

## **MicroVention Wins FDA Approval for its HydroCoil Embolic System for the Treatment of Cerebral Aneurysms**

*Company Also Begins Enrollment in Post-Market Clinical Study*

ALISO VIEJO, Calif. -- August 15, 2002 -- MicroVention, Inc. announced today it has received 510(k) clearance from the United States Food and Drug Administration (FDA) to market its HydroCoil Embolic System for the treatment of cerebral aneurysms. The company also announced it has received CE Mark for the HydroCoil, allowing it to sell the product in all countries of the European Union and the European Free Trade Area.

The HydroCoil is a unique endovascularly placed embolization device combining a proprietary highly expandable microporous polymer with platinum microcoil technology. The HydroCoil combines the safety and ease of use of platinum coils with the filling and healing properties of the expandable polymer.

MicroVention estimates the worldwide market for endovascular devices for the treatment of cerebral aneurysms will grow from approximately \$150 million annually to over \$500 million within the next several years. Over 125,000 cerebral aneurysm patients are treated annually worldwide. The HydroCoil offers a new therapeutic alternative to the current treatment choices: platinum coil embolization and neurosurgical clipping. Since introduced by Target Therapeutics, now a division of Boston Scientific (BSX), platinum coils have been used for aneurysm embolization for approximately 10 years.

The company also announced that physicians have treated the first 35 patients with its HydroCoil for the treatment of cerebral aneurysms. "The HydroCoil is a very promising new aneurysm embolization device because it provides complete filling. In both our preclinical work and early clinical studies, it has shown an excellent healing response. These are two of the most important clinical aspects for aneurysm treatment and the results to date look positive for the long-term outcome of the HydroCoil," said Professor Jacques Moret of Paris, France.

"Early data from patients treated with the HydroCoil is very encouraging and suggests that it may change the way cerebral aneurysms are treated," said Dr. Pedro Lylyk of Buenos Aires, Argentina. "The ability to treat cerebral aneurysms using this minimally invasive technique may allow a greater number of patients who suffer from aneurysms to avoid the morbidity associated with traditional surgical approaches," added Dr. Lylyk.

"This initial research by two of the world's leaders in the field, Drs. Moret and Lylyk, demonstrate the ability of the company's HydroCoil Embolic System to effectively treat a broad range of cerebral aneurysms," commented Robert Rosenbluth, President and Chief Executive Officer of MicroVention. "This pioneering work provides the foundation for our upcoming, multi-center study," added Rosenbluth.

### **Clinical Study Enrollment to Begin**

The company also announced the start of enrollment in the HEAL (HydroCoil for Endovascular Aneurysm occLusion) post-market clinical study, which plans to evaluate approximately 200 patients at 20 domestic and international neurovascular centers. The study is designed to examine the performance of the HydroCoil in the treatment of cerebral aneurysms. "In sponsoring the HEAL study, MicroVention is showing its commitment to aneurysm treatment, as well as demonstrating the benefits of this revolutionary technology," said Rosenbluth.

### **About MicroVention, Inc.**

Founded in 1997, MicroVention ([www.microvent.com](http://www.microvent.com)) is a privately held medical device manufacturer based in Aliso Viejo, CA. MicroVention's approach to treating cerebral aneurysms and other neurovascular disorders incorporates three technology platforms -- complex platinum coils, expansile hydrogels and endovascular detachment systems, which enable improved embolization therapy for neurovascular abnormalities. The company is currently marketing its MicroPlex Coil System, a detachable platinum coil for endovascular embolization. The MicroPlex consists of both helical coils and a unique complex coil. The MicroPlex Complex Coil has demonstrated improved ability to treat aneurysms with complicated anatomy and particularly those with wide necks. Both the HydroCoil and MicroPlex coils are detached from a delivery system by the physician using a proprietary HydroLink detachment system incorporating micro-fluidic actuation for instantaneous release.

### **MicroVention Contacts:**

Robert Rosenbluth, President, CEO

William Hughes, Vice President, CFO

Ph. 949-768-1184

Fx. 949-768-0464