Industry Spotlight

Renal Cancer Drugs Show Similar Survival Rates

A phase three trial showed that an already approved drug, sorafenib (Nexavar, manufactured by Bayer Pharma), and tivozanib share a similar survival period for patients with advanced renal cell cancer.

Sorafenib, also used for liver cancer, is a treatment for advanced renal cell cancer, and patients use it after earlier treatments with interferon-α or interleukin-2 have failed or if physicians deem these treatments inadequate. Sorafenib is a multikinase inhibitor (a tyrosine kinase inhibitor, an angiogenesis inhibitor, and a vascular endothelial growth factor [VEGF] inhibitor).

Tivozanib, the study drug, is a selective inhibitor of all three VEGF receptors that was designed to block VEGF while minimizing toxicities to other areas. Tivozanib is an oral, once-daily investigational tyrosine kinase inhibitor. Earlier, the TIVO-1 trial showed positive top-line results in advanced renal cell cancer, and the agent is being studied for use against other tumors.

Tivozanib and sorafenib treatment for patients with advanced renal cell carcinoma showed statistically similar overall survival, according to research reported at the Genitourinary Cancers Symposium by Robert J. Motzer, MD, a medical oncologist at Memorial Sloan-Kettering Cancer Center in New York.

At the time of final overall survival analysis, which was 2 years after the last patient was enrolled, 219 subjects had died: 118 (45.4 percent) in the tivozanib arm and 101 (39.3 percent) in the sorafenib arm. The median survival rates were 28.8 months for tivozanib and 29.3 months for sorafenib, which was not a significant difference.

Of the 257 patients taking sorafenib at randomization, more than half, (155, or 60.3 percent) had started taking next-line tivozanib by the time the data were analyzed.

Lead researcher Motzer presented final overall survival data from 1517 patients who were randomized to receive either tivozanib 1.5 mg a day (3 weeks on, 1 week off) or sorafenib 400 mg a day (twice daily, continuously), according to PharmPro.com. In the extension study, patients who experienced progression while taking sorafenib were eligible to receive tivozanib, which researchers said may account for a slightly longer survival time in the patients taking sorafenib.

Some side effects that bother renal cancer patients, including skin toxicity, diarrhea, nausea, and fatigue, were not as common with tivozanib. The lower toxicity and rate of side effects were positive features for a first-line therapy for advanced kidney cancer, Motzer said.

The manufacturers of tivozanib, AVEO Pharmaceuticals in Cambridge, MA, and Astellas Pharma, Inc., in Tokyo, were excited about the news when safety and other data from the study TIVO-1 were announced in 2012. "We are delighted with the outcome of TIVO-1 and to be collaborating with AVEO on tivozanib at this critical juncture," said Steven Ryder, MD, president of Astellas Pharma Global Development. "Tivozanib is an important asset to our strategy of becoming a global category leader in oncology."

NxStage Has Solid 2012

NxStage, a manufacturer of home-based dialysis equipment like the NxStage System One (to date the only portable home system cleared by the U.S. Food and Drug Administration for use in home hemodialysis) and other dialysis products, announced fourth-quarter and year-end results for 2012.

Revenue for 2012 increased 11 percent to a total of $242.1 million, compared with revenue of $217.3 million for 2011. Revenue for the fourth quarter of 2012 increased 14 percent to a record $65.0 million, compared with revenue of $57 million for the fourth quarter of 2011.

NxStage at the same time reported a net loss of $15.2 million (or $0.26 per share) for 2012, compared with a net loss of $21.4 million (or $0.39 per share) in 2011.

NxStage attributed the performance to growth in the home-based dialysis market because of the growing adoption of home hemodialysis with the System One.

NxStage has also enjoyed three recent occurrences that have positioned the company well to do business with members of the European Union (EU). The company obtained CE Mark approval (for doing business in the EU) for its high-flow dialysis capabilities, for its single-needle technology, and for nighttime home hemodialysis with the System One. Although it has been approved for home hemodialysis in the United States, the System One is not currently approved for nocturnal home hemodialysis. NxStage is presently conducting a trial in the United States for this indication.

Separately, NxStage announced plans to transition to a direct sales operation in the United Kingdom, cutting out a distributor relationship. The company anticipates that this action will further strengthen its relationships with local customers and position it to take advantage of new product approvals more rapidly.

"With increasing confidence in our ability to drive continued growth with new direct-to-patient marketing programs, we believe the overall effect of our product execution is that we are better positioned to accelerate adoption of our therapies with much greater potential than in the past," said NxStage chief executive officer Jeffrey Burbank. "With the benefit of these programs largely expected in 2014, we expect top-line 2013 revenue to remain strong and grow at a rate similar with 2012, followed by accelerated success and over 15 percent annual revenue growth in 2014 and beyond, excluding any benefit of service revenue from NxStage-owned centers of excellence."

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