

Dealdoc

Distribution agreement for MiStent coronary stent

Stentys Micell Technologies

Nov 03 2014

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Companies:

Announcement date:

Deal value, US\$m:

Stentys

Micell Technologies

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n/d

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- Financials
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Details

Announcement date: Nov 03 2014

Drug delivery

Industry sectors: Medical device

Specialty pharma

Exclusivity:ExclusiveAsset type:TechnologyTherapy areas:CardiovascularTechnology types:BiomaterialsDeal components:DistributionGeographic focus:Worldwide

Asia » China Asia » Japan

Excluded geography: Asia » South Korea

North America » Canada North America » United States

Financials

Deal value, US\$m: n/d

Termsheet

STENTYS has entered into a five year agreement with Micell Technologies to be the exclusive distributor of the MiStent coronary stent worldwide (excluding the United States, Canada, China, South Korea and Japan).

The MiStent Sirolimus Eluting Absorbable Polymer Coronary Stent System (MiStent SES) is a balloon-expandable stent designed for rapid healing and slow progression of coronary artery disease.

The bioabsorbable coating of MiStent SES disappears within three months of implantation to promote fast vessel healing.

However, sirolimus elution is precisely and consistently controlled up to nine months after implantation, thereby inhibiting vessel re-narrowing.

These unique properties of both fast polymer absorption and sustained drug release are made possible by an innovative proprietary coating technology that allows sirolimus to be encapsulated as tiny crystals; once the polymer is gone, the crystals slowly dissolve into the tissue surrounding the stent providing a continued local anti-proliferative and anti-inflammatory effect for several months.

Press Release

STENTYS Expands Product Offering To All Coronary Stent Indications Through Exclusive Agreement With Micell To Distribute Its Novel **Drug-Eluting Stent**

PRINCETON, N.J. & PARIS--(BUSINESS WIRE)--Regulatory News:

STENTYS (Paris:STNT) (FR0010949404 — STNT), a medical technology company commercializing the world's first and only Self-Apposing® coronary stent, today announced it has entered into a five year agreement with Micell Technologies Inc. to be the exclusive distributor of the MiStent coronary stent worldwide (excluding the United States, Canada, China, South Korea and Japan).

Gonzague Issenmann, Chief Executive Officer and co-founder of STENTYS, explains: "We are thrilled to launch this exciting new product that is designed to outperform the market-leading workhorse stents thanks to a unique coating technology. Our customers will now have the opportunity to use MiStent for routine procedures and STENTYS Self-Apposing stent for complex vessel anatomy that requires optimal apposition, both of which are designed for safe vessel healing and improved patient outcomes."

"This long-term partnership is one more building block of the company's growth strategy. With two CE marked Sirolimus-eluting stents covering all coronary indications and commercialized through our fast increasing sales network, we will strengthen our market position, increase access to our target audience, as well as create an opportunity for even greater revenue growth," concluded Gonzague Issenmann.

The MiStent Sirolimus Eluting Absorbable Polymer Coronary Stent System (MiStent SES®) is a balloon-expandable stent designed for rapid healing and slow progression of coronary artery disease. The bioabsorbable coating of MiStent SES disappears within three months of implantation to promote fast vessel healing. However, sirolimus elution is precisely and consistently controlled up to nine months after implantation, thereby inhibiting vessel re-narrowing. These unique properties of both fast polymer absorption and sustained drug release are made possible by an innovative proprietary coating technology that allows sirolimus to be encapsulated as tiny crystals; once the polymer is gone, the crystals slowly dissolve into the tissue surrounding the stent providing a continued local anti-proliferative and anti-inflammatory effect for several months.

MiStent SES has been studied clinically in the DESSOLVE I and II trials. The first trial on 30 patients showed no reduction in artery lumen diameter between 8 and 18 months (late lumen loss of 0.09mm). The second trial of 184 patients, which compared MiStent SES and Medtronic Endeavor® DES, showed lower MACE at three years in the MiStent SES arm (8.3% vs 15.3%, p=0.2), with a very low rate of re-intervention for MiStent SES (TLR of 2.5% at 3 years) and no definite or probable stent thrombosis.

MiStent SES has received CE Marking and has not yet been marketed. STENTYS plans to launch the product in H1 2015 in Europe, to be followed by the many geographies where STENTYS has built a commercial network. STENTYS and Micell will partner to conduct MiStent's post-market study, DESSOLVE III.

About DESSOLVE I and DESSOLVE II Studies The DESSOLVE I trial treated 30 patients suffering from stable angina with MiStent SES® in de novo coronary artery lesions, across five study centers in New Zealand, Australia and Belgium. The primary efficacy endpoint was in-stent late lumen loss and showed no progression beyond eight months. At three years, MACE was 6.9% due to two non target vessel MI and TLR was 0.0%.

The DESSOLVE II trial is a randomized, multi-center study of 184 patients with documented stable or unstable angina pectoris. The primary endpoint is superiority of the MiStent SES in minimizing in-stent late lumen loss at nine months, compared to Medtronic's Endeavor® Sprint DES. Data analysis confirms that DESSOLVE II met all study objectives. At three years, MACE was 8.3% and TLR was 2.5%.

About Micell Technologies Micell Technologies is a biomedical company that is enhancing the performance of cardiovascular medical devices with innovative drug-delivery systems. Its unique surface and polymer modification technologies enable Micell to precisely and consistently control drug elution and polymer exposure duration, creating the potential for a therapeutic solution to coronary artery disease without the long-term safety concerns of currently available drug-eluting stents. Micell is also developing a drug-coated balloon for vascular interventions. More information is available at www.micell.com.
Filing Data
Not available.
Contract
Not available