Lilly's Pain Clinical Trial Protocol Selected for FDA Complex Innovative Trial Designs Pilot Meeting Program

September 5, 2019

INDIANAPOLIS, Sept. 5, 2019 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) today announced the U.S. Food and Drug Administration (FDA) has accepted its application to enter the Complex Innovative Trial Designs (CID) Pilot Meeting Program, an initiative which aims to further modernize drug development, improve efficiency, and promote innovation. Lilly's proposed program involves a master protocol for the development of novel approaches to the treatment of multiple types of chronic pain, one of the largest unmet medical needs in the United States.

"Lilly is committed to advancing medical and regulatory science to address the public health challenge of unresolved pain," said Carl Garner, Ph.D., vice president of regulatory affairs at Lilly. "Through the CID program and our partnership with the FDA, we aim to not only drive novel approaches to the research and development of new treatments for one of today's highest areas of unmet need in healthcare, but also improve and inform the efficiency and speed of developing new medicines across all disease areas."

The CID program is an initiative under the 21st Century Cures Act, as well as a performance goal agreed to under the Prescription Drug User Fee Act VI. The program supports the goal of facilitating and advancing the use of complex adaptive, Bayesian, and other novel clinical trial designs. The FDA considers several factors when selecting qualifying programs, including the level of innovation of the trial design, and the therapeutic need.

"Lilly is excited to partner with the FDA on this innovative trial which will evaluate multiple interventions in several chronic pain conditions via one streamlined clinical protocol," commented Karen Price, Ph.D., senior research advisor, Statistical Innovation Center at Lilly. "This design will enable both statistical advances and operational efficiencies, facilitating faster evaluation of potential solutions. The learning from this CID will contribute to broader utilization of the innovative statistical approaches required for these types of designs."

About Chronic Pain
Chronic pain, defined as pain persisting for 3 to 6 months or more, affects around 20 percent of the population, and is one of the most frequent reasons for seeking medical care.[1] It accounts for 15 to 20 percent of all physician visits[1], and causes an estimated $560 to $635 billion burden in direct and indirect costs.[2] Chronic pain causes substantial limitations in general activity and daily living, and it affects social and family interactions, and causes severe work restrictions.[3]

"Chronic pain poses unique scientific, medical and social problems, and Lilly is dedicated to collaborating with regulatory agencies, physicians, and patient advocacy groups across the healthcare ecosystem in order to help address these problems," commented Mark Mintun, M.D., vice president of pain and neurodegeneration research at Lilly. "Real solutions will depend on a holistic transformation in the way we investigate these new medicines in clinical trials, and we are excited about our participation in the CID program as one way to accelerate this research to enable better treatment options for patients."

About Eli Lilly and Company
Lilly is a global healthcare leader that unites caring with discovery to 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 www.lilly.com and www.lilly.com/newsroom. P-LLY

[1] Treede et al. 2015
[2] Aronoff 2016
[3] Von Korff et al. 2016

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