Industry Spotlight

NICE Issues New Guidance on Kidney Diseases

The U.K.’s National Institute for Health and Clinical Excellence (NICE) has issued a final appraisal decision and rejected the drug axitinib (marketed as Pfizer as Inlyta) for the treatment of advanced kidney cancer. NICE also recently provided management guidance for patients with hyperphosphatemia, which often accompanies chronic kidney disease (CKD).

The decision on axitinib mirrored NICE’s initial recommendations about the medication. In comments to the National Health Service (NHS)—which delivers publicly funded health throughout the U.K.—about the draft guidance on axitinib, NICE’s Chief Executive Sir Andrew Dillon said, “We do not want to divert NHS funds to a treatment that costs more but doesn't help people live longer.”

The precise decision by the independent NICE appraisal committee was that axitinib shouldn’t be recommended for use after failure of prior treatment with sunitinib or a cytokine.

The Department of Health instructed NICE to examine the use of axitinib for the two populations specified in drug labeling, those previously treated with sunitinib, and those previously treated with a cytokine therapy. Experts told the appraisal committee that the use of cytokines is decreasing in clinical practice because most patients now start treatment with NICE-recommended sunitinib or pazopanib.

The data that Pfizer submitted for evaluation hurt the drug's case. The trial data provided included a direct comparison of the drug to sofonib, a drug not recommended by NICE and not identified in the scope of the case. The trial also lacked a comparison to “best supportive care”—the care that the majority of patients receive currently. Thus, an indirect and simulated comparison was made using separate data from another trial, according to documents on the NICE website.

When the committee considered this comparison, they noted that limited analysis was completed to identify uncertainties within this simulated method of comparison, and thus, they were concerned about its validity and reliability. The draft guidance is now with a named group of consultees, who can appeal the decision. Until NICE issues final guidance, NHS bodies will make decisions locally on the funding of specific treatments. This draft guidance does not mean that people currently taking axitinib will stop receiving it. They have the option to continue treatment until they and their clinicians consider it appropriate to stop.

Earlier in March, NICE issued guidelines for the management of increased serum phosphate level in the blood, or hyperphosphatemia, which is a common comorbidity among people who have CKD.

The NICE recommendations include offering calcium acetate as the first-line treatment in adults to control serum phosphate in addition to dietary management. For children, doctors should offer a calcium-based phosphate binder. The guideline also makes recommendations on second-line phosphate binder usage. The guidelines further call for giving individualized information on dietary phosphate management and assessing a patient’s serum phosphate control during every routine clinical visit.

Fat-Derived Regenerative Cells Patented to Treat Kidney Disease

Cytori Therapeutics, Inc., has received a patent for a new method of treating renal diseases using adipose-derived regenerative cells (ADRCs), cells derived from fat tissue. The company announced that the patent covers treatment of a broad range of renal disorders, including acute kidney disease as well as chronic kidney disease (CKD).

The patent also covers several ways of delivering the cells, including directly to the kidney or to the renal blood vessels. Cytori won the U.S. patent in part with data from a preclinical study showing that ADRCs improve renal function and reduce the death rate in acute kidney injury. In the study, animals received either ADRCs or delivery of a control material after a renal injury. Survival in the ADRC-treated group was 100 percent, which was a statistically significant outcome compared to only 57 percent survival in the control group. Functional and histologic improvements in serum creatinine, blood urea nitrogen, and renal cell necrosis in the ADRC group were also statistically significant.

Based in San Diego, Cytori is a regenerative medicine company that develops and manufactures medical devices that allow for therapeutic use of adult stem and regenerative cells that naturally occur in fat tissue. Until now, the company’s commercial activities have been focused on cosmetic and reconstructive surgery, cell banking, and tools for medical research.

“The renal patents are an important addition to our growing portfolio of ADRC patents,” said Cytori CEO Chris Calhoun. “CKD is an important comorbidity of cardiovascular disease, Cytori’s core focus.”

Calhoun said Cytori potentially could find a partner on this new indication to bring the therapy to market. The company has related patents in Europe to cover treatment of a broad range of renal disorders.

In 2012, Cytori’s operations had total product and contract revenue growth of 14 percent year-over-year, with $4.4 million coming from Japan out of the annual total of $14.5 million. In the fourth quarter of 2012, the company had a quarterly gross profit of $2.6 million, which was greater than sales and marketing expenses of $2.1 million.

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