Industry Spotlight

Medgenics' Biopump Shows Good Early Results

Medgenics has announced early data from its phase II clinical trial with the EPODURE biopump device. This trial used the company's proprietary biopump to deliver the drug erythropoietin, or EPO, to anemic patients with chronic kidney disease who had not yet begun dialysis.

The company, based in Karmiel, Israel, has produced biopump applications for treating several chronic diseases, including hepatitis C, and is in the early stages of developing a biopump application that would treat hemophilia.

The biopump allows patients to produce, in their bodies on a long-term basis, their own natural human protein therapy. Cells are taken from patients, treated, placed in the biopump, and then the sterilized pump is implanted.

The recent trial results showed that the EPODURE pump produced an environment that let hemoglobin remain in a desired range for 2 to 4 months without any additional injections. The company noted that that the treatment never went past the typical normal range for hemoglobin.

The company plans a larger phase II trial for later this year, according to the firm's website.

"We believe that EPODURE could improve the safety and efficacy of anemia treatments while enhancing patient quality of life by providing a more reliable treatment that reduces or eliminates the need for frequent EPO or ESA injections," said Medgenics chief executive Andrew Pearlman. He added that the system "could provide clear cost benefits to payers."

In recent years EPO drugs have been in the news for several reasons, including investigations into dialysis provider DaVita for overuse of the drug Epogen (made by Amgen), and double billing the government for drug that is left in vials and reused, according to a July 2012 *Denver Post* story. DaVita agreed to pay $55 million to settle over allegations of drug overuse; the company denied any wrongdoing.

Amgen also has settled suits, entering a guilty plea at the U.S. District Court in Brooklyn for misbranding its anemia drug, Aranesp, which meant that the company was accused of selling it for uses not approved by the FDA.

NxStage Gets FDA Clearance for New High-Flow Capabilities

On April 30, the U.S. Food and Drug Administration (FDA) granted NxStage Medical clearance for its new high-flow capabilities with the NxStage System One, a portable hemodialysis system cleared for home use. With this clearance, NxStage Medical, based in Lawrence, Mass., expects to begin offering its System One with new higher flow capabilities in the United States later in 2013.

The higher flow capabilities will allow practitioners to adjust the duration and frequency of patient prescriptions for dialysis at home.

"This latest regulatory milestone reflects strong and systematic execution against our product pipeline," said Jeffrey Burbank, chief executive officer at NxStage Medical, Inc. "NxStage therapy may be prescribed less frequently, for example, three times per week or every other day, at treatment times consistent with those that patients and physicians experience in-center (in dialysis centers) today."

NxStage's high flow capabilities also received CE mark approval (CE marking is the manufacturer's declaration that a product meets the requirements of the applicable European Union rules for marketing a product freely in those areas).