and immune inflammatory responses have proven to be hallmark symptoms in patients facing severe COVID-19 infections. These patients may face increased risk of acute respiratory distress syndrome (ARDS), stroke and death. Initial therapies entering into COMMUNITY were selected based upon their potential to suppress or control the immune response or the resulting inflammation. None of these therapies have been approved by the FDA, EMA, or other health authorities for the treatment of COVID-19 or its symptoms and are still investigational. These include:

- Amgen's OTEZLA® (apremilast), which may suppress immune response inflammation;
- Takeda's investigational intravenous administration of lanadelumab, which modulates the kallikrein-kinin system and suppresses production of bradykinin, potentially lessening inflammation;
- UCB's zilucoplan, an investigational medicine that may reduce overactivation of the immune system that contributes to ARDS.

OTEZLA entered COMMUNITY this week. It is expected lanadelumab and zilucoplan will enter in the coming weeks. Other anti-viral, immunomodulating and vascular agents may enter in the coming months.

COMMUNITY is studying hospitalized COVID-19 patients. This includes confirmed COVID-19 patients who may require either ongoing medical care, supplemental oxygen, noninvasive ventilation or high-flow oxygen devices, or invasive mechanical ventilation or extracorporeal membrane oxygenation (ECMO). By enrolling both hospitalized Intensive Care Unit and non-Intensive Care Unit patients, the trial seeks to yield greater

understanding of how therapeutic interventions may be used with hospitalized COVID-19 patients experiencing a range of symptoms.

About COMMUNITY
COMMUNITY is an adaptive, randomized, double-blind, placebo-controlled platform study designed to assess multiple candidates as a potential treatment for hospitalized patients with COVID-19, a disease caused by severe acute respiratory syndrome coronavirus 2 (SARS CoV 2). The focus of the trial is to identify an effective treatment(s) for hospitalized COVID-19 patients, who are Grade 2 to Grade 5 on a Clinical Severity Status 8-Point Ordinal Scale.

The primary endpoint of COMMUNITY is time to confirmed clinical recovery without being re-hospitalized through Day 29 based on the clinical severity status scale, which is defined as achieving a score of 6, 7, or 8. Key secondary endpoints are oxygen-free recovery, improvement from baseline or fit for discharge from baseline, and all-cause mortality.

Patients will be randomized equally to either the candidate agent plus the standard of care or a placebo plus standard of care in a double-blind fashion. Patients who are randomized to placebo plus standard of care will be subsequently randomized equally to a matching placebo corresponding to an available agent.

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 the 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 hospitalized patients who need treatment options. Activities are testing re-purposed molecules and early stage candidates. Member companies have 40 trials expected to have findings in the coming months.

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

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 50 countries as an oral treatment for inflammatory diseases such as psoriasis and psoriatic arthritis. 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 in treatment of hospitalized COVID-19 patients.

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 lanadelumab

Lanadelumab is a fully human monoclonal antibody that specifically binds and inhibits plasma kallikrein activity. Lanadelumab is produced in Chinese Hamster Ovary (CHO) cells by recombinant DNA technology.

Based on its mechanism of action, lanadelumab may prevent the pro-inflammatory effects of SARS-COV2 and the extravasation and accumulation of fluid within the lungs during a serious and prolonged COVID-19 illness by decreasing plasma kallikrein activity and regulating excess bradykinin signaling. In addition, lanadelumab-induced plasma kallikrein inhibition may help to reduce inflammation and coagulation driven by FXII, which is activated by plasma kallikrein through a positive feedback loop. An investigational intravenous administration of lanadelumab is being studied.

Lanadelumab (marketed under the tradename TAKHZYRO®) is approved as a subcutaneous formulation for prophylaxis to prevent attacks of hereditary angioedema (HAE) in patients ≥12 years of age.

U.S. INDICATION AND IMPORTANT SAFETY INFORMATION
INDICATION
TAKHZYRO (lanadelumab-flyo) is indicated for prophylaxis to prevent attacks of hereditary angioedema (HAE) in patients ≥12 years of age.

