Coherex Medical, Inc., a privately held medical device company, today announced it has successfully completed the first human cases of its Coherex FlatStent(TM) PFO Closure System.

Under the direction of Professor Horst Sievert, M.D. (an internationally renowned interventional cardiologist and Principal Investigator for the COHEREX-EU Study), Coherex(TM) successfully conducted procedures in Frankfurt, Germany yesterday to close the common heart defect known as a Patent Foramen Ovale (PFO). Joining Dr. Sievert in these cases were:

-- Brian Whisenant, M.D., Coherex founder and chairman, and Interventional Cardiologist with the Utah Heart Clinic at LDS Hospital in Salt Lake City;
-- Robert Sommer, M.D., Director of the Adult Invasive Congenital Heart Services Center at New York-Presbyterian Hospital/Columbia University Medical Center and Associate Professor of Clinical Medicine and Pediatrics at Columbia University; and
-- Jonathan M. Tobis, M.D., Professor of Medicine and Director, Interventional Cardiology at the David Geffen School of Medicine at UCLA.

"The Coherex FlatStent PFO Closure System worked flawlessly during each of our procedures, just as we expected," Dr. Sievert said. "The device was extremely easy to use and there have been no complications from its use in any of the cases. The Coherex FlatStent marks the beginning of a new era of medical device technology and significantly raises the bar by providing a simple and safe alternative in PFO closure for physicians and their patients."

"These fantastic results are the product of many years of research and hard work by Coherex' employees," said Richard J. Linder, Coherex president and CEO. "Our assertion that the Coherex FlatStent is a new breed of stent to treat heart defects has now been successfully validated in patients and confirms the confidence our investors have had in our vision. We look forward to additional clinical research in Europe as part of the COHEREX-EU Study."

These initial procedures were performed at Sankt Katharinen Hospital in Frankfurt as part of the company's COHEREX-EU Study. Coherex expects to include data from these cases in its application for CE Mark clearance.

"The FlatStent technology was straightforward and extremely easy to use and was successfully implanted in all of the patients today," Dr. Sommer said. "The device is unique in its construction and is designed to sit almost entirely within the PFO tunnel, with minimal mass and minimal left atrial exposure."
"The FlatStent technology is an exciting new advance in PFO closure since nearly the entire device is embedded within the inter-atrial tunnel," Dr. Tobis said. "My expectation is that the scar tissue will remain within the tunnel and effectively close the right to left shunt. This should have a significant effect in preventing paradoxical emboli in stroke patients, and hopefully we can demonstrate in future clinical trials that migraine headaches will also be reduced with the Coherex FlatStent."

"We are thrilled to have the world's leading interventional cardiologists participating in the COHEREX-EU Study with the Coherex FlatStent," Dr. Whisenant said. "I found the device to be intuitive and simple to use, and believe it may well indeed be one of the most important advancements in the treatment of structural heart disease. Yesterday's successful procedures reflect the incredible ingenuity and commitment of the entire Coherex team."

About Patent Foramen Ovale (PFO) Heart Defects

A foramen ovale is a tunnel-like opening between the upper chambers of the heart that allows blood to bypass the lungs and is present in all fetuses. Normally, the foramen ovale closes soon after an infant is born. However, if this opening fails to close naturally after birth the opening is said to remain patent and the condition is called a patent foramen ovale (PFO).

A common heart defect that occurs in roughly 25 percent of the population, PFOs allow blood to bypass the lungs and shunt directly from the right side of the heart to the left, thus

-- increasing the likelihood that blood clots in the heart flow directly to the brain; and

-- preventing the filtration of chemicals out of the blood that occurs in the lungs.

There are at least two medical conditions that may benefit from PFO closure: stroke and migraine. According to the Stroke Council of the American Heart Association, approximately 500,000 strokes each year worldwide may be attributable to the presence of a PFO, which represents a potential annual market size of close to $2 billion.

Migraine affects approximately 12 percent of adults. Multiple retrospective studies have demonstrated a marked reduction in migraine symptoms following PFO closure. As such, the worldwide market potential for PFO closure to treat migraine patients has been estimated to be more than $15 billion per year.

About the Coherex FlatStent PFO Closure System

The Coherex FlatStent PFO Closure System is similar in use and function to self-expanding vascular stents which are widely used by Interventional Cardiologists. However, Coherex' patent-pending FlatStent Closure System incorporates a unique fusion of PFO closure mechanisms and accepted medical practices in a design expected to naturally seal a PFO tunnel.
About Coherex Medical

Formed in 2003 by Brian Whisenant, M.D., Coherex Medical is focused on addressing structural heart disease and conditions through medical devices. For more information, please visit www.coherex.com or call 801-433-9900.

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