

Amaranth Medical Completes MEND-II and RENASCENT Studies and Initiates Study of 120-Micron APTITUDE Sirolimus-Eluting Bioresorbable Scaffold

FORTITUDE Clinical Findings Presented
at Transcatheter Cardiovascular Therapeutics Meeting

MOUNTAIN VIEW, CA, Oct. 15, 2015 (GLOBE NEWSWIRE) -- [Amaranth Medical](#), a privately held medical device company, announced that enrollment has successfully concluded in its multi-center, international CE Mark clinical trials: MEND-II and RENASCENT-I, which assessed Amaranth's [FORTITUDE](#)[®] sirolimus-eluting bioresorbable scaffold (BRS) in patients with symptomatic coronary artery disease. All patients have entered the nine-month follow-up period, which is expected to conclude by mid-2016. Dr. Juan F. Granada, chief scientific advisor of Amaranth and executive director and chief innovation officer of the CRF-Skirball Center for Innovation, presented findings from these studies on October 15 during the *Bioresorbable Vascular Scaffolds, Part 2* didactic symposium at the Transcatheter Cardiovascular Therapeutics (TCT) annual meeting.

"Preliminary findings of these important studies are very exciting and continue to highlight the competitive advantages of the technology. FORTITUDE demonstrated a high device success rate and excellent peri-procedural clinical outcomes in all patients enrolled," stated Dr. Granada. "Our experience with this 150-micron scaffold has been quite positive, but without any doubt the future relies on the miniaturization of current BRS technologies, leading to easier navigation and a reduction of current thrombotic risk."

In addition, Amaranth announced plans to initiate RENASCENT-II, a study of a new 120-micron BRS. The study will take place in several centers in Italy and Colombia, South America with Dr. Antonio Colombo, director of the Hemodynamics Division at Ospedale San Raffaele in Milan, Italy, and Dr. Juan F. Granada serving as co-primary investigators.

"We plan to apply for a CE Mark following the conclusion of the nine-month patient follow-up period," added [Kamal Ramzipoor](#), president and CEO of Amaranth. "If granted a CE Mark, we would be in a position to commercialize our first product in 2017."

Dr. Colombo, primary investigator of the RENASCENT-I trial and co-primary investigator of RENASCENT-II, added, "The excellent results of RENASCENT-I are paving the way for RENASCENT-II, a study with a new 120-micron BRS. We are entering the era of BRS without compromises."

In addition to the 150- and 120-micron scaffolds, Amaranth's product pipeline includes the development of scaffolds under 100-micron wall thickness, which have demonstrated the ability to maintain biomechanical properties similar to previous generations of BRS. It is Amaranth's proprietary polymer's mechanical properties that enable the construction of scaffolds with strut thicknesses similar to those of metallic drug-eluting stents, without compromising on the key attributes such as radial strength, surface area and recoil.

"We believe that Amaranth is in a unique position to continue the miniaturization process of their devices while retaining the optimal biomechanical properties demonstrated in their earlier generation devices, including enhanced deliverability and treatment of more complex atherosclerotic lesions, thus becoming a trend setter in the bioresorbable scaffold field." Dr. Granada concluded.

About Amaranth Medical

Amaranth Medical, Inc. is a medical device company which has created a novel technology platform for the development and manufacturing of fully bioresorbable scaffolds. The Company's lead product is the FORTITUDE[®] scaffold, which is designed to afford the strength of metal stents to assist the artery during the remodeling process following an interventional procedure--without leaving behind a permanent implant with inherent clinical limitations. Amaranth Medical is headquartered in Mountain View, California, and its research and manufacturing operations are located both in Singapore and at its Silicon Valley headquarters. Amaranth Medical is led by Kamal Ramzipoor, and its investors include Charter Life Sciences, Bio*One Capital, Philip Private Equity, DCP Management and Venstar Capital.

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