New Anticoagulant DrugsShow Increased Risk for Developing Serious Adverse Events

Independent drug safety analysis from AdverseEvents, Inc. evaluatesadverse events for treatments for atrial fibrillation – the newly approved drug, Savaysa, and Eliquis

SANTA ROSA, Calif., Feb. 10, 2015 –AdverseEvents, Inc., a healthcare informatics company that provides comprehensive analysis of post-marketing drug side effect data, has published a safety comparison report for the recently approved anticoagulant, Savaysa (edoxaban tablets, Daiichi Sankyo).The report comparesthe clinical trial information for Savaysa to post-marketing case reports for Eliquis (apixaban, Bristol-Myers Squibb), another direct factor Xa inhibitor which is currently on the market. Initial analysis from AdverseEvents shows that both drugs increase risk of developing serious, distinct adverse events: Savaysa carries risk for interstitial lung disease (ILD) and increased risk of stroke, while Eliquis' label has several warnings for hypersensitivity reactions. Because of this increased risk, AdverseEvents will monitor incoming case reports as they become available to make further assessments of Savaysa's post-marketing safety profile.

Anticoagulants like Savaysa and Eliquis are indicated to reduce the risk of stroke and blood clots (systemic embolism) in patients with atrial fibrillation (AF) not caused by a heart valve problem.More than 2.7 million Americans haveAF, anarrhythmia of the heart where the atria (the heart's pumping chambers) quiver instead of beat. As a result, not all of the blood is pumped out of the heart, allowing pools to collect in the heart chamber, where clots may form. An embolic stroke is a type of ischemic stroke that occurs when a piece of an atrial blood clot (embolus) is pumped out of the heart, circulates to the brain and becomes lodged in an artery.[1]

Report methodology/findings

Clinical trial information for Savaysa was compared to the post-marketing data available for Eliquis because a previous report by AdverseEvents from February 2014 concluded that Eliquis may be a safer choice within the anticoagulant class of drugs. Employingits proprietary RxFilter,AdverseEvents determined Eliquis' Reporting Odds Ratio (ROR) values for cases that matched on-label Savaysa adverse events.There were 20 Savaysa on-label adverse events with corresponding primary suspect case counts for Eliquis that had an ROR score greater than one (ROR>1.0), indicating that there is a higher than expected reporting rate for a given adverse event/drug combination.

AdverseEvents will provide an initial safety comparison score for Savaysa once sufficient cases have been recorded in FDA Adverse Event Reporting System (FAERS) and incorporated into its database.

To view the report in its entirely (for media use only), please click here.

- more -

[1] American Stroke Association, http://www.strokeassociation.org/STROKEORG/LifeAfterStroke/HealthyLivingAfterStroke/ManagingMedicines/Anti-Clotting-Agents-Explained_UCM_310452_Article.jsp

Media interested in providing a link to the report can use the following URL: http://info.adverseevents.com/anticoagulant-savaysa-report

About AdverseEvents, Inc.
AdverseEvents is a California-based healthcare informatics company that improves patient safety and reduces systemic healthcare costs through the comprehensive analysis of post-marketing drug side effect data. Utilizing data-mining and analysis technology, through its proprietary RxSuite of analytics, AEI makes post-marketing drug safety data accessible, actionable, and predictable. More information can be found at http://adverseevents.com/home.

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