Nfocus Neuromedical Announces FDA 510(k) Clearance for Next Generation Device to Treat Vascular Lesions

PALO ALTO, Calif., Jan. 11, 2011 /PRNewswire/ -- Nfocus Neuromedical, Inc., an innovative medical device company with a focus on the next generation treatment for brain aneurysms, today announced that the company received U.S. Food and Drug Administration 510(k) clearance for its Acta™ Vessel Occlusion System (VOS). The Acta VOS provides physicians with a minimally-invasive alternative to current treatment options for an array of common and potentially serious vascular lesions.

The Acta VOS is designed to occlude (close) targeted veins and arteries with great precision. Vascular occlusion is often used to block blood flow to malformed, weakened or leaking vessels, or to benign or malignant tumors.

"The Acta VOS and the Nfocus technology platform on which it's based address an important and, to this date, insufficiently resolved medical need," said Eric Milledge, chairman and CEO, Nfocus Neuromedical. "The Acta 510(k) clearance is a tangible demonstration of our company's progress and is the first step toward clearance of the Nfocus platform of braided occluders, which includes the Luna™, our flagship product for treating brain aneurysms."

Vascular occlusions were historically accomplished by surgically closing the targeted blood vessel – a traumatic and expensive procedure. More recently, surgeons began placing small wire coils and other vascular plugs through catheters to stop blood from flowing to the area of concern. However, several coils may be required to occlude a single vessel, and occlusions frequently re-open. Pre-clinical studies demonstrate that the Acta VOS stops blood flow in a vessel more quickly and durably than both coils and a predicate plug device.

The Acta VOS uses a self-expandable, multi-layer oval implant made from Nitinol, a nickel-titanium alloy. Nitinol's properties allow the device to easily compress within a conventional catheter, and then rapidly open to full size once deployed within a vessel. The Acta VOS is mounted on an elegant delivery system that allows physicians to easily retract and reposition the device. Once the device is deployed and the desired location is achieved, a single lever detaches the Acta VOS, leaving it behind to occlude blood flow.

"The FDA has rigorous requirements for embolization devices such as the Acta VOS," said Robert O'Holla, vice president of regulatory affairs, Nfocus Neuromedical. "This 510(k) clearance provides strong validation for both our technology platform and development approach."

About Nfocus Neuromedical, Inc.
Nfocus is developing the next generation treatment for brain aneurysms. The company's innovative LUNA™ product is a single-deployment, easy-to-use embolization device designed to be a direct replacement to detachable coils. Nfocus is backed by three major U.S. and OUS-based venture funds: DFJ ePlanet Capital, Technology Partners, and

InCube Ventures. Other investors include Raffles Capital and Endeavor Vision. More information can be found at www.nfocusneuro.com.

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