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FDA approves new antiplatelet drug used during heart procedure

The U.S. Food and Drug Administration on 22 June 2015 approved an intravenous antiplatelet drug named Kengreal (cangrelor) which prevents formation of harmful blood clots in the coronary arteries, the blood vessels that supply blood to the heart. It is approved for adult patients undergoing percutaneous coronary intervention (PCI), a procedure used to open a blocked or narrowed coronary artery to improve blood flow to the heart muscle.

Percutaneous Coronary Intervention (PCI) is performed on nearly 500,000 people every year in USA as according to the Centers for Disease Control and Prevention. The coronary arteries are opened by inflating a balloon at the site of the narrowing, usually followed by placement of a small mesh tube, called a stent, to keep the artery open.

By preventing platelets from accumulating, Kengreal reduces the risk of serious clotting complications related to the procedure, including heart attack and clotting of the stent (stent thrombosis).

“For patients undergoing percutaneous coronary intervention, blood clotting can cause serious problems,” said Norman Stockbridge, M.D., Ph.D., director of the Division of Cardiovascular and Renal Drugs in the FDA’s Center for Drug Evaluation and Research. “The approval of Kengreal provides another treatment option for patients.”

As with other FDA-approved anti-platelet drugs, bleeding, including life-threatening bleeding, is the most serious risk of Kengreal.

Kengreal significantly reduced the occurrence of heart attack, the need for further procedures to open the artery and stent thrombosis and overall occurrence of serious bleeding was low.

Kengreal is manufactured by The Medicines Company based in Parsippany, New Jersey.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation’s food supply, cosmetics, and dietary supplements, products that give off electronic radiation and for regulating tobacco products.

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SEC Announces Enforcement Action for Illegal Offering of Security-Based Swaps

The Securities and Exchange Commission on 17 June 2015 has announced an enforcement

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action against a company which illegally offered complex derivatives products to retail investors.

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The Dodd-Frank Act implements two key requirements for any security-based swaps offering to a retail investor who doesn't meet the high standard of an "eligible contract participant" defined in the law to make financial information and other significant details about the offering fully transparent to retail investors, and limit the transactions to platforms subject to the highest level of regulation. A registration statement must be effective for the offering, and the contracts must be sold on a national securities exchange.

It was found by SEC investigators that the Silicon Valley-based Sand Hill Exchange was offering and selling security-based swaps contracts to retail investors outside the regulatory framework of a national securities exchange and without the required registration statements in effect. With cooperation from the company the platform was shut down when violations were detected to protect investors from any harm.

"The Dodd-Frank Act prohibits security-based swaps from being offered in the darkness to retail investors, and we were able to act quickly before any losses materialized in this offering that occurred outside the proper

regulatory framework," said , Deputy Chief of the SEC Enforcement Division's Complex Financial Instruments Unit. "We will continue to scrutinize this space for companies circumventing the law to offer security-based swaps without the safeguards provided to retail investors."

It was found out by SEC's order that the Sand Hill violated Section 5(e) of the Securities Act and Section 6(l) of the Securities Exchange Act of 1934. Without admitting or denying the findings, Sand Hill, agreed to cease and desist from committing or causing any future violations of the securities laws. Sand Hill agreed to pay a $20,000 penalty.

The Complex Financial Instruments Unit will continue its scrutiny of the retail market for conduct that may violate the Dodd-Frank Act's swaps provisions, including online competitions creatively monetizing what actually constitute security-based swaps transactions vision of Corporation Finance.

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