Gilead Announces Phase 1 Data for Investigational Therapy, GS-6615, in Patients with Long QT-3 Syndrome

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Data Presented at Heart Rhythm 2014 Support Plans for Phase 2 Clinical Trial in LQT3 Patients

SAN FRANCISCO--(BUSINESS WIRE)--May 9, 2014-- Gilead Sciences, Inc. (Nasdaq: GILD) today announced results from a Phase 1 clinical trial (GS-US-279-0110) of GS-6615, an investigational, selective late sodium current inhibitor, showing a shortening of the QTc interval (the time interval between the start of the Q-wave and end of the T-wave in the heart's electrical cycle) in patients with long QT-3 (LQT3) syndrome. LQT3 is a genetic disorder that prolongs the heart's QTc interval and can cause life-threatening cardiac arrhythmias (abnormal heartbeats). Results from this study (Abstract #AB34-05) will be presented today in San Francisco at the annual meeting of the Heart Rhythm Society.

The congenital long QT syndromes (LQTS) are a group of inherited disorders that affect the heart's electrical system and are characterized by irregular or rapid heartbeats that can lead to syncope (fainting), cardiac arrest or sudden cardiac death. Normal QTc intervals range from 380-460 milliseconds (ms) and LQTS patients typically have a QTc above 470 ms. LQTS symptoms can occur during strenuous exercise, emotional stimulation or sleep. The most common types are LQT1, LQT2 and LQT3. LQT3 is linked to a mutation in the gene encoding the cardiac sodium channel (SCN5A). Currently, there are no approved medications for patients with LQT3.

"Over the last several decades, knowledge about LQTS has increased greatly, including our understanding of genetics associated with different forms of the disease," said Arthur J. Moss, MD, Professor of Cardiology, Department of Medicine, University of Rochester Medical Center, Rochester, NY. "A key example of this progress is the discovery that LQT3 is caused by SC5NA mutations in cardiac sodium channels. Discoveries such as this have helped enable the discovery and development of much-needed novel therapies for patients with this life-threatening disease."

In this study, ten LQT3 patients were evaluated at the Clinical Research Center at the University of Rochester, where they received single oral doses of GS-6615 ranging from 10 mg to 60 mg. The study enrolled patients with a QTc above 480 ms. The QTc pre-dose (Day -1) was compared to QTc on drug (Day 1) during time-matched 12-hour periods. In the study, QTc shortening was observed at all dose levels, with maximal QTc shortening ranging from -44 ms to -80 ms. No safety concerns were observed during administration with GS-6615.

"QTc shortening observed in this study provides clinical evidence suggesting that GS-6615 is an inhibitor of the late sodium current with the potential to play an important role in the treatment of patients with LQT3," said Wojciech Zareba, MD, PhD, lead investigator for the Phase 1 GS-6615 study and Professor of Medicine, Director of Cardiology Clinical Research and Director of the Heart Research Follow-Up Program at University of Rochester Medical Center.

Based on these results, Gilead plans to initiate a Phase 2 study of GS-6615 in LQT3 patients later this year. Additionally, based on pre-clinical data for GS-6615 and clinical data involving the role of late sodium current inhibition in other cardiovascular diseases, Gilead plans to initiate Phase 2 clinical trials in patients with hypertrophic cardiomyopathy (HCM) and ventricular tachycardia and ventricular fibrillation (VT/VF).

About GS-6615

GS-6615 is a potent and selective inhibitor of the cardiac late sodium current, which is associated with various genetic and acquired cardiovascular disorders, including long QT-3 (LQT3) syndrome, hypertrophic cardiomyopathy (HCM) and ventricular tachycardia and ventricular fibrillation (VT/VF).

GS-6615 is an investigational product and its safety and efficacy have not been established.

About Gilead Sciences

Gilead Sciences is a biopharmaceutical company that discovers, develops and commercializes innovative therapeutics in areas of unmet medical need. The company's mission is to advance the care of patients suffering from life-threatening diseases worldwide. Headquartered in Foster City, California, Gilead has operations in North and South America, Europe and Asia Pacific.

Forward-Looking Statement

This press release includes forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 that are subject to risks, uncertainties and other factors, including the possibility of unfavorable results from additional clinical trials involving GS-6615 in patients with LQT3, HCM and/or VT/VF. In addition, Gilead may be unable to initiate the Phase 2 trials in the currently anticipated timelines, may be unable to enroll patients in the studies and may need to modify or delay these studies. Further, Gilead may make a strategic decision to discontinue development of GS-6615 if, for example, Gilead believes commercialization will be difficult relative to other opportunities in its pipeline. As a result, GS-6615 may never be commercialized. These risks, uncertainties and other factors could cause actual results to differ materially from those referred to in the forward-looking statements. The reader is cautioned not to rely on these forward-looking statements. These and other risks are described in detail in Gilead's Quarterly Report on Form 10-Q for the quarter ended March 31, 2014, as filed with the U.S. Securities and Exchange Commission. All forward-looking statements are based on information currently available to Gilead, and Gilead assumes no obligation to update any such forward-looking statements.

For more information on Gilead Sciences, please visit the company's website at www.gilead.com, follow Gilead on Twitter (@GileadSciences) or call Gilead Public Affairs at 1-800-GILEAD-5 or 1-650-574-3000.

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