Data from ACTT-2 Trial of Baricitinib in Hospitalized COVID-19 Patients Supportive of the EUA Published in New England Journal of Medicine

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INDIANAPOLIS, Dec. 11, 2020 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) and Incyte (NASDAQ: INCY) announced today that *The New England Journal of Medicine* has published peer-reviewed results from the Adaptive COVID-19 Treatment Trial (ACTT-2) sponsored by the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH). The Phase 3 study included 1,033 patients from 67 trial sites in eight countries. These results support the emergency use authorization (EUA) issued by the U.S. Food and Drug Administration (FDA) on Nov. 19 for baricitinib in combination with remdesivir in hospitalized patients with COVID-19 requiring supplemental oxygen.

"These published data from a rigorous, double-blind, placebo-controlled trial are critical in helping the scientific community make better-informed treatment decisions to improve clinical outcomes for patients," said Andre Kalil, M.D., professor at the University of Nebraska Medical Center, a principal investigator of the ACTT studies and lead study author of the ACTT-2 *New England Journal of Medicine* manuscript. "Results of this study demonstrated baricitinib in combination with remdesivir provided a faster median recovery time and reduced progression to ventilation or death compared to remdesivir alone in hospitalized COVID-19 patients on oxygen."

"Presently, there are limited published placebo-controlled data assessing treatment options to manage the symptoms and progression of COVID-19," said Anabela Cardoso, M.D., an author of the *New England Journal of Medicine* paper and Lilly global brand development lead, immunology. "We need high-quality research such as the ACTT-2 study to evaluate therapies to fight this pandemic and are pleased that this medicine is now available for patients under EUA."

Read the full NIAID press release on ACTT-2 results here.

Baricitinib, an oral JAK inhibitor, was discovered by Incyte and licensed to Lilly. Please see below for important warnings and information about the authorized use of baricitinib in the U.S. In the U.S., baricitinib has not been approved by the FDA to treat COVID-19, and the efficacy, safety and optimal duration of treatment of baricitinib for COVID-19 has not been established.

For information on the authorized use of baricitinib and mandatory requirements under the EUA, please review the FDA Letter of Authorization, Fact Sheet for Healthcare Providers and Fact Sheet for Patients, Parents and Caregivers (English; Spanish).

Authorized Use Under the EUA and Important Safety Information for baricitinib (in the United States) for COVID-19

Baricitinib is authorized for use under an Emergency Use Authorization (EUA) in combination with remdesivir, for treatment of suspected or laboratory confirmed coronavirus disease 2019 (COVID-19) in hospitalized adults and pediatric patients 2 years of age or older, requiring supplemental oxygen, invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO).

Baricitinib has not been approved for the treatment of COVID-19, but has been authorized for emergency use by the FDA. Baricitinib is authorized under an EUA only for the duration of the declaration that circumstances exist justifying the authorization of the EUA of baricitinib under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

Important Safety Information about baricitinib for COVID-19
The following provides essential safety information on the unapproved use of baricitinib under the Emergency Use Authorization.

Warnings

Serious Infections: Serious infections have occurred in patients receiving baricitinib. Avoid the use of baricitinib with known active tuberculosis. Consider if the potential benefits outweigh the potential risks of baricitinib treatment in patients with active serious infections other than COVID-19 or chronic/recurrent infections.

Thrombosis: In hospitalized patients with COVID-19, prophylaxis for venous thromboembolism is recommended unless contraindicated. If clinical features of deep vein thrombosis or pulmonary embolism occur, patients should be evaluated promptly and treated appropriately.

Abnormal Laboratory Values: Evaluate at baseline and thereafter according to local patient management practice. Monitor closely when treating patients with abnormal baseline and post-baseline laboratory values. Follow dose adjustments as recommended in the Fact Sheet for Healthcare Providers for patients with abnormal renal, hematological and hepatic laboratory values. Manage patients according to routine clinical guidelines.

Hypersensitivity: If a serious hypersensitivity occurs, discontinue baricitinib while evaluating the potential causes of the reaction.

