PRESS RELEASE

Chiesi USA Announces New Publication of Post Hoc Analysis on Timing of Ischemic Events in Cardiac Patients and Role of KENGREAL® (cangrelor) in Reducing Risk

- Post hoc analysis of the CHAMPION PHOENIX clinical trial demonstrates that the majority of ischemic events occurred early in percutaneous coronary intervention (PCI), and KENGREAL® (cangrelor) treatment significantly reduced these events in the first two hours post-randomization compared to clopidogrel (4.1% vs 5.4%, p=0.002)

Cary, North Carolina, January 25, 2022 – Chiesi USA (key-ay-zee), the U.S. affiliate of Chiesi Farmaceutici, an international research-focused healthcare Group (Chiesi Group), today announced the new publication of a post hoc analysis of the CHAMPION PHOENIX clinical trial that evaluated the timing, number and type of early cardiovascular events that occurred with treatment of KENGREAL® (cangrelor) compared to clopidogrel in patients undergoing PCI. The analysis is published in *Circulation: Cardiovascular Interventions*, a journal of the American Heart Association, and can be accessed here. The overall trial results of CHAMPION PHOENIX showing a significant benefit in the primary endpoint and key secondary endpoint were previously published in the *New England Journal of Medicine* and can be accessed here.

Patients undergoing PCI are at risk of thrombotic complications. KENGREAL is the only intravenous $P2Y_{12}$ platelet inhibitor indicated as an adjunct to PCI to reduce the risk of periprocedural myocardial infarction (MI), repeat coronary revascularization, and stent thrombosis (ST) in patients who have not been treated with a $P2Y_{12}$ platelet inhibitor and are not being given a glycoprotein IIb/IIIa inhibitor.

The current post hoc analysis found that in the first two hours post-randomization, KENGREAL significantly decreased the primary composite endpoint of death, MI, ischemia-driven revascularization (IDR) or ST by 25% when compared with clopidogrel (4.1% vs 5.4%; hazard ratio, 0.76 [95% CI, 0.64–0.90], p=0.002). Similar findings were seen when evaluating the secondary composite endpoint of death, Society of Coronary Angiography and Intervention (SCAI)-defined MI, IDR, or Academic Research Consortium (ARC)-defined ST at two hours (0.9% vs. 1.6%; hazard ratio 0.57 [95% CI, 0.40–0.80], p=0.001). There was no rebound increase in cardiovascular events during the time period in which patients were transitioned from KENGREAL to an oral $P2Y_{12}$ inhibitor.

The majority of cardiovascular events (63%) as defined within the secondary composite endpoint occurred within two hours after randomization, supporting prior findings of the increased risk of ischemic events in the early time period around PCI. The most common early event was SCAI-MI (44%), followed by ARC-ST (7%), IDR (7%) and death (5%).

"These data add to the main results as well as multiple prior analyses from CHAMPION PHOENIX demonstrating the efficacy of cangrelor in reducing important ischemic events, in particular in the early period of PCI when patients are at the highest risk of complications," stated study co-chair Deepak L. Bhatt, MD, MPH, Executive Director of Interventional Cardiovascular Programs at Brigham and Women's Hospital and Professor of Medicine at Harvard Medical School. "These results further strengthen the case for using cangrelor in appropriate PCI patients," added study co-chair Robert A. Harrington, MD, Chairman of Medicine and Arthur L. Bloomfield Professor of Medicine at Stanford University.

"These results demonstrate the importance of potent platelet inhibition during this critical window of treatment," said Martin Marciniak, Vice President and Head of U.S. Medical Affairs at Chiesi. "We are thankful for the contributions of everyone who participated in this valuable analysis, and we're committed to supporting advancements in interventional cardiology to improve care for cardiac patients."

