Renal Denervation on Way to United States Soon?

The renal denervation device market has several systems approved for use in Europe, but none so far has been approved by the U.S. Food and Drug Administration (FDA). Renal denervation is a catheter-based ablation procedure used to treat patients with high blood pressure resistant to drugs.

In June, the first clinical trial for a renal denervation device started enrolling in the United States, according to the Endovascular Today website. St. Jude Medical, Inc., reported that it won FDA approval to begin the EnligHTN IV renal denervation study, under an investigational device exemption. The EnligHTN IV study is a randomized, single-blind, controlled, multicenter (about 80 sites) trial that should enroll about 590 patients between the ages of 18 and 80 who have a systolic blood pressure of 160 mm Hg or greater and who take three or more antihypertensive medications, including a diuretic.

The European market is already full of contenders in the renal denervation marketplace. Overall, the predicted marketplace for renal denervation devices is about $30 billion, according to experts at manufacturer Vessix, *Bloomberg News* reported.

In early September, St. Jude Medical announced the CE Mark (European region) approval of its next-generation EnligHTN Renal Denervation System for treating patients with drug-resistant, uncontrolled hypertension. The system features an advanced generator that delivers simultaneous ablations with a multielectrode catheter and lowers the total ablation time from about 24 minutes to 4 minutes with the new system.

Device makers that have received approval to sell hypertension devices in Europe include the field's leader, Medtronic Inc.; St. Jude Medical, Inc.; Covidien Plc; ReCor Medical; and Vessix. Vessix also has won approval to be sold in Australia.

Boston Scientific bought Vessix last October and tabled its plans to produce its own renal denervation system. Under the terms of the deal, Boston Scientific made an upfront payment of $125 million and will make milestone payments of up to $400 million between 2013 and 2017, according to *Bloomberg News*.

Medtronic paid $800 million, plus milestone payments equal to the annual growth in sales through 2014 for Ardian, a maker of a renal denervation system.

Bernstein Research analyst Derrick Sung said that Boston Scientific is paying high in comparison with the most recent renal denervation deals. He said that Ardian's high price is justified by the fact that the intellectual property gives Medtronic a 2-year to 3-year lead in the United States. Covidien recently paid $60 million for Maya Medical, plus up to $170 million in milestone payments.

The new question is this: exactly when will these devices be approved for sale in the United States?

Test for Early Rejection of Transplanted Organs

For years, medical researchers have sought an early test to determine how well a transplant patient's body is accepting an organ. Half of kidney recipients have organ failure within 10 years of a transplant.

Now, two companies have produced a test that may help to solve the problem of detecting early rejection.

Graft-derived, cell-free DNA (GcfDNA) in the blood of transplant recipients is considered a potential biomarker for organ rejection. Previous attempts to determine GcfDNA levels, which required sequencing of both donor and recipient DNA, have been expensive, required a long turnaround, and also meant donor DNA specimens were necessary.

Chronix Biomedical researchers, along with research partner University Medical Center Göttingen, wanted to develop a new method that would address these drawbacks. As described by the team of scientists, the new method uses Bio-Rad Laboratories' Droplet Digital PCR (ddPCR) technology to overcome obstacles of earlier tests, which were both time-consuming and costly.

The new method reduces test time from 3 days or more to 1 day and cuts costs by 90 percent, the authors said. They were able to address the past need for donor DNA by preselecting single nucleotide polymorphisms (SNPs, small, comparable differences in sections of DNA) that ensure enough difference between donor and recipient DNA as to be detectable.

The method was presented at the American Association of Clinical Chemistry 2013 annual meeting.