FDA Approves First Biosimilar to Treat Cancer

The FDA approved the VEGF inhibitor bevacizumab-awwb (Mvasi; Amgen/Allergan) to treat five types of cancer in adults. It is the seventh biosimilar approved by the agency since 2015, but it’s the first for the treatment of cancer.

Mvasi is a biosimilar to bevacizumab (Avastin; Genentech), which loses patent protection in the United States in 2019. The two agents have nearly identical indications, which include nonsquamous non–small cell lung cancer, metastatic colorectal cancer, cervical cancer, renal cell carcinoma, and glioblastoma. Avastin is also labeled for ovarian cancer, which was not included in Mvasi’s FDA approval. Like Avastin, Mvasi carries black box warnings for gastrointestinal perforation, severe hemorrhage, and impaired wound healing.

A biosimilar gains approval based on data demonstrating that it is highly similar to an FDA-approved biological product and that there are no clinically meaningful differences between the biosimilar product and the reference product. The agency requires rigorous physicochemical testing of the biosimilar. Clinical trials play a smaller role in the process compared with approval of a novel compound.

“It’s a little bit foreign to clinicians, who have been educated to say, ‘That’s all interesting but show me the big, randomized clinical trials that prove efficacy and safety.’ We’ve got to learn more about the rigor of some of these other types of studies,” says James Stevenson, PharmD, professor of clinical pharmacy at the University of Michigan in Ann Arbor and president of St. Paul, MN–based Visante, a medication management-consulting firm.

Stevenson expects clinicians will have more opportunities to evaluate the studies behind biosimilars’ approvals. “Over 50% of the drugs in the pipeline are biologics,” he says. “Because of the number of drugs as well as the spend on these drugs, there’s a lot of interest in biosimilars and how they might be able to help us control expenses and improve access to care.” Amgen and Allergan have yet to release information regarding pricing or drug availability for Mvasi.

Financial impacts remain uncertain for patients—and to some extent for pharmaceutical companies as well. Stock analyst Todd Campbell, president of E.B. Capital Markets in Durham, NH, says that Amgen and Allergan are companies to watch, given their collaboration on multiple biosimilars in the pipeline, but he notes that “it’s too soon to know which company will come out on top in oncology.”

More announcements regarding cancer-treating biosimilars can be expected over the next year. Sanduz submitted a biologic license application for a new rituximab product last month, and the FDA’s Oncology Advisory Committee unanimously recommended approval of Mylan’s biosimilar of trastuzumab in July 2017. A final decision on the trastuzumab product is anticipated by the end of the year. —Jordan Calmes-Miller

Approved Drugs Might Work in More Cancers

A precision medicine trial aimed at identifying patients with rare cancers or those who have exhausted standard treatment options suggests that drugs approved for specific types of cancer might work in other tumor types that harbor the same genetic mutations. Preliminary results from the trial were presented in September at the ESMO 2017 Congress, the annual meeting of the European Society for Medical Oncology, in Madrid, Spain.

Researchers with the Center for Personalized Cancer Treatment (CPCT), a network of more than 40 hospitals in the Netherlands, performed whole-genome sequencing on biopsies taken from about 2,000 patients with all types of metastatic cancer to create a database of genetic mutations that appear in multiple tumor types. The database is being used to inform enrollment in a multiarm trial that includes 19 different approved drugs.

To date, 70 patients have been enrolled out of more than 250 cases submitted for review. To be eligible for the trial, patients must have been diagnosed with solid tumors, lymphoma, or multiple myeloma, have exhausted standard treatment options, and have actionable tumor mutations—meaning that they can be targeted by one or more of the study drugs.
CANCER DISCOVERY

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