

# Surgeons Implant Two-Part Heart Valve System

(BUSINESS WIRE)-- ValveXchange, Inc. has performed successful first-in-man surgeries demonstrating the practicality and advantages of its novel Vitality(TM) two-part heart valve system.

The surgeries were performed by two highly renowned U.S. cardiac surgeons, Lars Svensson, MD, PhD of The Cleveland Clinic and W. Randolph Chitwood, MD of The East Carolina Heart Institute, working with Adrian Ebner, MD at his facilities in Asuncion, Paraguay. The surgeries took place Sept. 26 and 27, 2011. Three men aged 49, 62 and 72 received the Vitality(TM) heart valves. All have been discharged and are recovering normally.

The mission of ValveXchange(R) is to bring the full, active lifestyle advantages of tissue heart valves to patients of all ages. Currently, tissue valves are recommended only for older patients because the leaflet sets wear out every 10-15 years, requiring repeated open-heart surgeries. Younger patients today receive mechanical heart valves that do not wear out, but require lifelong high doses of anticoagulation drugs that force a sedentary lifestyle with serious side effects.

The ValveXchange(R) concept is a two-part valve with a permanently implanted base and an easily replaceable leaflet set. The leaflet set is designed to be replaced transapically (through the apex of the heart), accessed by a small incision between the ribs and not requiring any future open-heart surgeries. ValveXchange(R) is currently developing the tool set for the transapical leaflet replacement procedure. Leaflets can also be replaced using standard and minimally invasive surgical techniques that are faster and simpler than traditional valve replacement surgeries.

Of the FIM surgeries Dr. Chitwood said, "These cases went extremely well. We think we've got an excellent valve concept. You can look below the valve before you put the leaflet set in and see exactly how the valve is seated. The patients have come off bypass without any difficulty, excellent gradients, good cardiac outputs and good ventricular function." Dr. Svensson added, "With other valves if you break a suture you're basically committed to taking the valve off and out. Here there are no leaflets, so it's very easy to see and put in extra sutures."

Larry Blankenship, Chairman and CEO of ValveXchange(R), said, "This highly successful FIM implantation series takes ValveXchange(R) to a new level, and brings us closer to our goal of providing the advantages of tissue valves to all patients. Our next step will be to begin clinical trials in the European market."

The ValveXchange(R) technology was invented by company founder and noted heart valve scientist Dr. Ivan Vesely, a PhD Biophysicist. Dr. Vesely said, "Even though we worked on this technology for many years and have done extensive laboratory testing to make sure that all goes perfectly during human trials, it is still

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very gratifying to see how smoothly the implant procedures went and how well the patients did after the surgery."

ValveXchange(R) will now be pursuing clinical trials in Europe, which allows the most straightforward and predictable regulatory approval pathway. Clinical trials are expected to begin in early 2012 with European regulatory approval expected in late 2012 or 2013.

All ValveXchange(R) heart valves are designed for long durability and leaflet exchangeability. The Vitality(TM) model, which has just been implanted in the FIM studies, is intended for the broad adult aortic valve marketplace. ValveXchange(R) also is developing the Vanguard(TM) series of transcatheter valves (for transapical and transfemoral implant) that are being designed to incorporate the same durability as surgical valves and the same leaflet replacement feature as the Vitality(TM), but for the aged, non-surgical patient population.

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