CHAMPION PHOENIX was a randomized, double-blind, placebo-controlled phase III trial part of a clinical development program that established the efficacy and safety of KENGREAL. The trial consisted of 11,145 patients undergoing either urgent or elective PCI and were receiving guideline-recommended therapy. Patients being treated with KENGREAL received a bolus followed by an infusion for two hours or for the duration of the procedure, whichever was longer. Patients received a loading dose of 600mg or 300mg of clopidogrel at the end of the infusion. The trial found that KENGREAL reduced the primary composite endpoint of death, MI, IDR, or ST at 48 hours in patients undergoing PCI, as well as the key secondary endpoint of ST.

This analysis presents findings that supplement the predefined, primary result of the CHAMPION PHOENIX trial. The CHAMPION PHOENIX trial was not designed to examine the impact of KENGREAL versus clopidogrel in the first two hours post-randomization. This analysis also characterizes a post hoc secondary composite endpoint described earlier that was not part of the original trial design.

Treatment protocols should account for individualization of care as KENGREAL may not be appropriate for some patients.

Indication

KENGREAL® (cangrelor) for Injection is a $P2Y_{12}$ platelet inhibitor indicated as an adjunct to percutaneous coronary intervention (PCI) to reduce the risk of periprocedural myocardial infarction (MI), repeat coronary revascularization, and stent thrombosis (ST) in patients who have not been treated with a $P2Y_{12}$ platelet inhibitor and are not being given a glycoprotein IIb/IIIa inhibitor.

Important Safety Information

KENGREAL® (cangrelor) for Injection is contraindicated in patients with significant active bleeding.

KENGREAL® is contraindicated in patients with known hypersensitivity (e.g., anaphylaxis) to cangrelor or any component of the product.

Drugs that inhibit platelet $P2Y_{12}$ function, including KENGREAL®, increase the risk of bleeding. In CHAMPION PHOENIX, bleeding events of all severities were more common with KENGREAL® than with clopidogrel. Bleeding complications with KENGREAL® were consistent across a variety of clinically important subgroups. Once KENGREAL® is discontinued, there is no antiplatelet effect after an hour.

The most common adverse reaction is bleeding.

Please see Full Prescribing Information.

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About Chiesi USA

Chiesi USA, Inc., headquartered in Cary, North Carolina, is a specialty pharmaceutical company focused on commercialization of products for the hospital and target office-based specialties. The Company is a wholly-owned subsidiary of family-owned Chiesi Farmaceutici S.p.A, a global R&D-focused pharmaceutical company based in Parma, Italy. In the United States, the Company delivers therapies and enhances care for patients in the areas of acute cardiology, neonatology and cystic fibrosis. Recognized as a Certified B Corporation™, Chiesi is dedicated to improving the health and well-being of its communities through its employee-led corporate social responsibility program, Chiesi in the Community. Innovation, collaboration and impact are the cornerstones of the Chiesi culture. For more information, visit www.chiesiusa.com.

About Chiesi Group

Based in Parma, Italy, Chiesi is an international research-focused pharmaceuticals and healthcare group with over 85 years' experience, operating in 30 countries with more than 6,000 employees (Chiesi Group). To achieve its mission of improving people's quality of life by acting responsibly towards society and the environment, the Group researches, develops and markets innovative therapeutic solutions in its three focus areas: AIR (products and services that promote respiration, from new-born to adult populations), RARE (treatment for patients with rare and ultra-rare diseases) and CARE

(products and services that support specialty care and consumer-facing self-care). The Group's Research and Development center is based in Parma and works alongside 6 other important research and development hubs in France, the U.S., Canada, China, the UK and Sweden to pursue its pre-clinical, clinical and regulatory programs. Chiesi, since 2019, is the world's largest B Corp certified pharmaceutical group. The global B Corp movement promotes business as a force for good. Moreover, Chiesi Farmaceutici S.p.A. has changed in 2018 its legal status to a Benefit Corporation, by incorporating a double purpose for the creation of shared value, and to generate value for its business, for society and the environment. As a Benefit Corporation, Chiesi Farmaceutici S.p.A. is required by law to include objectives of common benefit in its bylaws and to report annually in a transparent way. The Group is committed to becoming carbon neutral by the end of 2035.

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