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Janssen Collaborates with Premier Inc. on Unique Study to Improve Stroke Risk Management among Hospitalized Patients with Atrial Fibrillation

The QUANTUM AF study will evaluate the impact of a hospital quality improvement program on the use of new guidelines to treat patients with atrial fibrillation (AF) at risk for ischemic stroke

TITUSVILLE, N.J., April 3, 2017 – Janssen Pharmaceuticals, Inc. (Janssen) today announced it has collaborated with Premier Inc. on the first and largest study of its kind to address an unmet medical need for hospitalized patients with atrial fibrillation (AF) who are at risk for ischemic stroke. Named QUANTUM AF (Quantify Use of ANTicoagUlation to improve Management of AF), the study will evaluate the effect of a structured hospital quality improvement (QI) program on oral anticoagulant (OAC) use in these patients.

Nearly six million Americans are diagnosed with AF, an irregular heartbeat that can lead to blood clots, stroke, heart failure and other heart-related complications. It is the most common serious heart rhythm abnormality in people over the age of 65.^{1,2,3} When a clot forms in the heart due to AF, it can travel to

¹ American Heart Association. (2017, February 6). What is Atrial Fibrillation?
http://www.heart.org/HEARTORG/Conditions/Arrhythmia/AboutArrhythmia/What-is-Atrial-Fibrillation-AFib-or-AF_UCM_423748_Article.jsp. Accessed March 2017.

the brain and cause a stroke. Since one in three people with AF will have a stroke at some point in their life, most recent guidelines recommend using OAC therapy, which has been proven to reduce the risk of stroke by 60 percent.⁴ However, according to a recent study, only half of AF patients at risk for stroke are treated with an OAC at discharge.⁵

“The enormous number of people with AF who leave the hospital without medication, and therefore are at risk for stroke, represents a tremendous unmet medical need,” said Paul Burton, MD, PhD, FACC, Vice President, Medical Affairs, Janssen. “We’re thrilled to collaborate with Premier on the QUANTUM AF initiative in an effort to understand this significant need and help ensure patients are appropriately protected against a stroke when they leave the hospital.”

This prospective, parallel-group, cluster-randomized study will involve approximately 150 hospitals which researchers will assign in a 1:1 ratio either to the QI program arm or to the Usual Care arm. The study will determine whether the implementation of a QI program, including educational and process-based interventions, compared with standard hospital practice, will result in a greater proportion of patients with AF appropriately treated with an OAC. Hospitals assigned to the QI program arm will participate in QI program initiatives and activities, such as webinars, coaching calls with experts and other online resources. Hospitals assigned to the Usual Care arm will continue with their standard hospital practice in treating patients with AF.

The primary objective will be measured by analyzing data collected on OAC use for each eligible AF patient around the time of hospital discharge. Secondary objectives include: evaluating the effect of the QI program versus Usual Care on the rate of readmission to the same hospital; determining whether hospital characteristics are predictive of improvement in rates of appropriate OAC use; and evaluating the effect of the QI program on OAC use. The study is expected to last approximately 20 months.

About the Janssen Pharmaceutical Companies

At the Janssen Pharmaceutical Companies of Johnson & Johnson, we are working to create a world without disease. Transforming lives by finding new and better ways to prevent, intercept, treat and cure disease inspires us. We bring together the best minds and pursue the most promising science. We

² Go AS, Mozaffarian D, Roger VL, et al; on behalf of the American Heart Association Statistics Committee and Stroke Statistics Subcommittee. Heart disease and stroke statistics—2014 update: a report from the American Heart Association. *Circulation*. 2014;129:e28–e292.

³ Colilla S, et al. Estimates of Current and Future Incidence and Prevalence of Atrial Fibrillation in the U.S. Adult Population. *American Journal of Cardiology*. 2013; 112(8):1142-1147.

⁴ StopAfib.org. (2008, December 23) Stroke Risks from AFib. <http://www.stopafib.org/stroke.cfm>. Accessed February 2017.

⁵ Pokorney, Sean D, et al. Low Rates of Oral Anticoagulation Use Among Patients Hospitalized With Atrial Fibrillation and at High Risk for Stroke. *Circulation*. 2016;134:A17636, originally published November 11, 2016.

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