FDA Approves New Therapy for Myelodysplastic Syndromes That Can Be Taken at Home

This represents an important advance for patients who previously needed to visit a health care facility.

July 7, 2020 By Food and Drug Administration (FDA)

Today, the U.S. Food and Drug Administration approved Inqovi (decitabine and cedazuridine) tablets for treatment of adult patients with myelodysplastic syndromes (MDS) and chronic myelomonocytic leukemia (CMML). This represents an important advance in treatment options for patients with MDS, a type of blood cancer, who previously needed to visit a health care facility to receive intravenous therapy.

“The FDA remains committed to providing additional treatments to patients during the coronavirus pandemic. In this case, the FDA is making available an oral outpatient treatment option that can reduce the need for frequent visits to health care facilities,” said Richard Pazdur, M.D., director of the FDA’s Oncology Center of Excellence and acting director of the Office of Oncologic Diseases in the FDA’s Center for Drug Evaluation and Research. “At this critical time, we continue to focus on providing options to patients with cancer, including regimens that can be taken at home.”

Inqovi is taken as one tablet by mouth once daily for five consecutive days of each 28-day cycle.

The approval was based on clinical trial results which showed similar drug concentrations between intravenous decitabine and Inqovi. Additionally, about half of the patients who were formerly dependent on transfusions were able to no longer require transfusions during an 8-week period. The safety profile of Inqovi was also similar to intravenous decitabine.

Some common side effects of Inqovi included fatigue, constipation, hemorrhage, muscle pain, mucositis (mouth sores), arthralgia (joint pain), nausea, and fever with low white blood cell count. Inqovi can cause fetal harm, and both male and female patients of reproductive age are advised to use effective contraception.

The FDA granted this application Priority Review. This review also used the Oncology Center of Excellence Assessment Aid and the Office of Pharmaceutical Quality’s Assessment Aid. These are voluntary submissions from the applicant to facilitate the FDA’s review. Inqovi received Orphan Drug designation, which provides incentives to assist and encourage the development of drugs for

rare diseases.

The FDA collaborated with international agency counterparts on the review of this application as part of Project Orbis.

The FDA granted this approval to Astex Pharmaceuticals, Inc., a subsidiary of Otsuka Pharmaceutical Co. Ltd.

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