Industry Spotlight

Acceleron Tests Drugs for Renal Patients

Acceleron Pharma (Cambridge, MA), focuses on designing protein therapeutics for cancer and rare diseases. Two of its new products under development involve patients with renal conditions.

Acceleron and Celgene Corp., based in Summit, NJ, are jointly developing a drug candidate called sotatercept, a fusion protein that acts by increasing the production of mature red blood cells into circulation, which may benefit patients with advanced chronic kidney disease.

Recently, Acceleron reported that it was about to receive a $7 million milestone payment under a collaboration agreement with Celgene, which recently opened a phase 2 clinical trial of sotatercept in patients undergoing hemodialysis.

In previous clinical studies, sotatercept has shown "encouraging activity by increasing red blood cells as well as bone mass in patients," said Matthew Sherman, MD, Acceleron's chief medical officer. "We believe that the distinct profile of sotatercept could benefit many patients, including those who have end stage renal disease, the most advanced stage of chronic kidney disease." He noted that the compound is also being studied in phase 2 trials in people with several rare hematologic diseases, including β-thalassemia and myelodysplastic syndromes.

A year ago, Acceleron started a phase 2 study of dalantercept, a novel blood vessel inhibitor that targets the activin receptor-like kinase 1 (ALK1) pathway. The two-part, randomized phase 2 study is a study of dalantercept in combination with axitinib (Inlyta by Pfizer). Axitinib is a vascular endothelial growth factor (VEGF) receptor tyrosine kinase inhibitor, intended to treat patients with metastatic renal cell carcinoma.

"Many patients with renal cell carcinoma respond to treatment with a VEGF inhibitor yet their disease subsequently progresses," said Michael B. Atkins, MD, deputy director of the Georgetown Lombardi Comprehensive Cancer Center, Georgetown University Medical Center. "My colleagues in the kidney cancer research community and I are optimistic that combining two therapies with distinct anti-angiogenesis (anti-blood vessel growth) mechanisms.…can provide a more effective and durable antitumor response in these patients."

Acceleron, its partners, and its collaborators have initiated seven phase 2 studies across three of Acceleron's programs—dalantercept (known first as ACE-041), sotatercept (ACE-011), and ACE-536—since November 2012.

Merck and GSK Team on Renal Cancer Combo Drug

Pharmaceutical giant Merck announced that it has launched a clinical trial that evaluates a combination of its own drug with one of GlaxoSmithKline's oral drugs to fight advanced renal cell cancer.

Merck's new offering is an investigational anti-PD-1 immunotherapy called MK-3475, along with Glaxo SmithKline's orally administered kinase inhibitor, pazopanib.

Iain Dukes, senior vice president for licensing and external scientific affairs at Merck, said, "We look forward to initiating further collaborations to investigate MK-3475 in combination with other anticancer agents across a range of tumor types."

Industry website Fierce Biotech said the anti-PD (programmed cell death) drug would be a "badly" needed commodity, if successful. "Under growing pressure from Wall Street, which has come to expect . . . disappointment, delay and failure from Merck over the past few years, the pharma giant is circling its best research wagons around this PD-1 immunotherapy drug," Fierce Biotech stated on its website.

By blocking PD-1, MK-3475 allows the body's immune system T cells to act against cancer cells.

Glaxo SmithKline's pazopanib, marketed as Votrient, was approved by the U.S. Food and Drug Administration for the treatment of patients with advanced renal cell carcinoma in October 2009 and is now approved in more than 80 countries.

Renal cell carcinoma is one of the targets that Merck is tackling in an ambitious series of clinical trials. According to a profile of the drug published by Fierce Biotech, MK-3475 is being studied in 10 clinical trials that are estimated to enroll more than 4000 patients across a broad range of cancer types. In 2014, these include renal cell, bladder, colorectal, gastric, head and neck, melanoma, non-small cell lung, triple-negative breast, pancreatic, and hematologic cancers. For information on Merck's clinical trials, visit http://www.merck.com/clinical-trials/.

Disasters Keep Dialysis Facilities and Companies Planning

A toxic leak into water sources in West Virginia and extreme winter weather over Canada and the United States had people working hard to keep dialysis facilities safe and operational in recent weeks.

A sudden leak of a chemical used in coal processing affected patients in and around Charleston, WV. The chemical had overflowed around the tank run by Freedom Industries. It then migrated over land and through soil into a river, about a mile from the affected West Virginia American Water Company plant, CNN reported. Tap water was affected in nine counties for several days, and customers had to stop all use of tap water.

The so-called polar vortex that descended over much of the United States in January also was a cause for reminders to people receiving dialysis to be prepared as road conditions worsened and utilities and deliveries were threatened. Dialysis providers updated websites with disaster preparedness plans. Fresenius North America provided this checklist for patients:

- Create a disaster kit with emergency supplies and at least one extra 3-day supply of medicines.
- Store a 3-day supply of food based on your emergency meal plan. Speak with your health care team about when to begin following your emergency plan. Limit fluid intake to 2 cups per 24 hours.
- Patients with diabetes should ask their doctor how to adjust their insulin dosage if severe flooding or storms are forecast.
- Make backup plans for rides to the local dialysis center.