See **Warnings and Precautions** in the FDA-approved full Prescribing Information for additional information on risks associated with longer-term treatment with baricitinib.

Serious Side Effects: Serious venous thrombosis, including pulmonary embolism, and serious infections have been observed in COVID-19 patients treated with baricitinib and are known adverse drug reactions of baricitinib.

There are limited clinical data available for baricitinib use in coronavirus 2019 (COVID-19). Additional information regarding baricitinib for its FDA-approved indication, including safety information, may be found in the full Prescribing Information, including Boxed Warning about Serious Infections, Malignancies, and Thrombosis, and Medication Guide.

Use in Specific Populations

Pregnancy: Baricitinib should be used during pregnancy only if the potential benefit justifies the potential risk for the mother and the fetus.

Renal Impairment: There are limited data for baricitinib in patients with severe renal impairment. Baricitinib is not recommended for patients who are on dialysis, have end-stage renal disease, or have acute kidney injury.

Hepatic Impairment: Baricitinib has not been studied in patients with severe hepatic impairment. Baricitinib should only be used in patients with severe hepatic impairment if the potential benefit outweighs the potential risk.

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About Lilly's COVID-19 Efforts

Lilly is bringing the full force of its scientific and medical expertise to attack the coronavirus pandemic around the world. Existing Lilly medicines are now being studied to understand their potential in treating complications of COVID-19, and the company is collaborating with two partner companies to discover novel antibody treatments for COVID-19. Lilly is testing both single antibody therapy as well as combinations of antibodies as potential therapeutics for COVID-19. Click here for resources related to Lilly's COVID-19 efforts and here for baricitinib's EUA.

About baricitinib (OLUMIANT ®)

OLUMIANT is a once-daily, oral JAK inhibitor approved in the U.S. and more than 70 countries as a treatment for adults with moderate to severe rheumatoid arthritis (RA) and was recently approved in the European Union for the treatment of adult patients with moderate to severe atopic dermatitis who are candidates for systemic therapy. The U.S. FDA-approved labeling for Olumiant includes a Boxed Warning for Serious Infections, Malignancy, and Thrombosis. See the full Prescribing Information here.

In December 2009, Lilly and Incyte announced an exclusive worldwide license and collaboration agreement for the development and commercialization of baricitinib and certain follow-on compounds for patients with inflammatory and autoimmune diseases.

About Eli Lilly and Company

Lilly is a global health care leader that unites caring with discovery to create medicines that make life better for people around the world. We were founded more than a century ago by a man committed to creating high-quality medicines that meet real needs, and today we remain true to that mission in all our work. Across the globe, Lilly employees work to discover and bring life-changing medicines to those who need them, improve the understanding and management of disease, and give back to communities through philanthropy and volunteerism. To learn more about Lilly, please visit us at lilly.com and lilly.com/newsroom. P-LLY

About Incyte

Incyte is a Wilmington, Delaware-based, global biopharmaceutical company focused on finding solutions for serious unmet medical needs through the discovery, development and commercialization of proprietary therapeutics. For additional information on Incyte, please visit Incyte.com and follow @Incyte.

Cautionary Statement Regarding Forward-Looking Statements

This press release contains forward-looking statements (as that term is defined in the Private Securities Litigation Reform Act of 1995) about OLUMIANT (baricitinib) as a potential treatment for patients with COVID-19 and as a treatment for patients with rheumatoid arthritis and other conditions, as well as its supply, and reflects Lilly's and Incyte's current beliefs and expectations. However, as with any such undertaking there are substantial risks and uncertainties in the process of drug development and commercialization. Among other things, there can be no guarantee that OLUMIANT will receive additional regulatory approvals or authorizations or be commercially successful, that we can provide an adequate supply of OLUMIANT in all circumstances, or that OLUMIANT will be safe and effective as a treatment for COVID-19. For further discussion of these and other risks and uncertainties, see Lilly's and Incyte's most recent respective Form 10-K and Form 10-Q filings with the United States Securities and Exchange Commission. Except as required by law, Lilly and Incyte undertake no duty to update forward-looking statements to reflect events after the date of this release.

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