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CorMedix Receives CE Mark for Neutrolin® Catheter Lock Solution

CorMedix Inc. announced on July 5, 2013, that it received CE Mark approval for Neutrolin®, a catheter lock solution, for patients with central venous catheters on hemodialysis secondary to advanced chronic kidney disease. The Neutrolin solution includes an anti-coagulant and broad-spectrum antimicrobial (antibacterial and antifungal) combination that is active against common microbes including antibiotic-resistant strains, and in addition, inhibits the formation of biofilm. Neutrolin, as a catheter lock solution, has been proven to significantly reduce the incidence of catheter related bloodstream infections (CRBIs) as well as maintain catheter patency by inhibiting thrombosis, thus reducing the need for systemic antibiotics and prolonging central venous catheter life.

CorMedix received the CE Mark for Neutrolin as a Class III device, which allows the company the ability to market and sell the catheter lock solution in European Union (EU) member countries that have adopted the Medical Devices Directive (MDD) without being subject to additional national regulations with regard to demonstration of performance and safety (although certain EU member countries may request or require additional performance and/or safety data on a case-by-case basis). The CE mark also permits the sale of Neutrolin in countries that have an MDD Mutual Recognition Agreement with the EU.
“Receipt of the CE mark for Neutrolin as a Class III device is a significant accomplishment for CorMedix, as this registration required rigorous regulatory review against high clinical and manufacturing standards,” said Randy Milby, CorMedix's Chief Executive Officer. “We are well prepared to make this important medical device available to patients with central venous catheters on hemodialysis. We look forward to Neutrolin being widely available in Europe with commercialization efforts led by national sales manager Joachim Petrak and his team at CorMedix Europe GmbH.”

CorMedix Europe GmbH will launch Neutrolin in Germany and Austria initially. The company is in discussions with potential partner companies to market in Europe, the Middle East and Asia. Neutrolin is indicated for the prevention of catheter related bloodstream infections (CRBI) and maintenance of catheter patency in hemodialysis (HD) patients. The company has longer term goals to expand its use in oncology patients requiring catheters as well as in additional indications. CorMedix is also now poised to pursue a regulatory strategy for approval of Neutrolin in the United States.

CorMedix also announced the receipt in late May of funds from two longtime investors Elliott Management and Kingsbrook Partners to further support the commercialization of Neutrolin.

Source: CorMedix

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