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Alvimedica Readies For Maiden Voyage Into US Drug-Eluting Stent Market

by Ahmet Sevindik

Having started out as a specialist in high-level medtech R&D and manufacturing in Turkey, Alvimedica has evolved to become a player in the interventional cardiology market with a portfolio of stents, balloons and catheters. It now has its eye on the $2.6bn US therapeutic interventional cardiology market for its *Cre8 EVO* drug-eluting stent.

With annual turnover of around $50m, Istanbul-based Alvimedica is enjoying high double-digit growth rates from sales of its interventional cardiology products in Europe, Asia and the Middle East. But the firm is keen to enter the US market; the US therapeutic interventional market had an estimated value of $2.6bn in 2015, according to *Meddevicetracker*'s "*US Markets for Interventional Cardiology Products*" report.

Alvimedica was founded in 2007 by the late Ishak Alaton, who had a vision of developing the company into a specialist in high-level R&D and manufacturing within Turkey's medical technology industry. Over the years, it has developed a number of coronary stents, balloon catheters and guiding catheters that are currently sold worldwide – 60% of its $50m revenue in 2015 came from Europe, 14% from Turkey and the remainder from South-East Asia, Russia and the Middle East. The company has an average growth rate of around 25%, although these rates are far higher in Asia (87%), Russia (57%) and the Middle East (34%). However, to date, the company does not have a US presence.

On Jan. 17, Alvimedica announced it had CE-marked Cre8 EVO and initiated Diab8, a 50-center, 3,000-patient randomized controlled trial that pits the performance of Cre8 EVO – which elutes Amphilimus, a proprietary sirolimus and fatty acid mix – against an everolimus-eluting stent in

Interventional Cardiology In Turkey

Turkey's stent market is worth about $120m

the treatment of coronary artery disease in diabetic patients. The 50 centers will be in 12 countries, although none of these are in the US, according to the firm. The data will hopefully provide further clinical support to the efficacy of Cre8 EVO.

annually and most of the products in this segment are being imported. The Turkish drug-eluting stent market grew 47.7 % last year, while the balloon angioplasty market grew 84% between 2014-2015.

Cre8 EVO stems from the Cre8 Amphilimus-eluting stent platform, which Alvimedica gained through its acquisition of Carbostent & Implantable Devices (CID), an Italian interventional cardiology company. The Cre8 stent technology features CID's proprietary coating, *Carbofilm*, a thin film of pure carbon with turbostratic crystal structure. When applied to the surface of an implantable device, like the stent, it gives the surface a very high degree of compatibility and hemo-compability, avoiding the risk of thrombosis. The absence of polymer in Cre8 stent further lowers the risk of stent thrombosis and reduces inflammatory response.

Cre8 EVO differs from the first-generation Cre8 stent by featuring a new stent architecture, which is designed for effective drug concentration within the vessel wall, including complex coronary anatomies and pathologies like those of diabetic patients. The very thin cobalt chromium body, sealed by the Bio Inducer Surface, provides high hemo- and bio-compatibility, increasing the rate of strut coverage and thus potentially reducing thrombogenicity.

Entering With Eyes Open

Alvimedica decided to move into the US market after it was encouraged by positive clinical feedback about Cre8, particularly when used in diabetic patients, and the significant sales growth of this product in the current countries it sells to. While the Turkish firm recognizes that it will come face to face with large, well-established drug-eluting stent rivals in the US, and that competition will be fierce, it is determined to take its chances, it told *Medtech Insight*.

The company stressed that in spite of the limited resources spent in the development of Cre8, and then Cre8 EVO – in comparison with giant US companies on their products – the clinical performances of this polymer-free DES is "unanimously recognized as the best-in-class in the market," with a lot of backing from clinical evidence and appreciation by key opinion leaders in many countries. The firm said it is confident that this, together with its know-how in high quality manufacturing, will help it succeed in the US.

In the meantime, Alvimedica is also exploring possible paths for a commercial partnership in the US market after Cre8 EVO clears the regulatory hurdle.