IMPORTANT SAFETY INFORMATION
Hypersensitivity reactions have been observed. In case of a severe hypersensitivity reaction, discontinue TAKHZYRO administration and institute appropriate treatment.

Adverse Reactions: The most commonly observed adverse reactions (≥10% and higher than placebo) associated with TAKHZYRO were injection site reactions consisting mainly of pain, erythema, and bruising at the injection site; upper respiratory infection; headache; rash; myalgia; dizziness; and diarrhea. Less common adverse reactions observed included elevated levels of transaminases; one patient discontinued the trial for elevated transaminases.

Use in Specific Populations: The safety and efficacy of TAKHZYRO in pediatric patients <12 years of age have not been established.
No data are available on TAKHZYRO in pregnant women. No data are available on the presence of lanadelumab in human milk or its effects on breastfed infants or milk production.

To report SUSPECTED ADVERSE REACTIONS, contact Dyax Corp., a Takeda company, at 1-800-828-2088, or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

For U.S. audiences, please see the full Prescribing Information including Patient Information for TAKHZYRO®.

About Zilucoplan
Zilucoplan, an investigational drug product, is a once-daily self-administered, subcutaneous peptide inhibitor of C5 which is in Phase III development for the treatment of generalized Myasthenia Gravis (gMG). Zilucoplan is also being investigated in immune-mediated necrotizing myopathy (IMNM), amyotrophic lateral sclerosis (ALS) and other tissue-based complement-mediated disorders. Zilucoplan has not been approved by any regulatory authority for any indication.

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 BeiGene, Ltd. or any collaboration or potential collaboration in pursuit of therapeutic antibodies against COVID-19 (including statements regarding such collaboration's, or our own, ability to discover and develop fully-human neutralizing antibodies targeting SARS-CoV-2 or antibodies against targets other than the SARS-CoV-2 receptor binding domain, and/or to produce any such antibodies 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 UCB
UCB (www.ucb.com) is a global biopharmaceutical company focused on the discovery and development of innovative medicines and solutions to transform the lives of people living with severe diseases of the immune system or of the central nervous system. With 7,600 people in approximately 40 countries, the company generated revenue of €4.9 billion in 2019. UCB is listed on Euronext Brussels (symbol: UCB).

UCB Forward-Looking Statements

This press release contains forward-looking statements based on current plans, estimates and beliefs of management. All statements, other than statements of historical fact, are statements that could be deemed forward-looking statements, including estimates of revenues, operating margins, capital expenditures, cash, other financial information, expected legal, political, regulatory or clinical results and other such estimates and results. By their nature, such forward-looking statements are not guarantees of future performance and are subject to risks, uncertainties and assumptions which could cause actual results to differ materially from those that may be implied by such forward-looking statements contained in this press release. Important factors that could result in such differences include: changes in general economic, business and competitive conditions, the inability to obtain necessary regulatory approvals or to obtain them on acceptable terms, costs associated with research and development, changes in the prospects for products in the pipeline or under development by UCB, effects of future judicial decisions or governmental investigations, product liability claims, challenges to patent protection for products or product candidates, changes in laws or regulations, exchange rate fluctuations, changes or uncertainties in tax laws or the administration of such laws and hiring and retention of its employees.

Additionally, information contained in this document shall not constitute an offer to sell or the solicitation of an offer to buy any securities, nor shall there be any offer, solicitation or sale of securities in any jurisdiction in which such offer, solicitation or sale would be unlawful prior to the registration or qualification under the securities laws of such jurisdiction. UCB is providing this information as of the date of this document and expressly disclaims any duty to update any information contained in this press release, either to confirm the actual results or to report a change in its expectations.

There is no guarantee that new product candidates in the pipeline will progress to product approval or that new indications for existing products will be developed and approved. Products or potential products which are the subject of partnerships, joint ventures or licensing collaborations may be subject to differences between the partners. Also, UCB or others could discover safety, side effects or manufacturing problems with its products after they are marketed.

Moreover, sales may be impacted by international and domestic trends toward managed care and health care cost containment and the reimbursement policies imposed by third-party payers as well as legislation affecting biopharmaceutical pricing and reimbursement.

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SOURCE COVID R&D Alliance

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