Industry Spotlight

A New Type of Anemia Drug

A new type of erythropoietin product may be coming soon for patients with chronic and advanced kidney disease in whom anemia may develop.

AstraZeneca, the second largest pharmaceuticals firm in the United Kingdom, had a dwindling drug pipeline and has completed a deal with FibroGen, a biotechnology company in the United States, for an experimental anemia drug, several news outlets reported recently. AstraZeneca paid for rights to a drug that could be worth more than $815 million.

FG-4592 is the name of the new compound, which is delivered in pill form rather than the conventional injection for anemia brought on by chronic kidney (CKD) disease and end stage renal disease (ESRD).

The treatment is the first of a new type of drug for kidney patients that boosts the production of red blood cells by making the body react as if it is at high altitude and needs more cells for oxygen delivery.

Pharmaceutical researchers believe that such drugs could create a new market in treating anemia and other serious conditions, including circulatory problems and wound damage, Reuters reported. The drug may someday be developed for other anemia conditions, AstraZeneca said on its website.

Right now, AstraZeneca will pay $350 million up front, plus development-related milestone payments of up to $465 million, for a total of $815 million for rights to FG-4592 in the United States, China, and selected markets. The Reuters news service said that there could be additional payments "if use of the drug is expanded beyond the initial target of treating anaemia [sic] in patients with chronic kidney disease and end stage renal disease."

The drug is a small-molecule compound that stops the activity of hypoxia-inducible factor prolyl hydroxylase in anemia patients with CKD. According to AstraZeneca, the drug brings about a natural response to conditions of low oxygen and turns on the process of making red blood cells. FG-4592 has been shown to correct anemia and maintain hemoglobin levels "without the need for supplementation with intravenous iron in CKD patients not yet receiving dialysis and in end stage renal disease patients receiving dialysis," the company noted.

Thomas B. Neff, chief executive officer of FibroGen, said that FG-4592 could offer anemia patients an easier oral therapy "that provides coordinated erythropoiesis [production of red blood cells], that increases natural erythropoietin within the normal physiological range, and that is effective without intravenous iron supplementation and without an increased risk for hypertension."

Neff said that AstraZeneca and FibroGen would make China the first-to-launch country for FG-4592 and that the companies want to innovate in the area of anemia therapy to CKD and ESRD patients in the United States, where clinical trials would be fully funded under the terms of the agreement.

Pascal Soriot, AstraZeneca's chief executive officer, said that the collaboration on FG-4592 is "an important addition to AstraZeneca's growing late-stage portfolio in cardiovascular and metabolic disease," one of the company's core therapy areas. "We know from our research into complications of renal disease that anemia continues to be a challenge for patients with chronic kidney disease, due in part to the inconvenience and complexity of existing injectable and intravenous therapies and the safety concerns associated with them," Soriot said.

U.S. Renal Care Makes Acquisition

U.S. Renal Care (USRC), based in Plano, TX, has nearly doubled its business reach by acquiring Ambulatory Services of America (ASA), an evidence-based practice of dialysis and radiation oncology services in Brentwood, TN.

The merger will nearly double USRC's current patient volume to about 14,000 with operations in more than 200 outpatient, home, and specialty hospital dialysis programs and facilities, business website Modern Healthcare reported. ASA had 79 dialysis centers at the time of the merger.

"Doubling the size of U.S. Renal Care means both greater access for patients and greater operational efficiency," USRC CEO Chris Brengard said. "We could not have chosen a better partner than ASA, given our mutual commitment to personal, professional dialysis care and our emphasis on physician-led facilities."

But even after doubling its dialysis business, the merged company stands at less than 10 percent of the total dialysis services market, according to ASA executive vice president and general counsel Doug Chappell, *Modern Healthcare* reported. The lion's share comes from Fresenius Medical Care, based in Germany, and DaVita, based in Denver. According to the Fresenius website, Fresenius North America has 64 percent of the parent company's approximately 257,916 patients, or about 165,000 patients.

As of June 30, 2013, DaVita reported operating or providing "administrative services at 2010 outpatient dialysis centers located in the United States serving approximately 159,000 patients."

Nxstage has a Record-Breaking Quarter, New Project

NxStage, which is a maker of home-based dialyzers as well as models for health care setting use, set a revenue record in its last financial quarter and had noteworthy sales of its home-use dialysis systems.

Revenue for the second quarter of 2013 increased 11 percent to $65.5 million. The same quarter in 2012 showed revenue of $59 million.

The company's financial report said that "higher revenues were driven by increased adoption of the NxStage System One" model, designed for home use. Home sector revenue increased to $32.7 million for the second quarter of 2013, compared with revenue of $30.7 million for the second quarter of 2012.

"Our results reflect solid progress and early benefit from our strategic growth initiatives, including our new, direct to patient marketing programs," said Jeffrey H. Burbank, who is NxStage's founder and CEO. Looking ahead, he said that the company believes its efforts to "further penetrate both the United States and international markets are on track to deliver 15 percent annual revenue growth in 2014 and beyond."

Although the home sector had the largest percentage increase in revenues, the company's other sectors also grew: critical care revenue increased to $10.8 million for the second quarter of 2013 compared with revenue of $9.4 million for the same quarter in 2012. In-center revenue (in dialysis centers) increased to $21.2 million for the second quarter of 2013, up from revenue of $18.2 million for the second quarter of 2012.

In late July, NxStage, based in Lawrence, MA, and other partners announced that they would team up on a new filtering device to remove harmful bacteria from blood. That project is part of the Defense Advanced Research Projects Agency (DARPA) and its goal is to develop an innovative medical filtration device that could save the lives of soldiers—and civilians—by treating them for sepsis. Up to 10 percent of combat wounds result in life-threatening infections that ultimately lead to sepsis conditions, announced Battelle, lead and coordinating partner in the project. Sepsis is also a problem for some patients in hospitals, especially those in septic shock.

DARPA created the Dialysis-Like Therapeutics (DLT) program to develop a portable device that creates a treatment for sepsis. The plan is for a final device that can remove blood from the body, separate harmful "dirty" agents from the blood and return "cleaned" blood to the body in a manner similar to dialysis treatment for kidney failure. Several organizations are working on various aspects of a system that will work in the field.

Subcontractor NxStage will design, develop, and ultimately manufacture and distribute the medical device once it obtains the proper regulatory approvals, after the device successfully passes through clinical trials in both military and nonmilitary settings.

Technology website Gizmodo said DARPA has made significant investments in its DLT effort to date to multiple contractors for the development of key blood purification and diagnostic technologies that could contribute to the device. For example, Harvard's Wyss Institute is developing a device that accepts blood infused with nanotubules designed to attract harmful bacteria. The nanotubule-bound bacteria are magnetized to stay in the device, and the cleaned blood is returned to the body.