

Johnson & Johnson multiple myeloma drug wins accelerated OK

November 16 2015, by Linda A. Johnson

A Johnson & Johnson drug won Food and Drug Administration approval Monday for treating the incurable blood cancer multiple myeloma in patients who've failed prior therapies and have few options left.

Darzalex is the first biologic drug and first monoclonal antibody—a genetically engineered drug designed to target diseased tissue and spare healthy cells—approved for multiple myeloma. The cancer, which occurs in infection-fighting white blood cells in the bone marrow, will strike 26,850 Americans and kill about 11,240 people in 2015, the National Cancer Institute estimates.

Darzalex, known chemically as daratumumab, helps immune system cells attack malignant multiple myeloma cells by binding to a protein on their surface. The infused drug is then believed to trigger death of tumor cells through multiple mechanisms, according to Johnson & Johnson's Janssen biologic drug unit.

Dr. Richard Pazdur, head of FDA's Office of Hematology and Oncology Products, said such targeting of proteins cancer cells' surface has led to important new cancer treatments.

The FDA granted accelerated approval based on two studies showing Darzalex reduced the size of or eliminated tumors in about one-third of patients.

In one study, 29 percent of the 106 participants responded to Darzalex

for 7.4 months, on average, before tumor growth resumed. In the other study, which included 42 patients, 36 percent had their tumors reduced or eliminated. Janssen is conducting further testing.

The biologic drug—produced in living cells rather than by mixing chemicals together—was approved for use in patients who have received three prior types of therapy and either didn't respond or relapsed after initial treatment, as is common with many cancer therapies. Patients in the studies had failed five treatments, on average.

"Darzalex gives people who have limited or no remaining options ... a real chance," Janssen said in a statement.

The infused drug is administered once weekly for the first two months and, if the patient continues responding, every two weeks for the next four months and then once per month. Each infusion has a list price of \$5,850, according to Janssen, so for patients responding to Darzalex, 23 treatments over one year would cost \$134,550. That's before any discounts insurers or other payers negotiate with J&J.

Darzalex can reduce levels of red blood cells that carry oxygen through the body, infection-fighting white blood cells and platelets needed for blood clotting. It should not be taken by pregnant women. The most common side effects reported were nausea, fatigue, pain in the back or infusion site, fever and cough.

"Multiple myeloma is a highly complex disease and remains incurable, with almost all patients relapsing or becoming resistant to therapy," Dr. Paul G. Richardson, a myeloma expert at the Dana-Farber Cancer Institute who participated in the patient testing, said in a statement.

In trading Monday, J&J shares rose \$1.34, or 1.3 percent, to \$101.22.

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