Consistent Positive Clinical Outcomes Of Stent System Presented

/PRNewswire/ -- IDEV Technologies, Inc. (IDEV) today announced the presentation of consistent positive clinical outcomes of the SUPERA® Peripheral Stent System from its SUPERB pivotal U.S. clinical trial and SUPERA 500 long-term registry conducted in Germany. IDEV's data confirms a robust and consistent growing body of clinical evidence for SUPERA's highly differentiated, disruptive and proprietary stent design. The presentation was given today by SUPERB co-primary investigator Lawrence Garcia, M.D., Chief, Interventional Cardiology and Vascular Interventions at Steward St. Elizabeth's Medical Center at the 24th Annual Transcatheter Cardiovascular Therapeutics (TCT) scientific symposium, sponsored by the Cardiovascular Research Foundation.

SUPERB, a Food and Drug Administration (FDA) Investigational Device Exemption (IDE) trial, demonstrated the highest patency rates in peripheral IDE stent trials for superficial femoral or proximal popliteal artery disease that have been publically reported (86% based on survival analysis at 12 months). In addition, it is the first femoral-popliteal artery IDE trial to record zero stent fractures for bare or drug coated nitinol-based technologies.

The SUPERA 500 Registry included a highly challenging real world patient population of 495 patients, 750 stents, and a mean stent length of nearly 13 cm, with 45% and 41% of the SUPERA stents placed in the distal SFA and proximal popliteal artery, respectively. The one and two-year patency rates were 84.1% and 73%, respectively, as measured by duplex ultrasound. Consistent with the SUPERB trial, there were zero reported stent fractures at one year and also at two years in the SUPERA 500 registry.

"Results showing SUPERA's ability to consistently achieve a durable high patency rate with zero stent fractures even in longer lesion lengths and in later years of follow-up are quite impressive," said Dr. Garcia. "When compared to standard nitinol stents, covered stent designs and drug-eluting stent technologies, the outcomes achieved with the SUPERA stent suggest that SUPERA may represent a new standard of stent design for treating superficial femoral artery (SFA) disease."

The SUPERA stent's interwoven nitinol wire technology platform offers significantly improved radial strength, flexibility and kink resistance, and is designed to adapt to the motion of the vascular anatomy. The SFA and popliteal arteries are exposed to significant mechanical stress with bending and rotation of the knee, and represent a harsh environment for any endovascular device. An ideal stent for use in these areas should offer a great range of motion without interrupting the anatomical function of the arteries.

"SUPERA is first in a new class of stents, vascular mimetic stents, engineered to mimic the vascular anatomy for optimal flexibility and strength," said Christopher Owens, President and CEO of IDEV. "The SUPERB and SUPERA 500 results validate the SUPERA design as well as data previously reported in numerous single-site registries and retrospective studies. With this data, and additional studies soon to be released, we are building one of the most robust bodies of evidence in PAD. We will continue to develop the SUPERA stent for other markets, lesion types and locations."

Data from the SUPERB trial will be utilized for IDEV's premarket approval (PMA) application with the FDA, which the Company anticipates filing in the fourth quarter of 2012.