Preliminary Results of Prospective Trial Suggest Warfarin May Be a Safer Option for Patients than Alternative Therapies

Dabigatran Associated with a Higher Rate of Complications Requiring Therapy Discontinuation

Waltham, MA – May 4, 2012 – Today, at the 2012 Thrombosis and Hemostasis Summit of North America, Alere Inc. (NYSE: ALR) announced preliminary results from the largest study to date, performed by anticoagulation expert and Standing Stone Chief Medical Officer, Mark Wurster, MD, comparing warfarin (Coumadin®) and dabigatran (Pradaxa®) therapies administered in a real-world setting. Findings from the study reveal that complications necessitating therapy discontinuation occurred more frequently with dabigatran than with warfarin. Additionally, complications related to dabigatran appeared very early in treatment, with patients reporting issues, on average, after just less than four months of therapy.

Dabigatran (Pradaxa®) is the first oral thrombin/Xa inhibitor cleared for use by the FDA in the United States. Commercially available since November 2010, the medication is intended for the prevention of thromboembolic complications related to atrial fibrillation. While pre-approval studies are numerous, reporting on the use of dabigatran after commercial release in real-world settings has generally been limited to individual cases. Moreover, little information is available about the frequency of side effects or complications for patients on dabigatran, especially in comparison to patients receiving warfarin therapy administered by organized anticoagulation clinics.

The "Dabigatran in the Real World" study was conducted at a large anticoagulation clinic following 2,200 patients on oral therapy. Beginning in November 2010, all clinic patients whose prescribing physicians requested a switch from warfarin to dabigatran were tracked prospectively for a one-year period. Each patient served as his or her own control, and primary outcome measures focused on clinical events that led to the discontinuation of dabigatran or warfarin. These include episodes of thrombosis, bleeding, treatment-related death and any other events that required therapy with either agent to be discontinued.

Results for each patient were obtained from the first six months of dabigatran use and compared to the prior six months of treatment on warfarin. A total of 113 patients had evaluable data; the mean exposure times to dabigatran and warfarin were 3.9 and 6 months, respectively. During the warfarin treatment period, primary outcomes included one hospitalization with the diagnosis of warfarin toxicity. During the dabigatran treatment period, primary outcomes included: one treatment-related death (GI bleed); four other bleeding episodes (two GI bleeds, one rectus sheath hemorrhage, one intracranial hemorrhage associated with trauma); one episode of deep venous thrombosis; one atrial thrombus; one transient ischemic attack; one skin rash; and four incidents of gastrointestinal symptoms requiring cessation of dabigatran. The frequency of primary outcomes during the warfarin treatment phase was 0.88%, compared to 11.5% during the dabigatran treatment phase ($p < 0.0014$).

Commenting on the preliminary results of the trial, Dr. Wurster said, "This is the largest series to date that examines how dabigatran is being administered in real-world settings, and I think our findings illustrate some areas of concern with respect to new agents for anticoagulation therapy. This is not to

say that our results indicate that dabigatran is not a good medicine, but we need more information regarding appropriate patient selection and monitoring. As the study progresses, we hope to be able to answer some of these questions."

The "Dabigatran in the Real World" study remains active, and the final report will include information on possible contributing factors like renal function, co-morbid conditions, and concomitant medication use. Meanwhile, results of the study to date support the conclusion that warfarin remains an affordable, effective, and safe option for many patients. Dr. Wurster will be hosting a webinar to discuss these findings on Wednesday, May 23rd at 3:00 PM ET. Click here to register.

About Alere™ Anticoagulation Solutions

Alere is the leader in anticoagulation monitoring and management services. We've helped over 10,000 clinicians track 450,000 patients and 30 million INR tests by providing the critical tools needed to safely manage anticoagulation patients. We improve clinical, operational and economic outcomes for physicians, and offer more freedom and better quality of life for patients. Our clinically proven, connected offerings consist of a finger-stick INR monitor, home INR monitoring service, and disease management software. Together these components provide increased INR visibility and decision-making support designed to improve patient safety across the continuum of care. For further information about Alere Anticoagulation Services, please call: 877-262-4669.

About Alere

By developing new capabilities in near-patient diagnosis, monitoring and health management, Alere (NYSE: ALR) enables individuals to take charge of improving their health and quality of life at home. Alere's global leading products and services, as well as its new product development efforts, focus on cardiology, infectious disease, toxicology, diabetes, oncology and women's health. Alere is headquartered in Waltham, Massachusetts. For more information regarding Alere, please visit www.alere.com.

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