

## Industry Spotlight

### Amgen Lawsuit Alleges Kickback Scheme to Spur Sales of Aranesp

The same day that a major national lawsuit was announced against it, Amgen released the published results from TREAT (the Trial to Reduce Cardiovascular Events with Aranesp Therapy), a large, randomized, double-blind, placebo-controlled, Phase III study of patients with chronic kidney disease. Published in the *New England Journal of Medicine* and presented at the ASN annual meeting, the study showed the anemia drug Aranesp failed to meet its primary objectives of a reduction in all-cause mortality and found a higher risk of stroke for patients on Aranesp compared with those taking a placebo.

The lawsuit was not about the performance of the anemia drug, however, but about the performance of the drug company representatives, who allegedly encouraged medical providers to bill insurers for samples of Aranesp that were supposed to be free to patients.

The suit alleges a subtle process through which Amgen, based in Thousand Oaks, Calif., provided beyond the usual amount of overfill in Aranesp samples while using less overfill in Procrit samples. Procrit is also manufactured by Amgen, but it is sold by Amgen's competitor, Johnson & Johnson.

The suit says that Amgen told medical practices that they would make more money if they used Aranesp, because they could bill insurers for that extra amount—whether they gave it all to a single patient or saved the extra portions to give to other patients, according to a report in *The New York Times*. The lawsuit also alleges that Amgen invited doctors on retreats and paid them for food and lodging, as well as for payment as advisers.

David Polk, a spokesperson for Amgen, said that the company could not comment on the lawsuit, but that Amgen has a solid compliance program and a code of conduct that employees are encouraged to follow.

The suit, filed in federal court in Massachusetts, includes plaintiffs in New York, California, Delaware, the District of Columbia, Florida, Hawaii, Illinois, Indiana, Louisiana, Massachusetts, Michigan, Nevada, New Hampshire, Tennessee, and Virginia. ●

### NxStage Announces FREEDOM Study Interim Results

NxStage Medical announced results from its FREEDOM (Following Rehabilitation, Economics and Everyday-Dialysis Outcome Measurements) trial during Renal Week 2009.

The FREEDOM study is a multicenter prospective cohort study designed to measure the clinical and economic benefits of daily home hemodialysis compared with conventional, thrice-weekly, in-center hemodialysis. Key interim findings included:

- a nearly 50 percent reduction in the average number of prescribed antihypertensive medications over 12 months;
- discontinuation of antihypertensive medications by 33 percent of patients; and
- a 50 percent or greater decrease in use of antihypertensive medications among 56 percent of patients.

Additional FREEDOM data demonstrated a 40 percent reduction in expected mortality of patients using daily home hemodialysis therapy with the NxStage System One compared with patients from the United States Renal Data System. ●

### Toward a Wearable Kidney

AWAK Technologies, Inc., of Singapore, unveiled its peritoneal dialysis-based wearable artificial kidney at Renal Week 2009 in San Diego.

The idea that a two-pound, comfortable AWAK (Automated Wearable Artificial Kidney) could be coming is heartening news for patients, and the company spoke of two pounds as a goal. Right now, the AWAK is a six-pound battery-operated prototype. The kidney would provide continuous dialysis through a peritoneal dialysis platform.

AWAK Technologies hopes to begin clinical trials soon, perhaps in early 2010, in Singapore and Los Angeles. The AWAK Technologies website notes that the company hopes the product will be commercially licensed by 2011.

The device works by infusing dialysate into the peritoneal cavity so dialysis can occur. "What differentiates AWAK from either existing peritoneal dialysis or hemodialysis technology is that it is both wearable and self-contained," the company states. "Patients are able to live their lives with unrestricted mobility. More importantly, they do not have to regularly replace the dialysate as the AWAK continually regenerates the used dialysate through a sorbent cartridge."

The technology is based on original joint research done at the University of California, Los Angeles, and the U.S. Department of Veterans Affairs.

In 2007, Xcorporeal of Los Angeles completed a study of its artificial kidney prototype and demonstrated feasibility. However, Xcorporeal was delisted from the NYSE AMEX exchange in August 2009 because the company had large financial losses. ●

### Alexion's Soliris Approved for Orphan Drug Status

Two international bodies approved the drug Soliris (eculizumab) for orphan drug status, giving manufacturer Alexion Pharmaceuticals, Inc., of Cheshire, Conn., special consideration on its way through the drug approval process. Orphan drugs are those that most likely wouldn't be developed because of the rarity of the disease they treat, in this case atypical hemolytic uremic syndrome (aHUS).

The prognosis for aHUS patients is grim. About 70 percent of patients with the most common mutation for aHUS experience chronic renal insufficiency, chronic dialysis, or death within one year of the first clinical episode.

Both the U.S. Food and Drug Administration and the European Commission have approved the orphan status. The intervention by government on behalf of orphan drug development can take a variety of forms, including tax incentives, better patent protection, and financially subsidized clinical research.

Alexion is currently enrolling patients in four clinical studies of Soliris as an investigational treatment for adolescent and adult patients with aHUS. Clinical studies are also currently being planned on the use of Soliris as a treatment for children with aHUS.

If the drug is approved for treatment, the drug's orphan status would let Alexion market Soliris for 10 years exclusively in Europe and for seven years exclusively in the United States. ●

## Letters

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