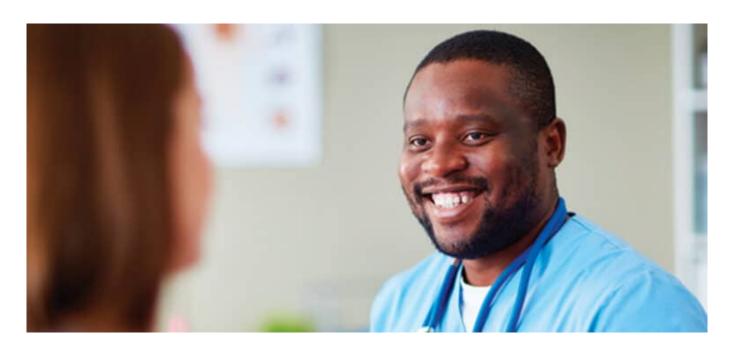
FDA approves Zinbryta to treat relapsing forms of MS



People with relapsing forms of MS now have another option when other therapies haven't worked for them.

by Marcella Durand

A new therapy approved by the U.S. Food and Drug Administration in May adds to the range of treatment options for people with relapsing forms of multiple sclerosis, primarily those who have already tried two or more disease-modifying therapies (DMTs).

Zinbryta[™], the brand name for daclizumab produced by Biogen and AbbVie, is an immune-modulating therapy taken by self-injection under the skin every four weeks. It works by blocking a docking site (receptor) for interleukin-2, a protein in the immune system that helps activate the T cells (a type of white blood cell) that are involved in MS attacks. It also helps increase immune cells that modulate MS inflammation.

In a phase 3 study involving 1,841 people with relapsing-remitting MS, it was shown to reduce the rate of relapses by 45 percent compared with Avonex, another DMT; it also reduced disease activity seen on MRI scans over three years. A smaller phase 2 trial, which compared Zinbryta with placebo, showed the medication was able to reduce relapse rates by an average of 54 percent.

"The approval of Zinbryta provides an important new therapeutic option for people with relapsing-remitting MS," said Kathleen Costello, associate vice president, Healthcare Access, at the National MS Society.

Zinbryta carries potential risks, and for that reason, it is recommended primarily for people who have not responded adequately to other MS therapies. While the most common side effects are skin rash and elevated liver enzymes, the most serious risk includes severe liver injury. The FDA recommends monitoring liver function prior to starting Zinbryta, then monthly before each dose and for up to six months after the last dose. People taking and prescribing Zinbryta will be enrolled in a Risk Evaluation and Mitigation Strategy. Other risks include non-infectious colitis (inflammation of the colon), skin reactions, enlarged lymph nodes, increased risk of infection and depression.

For information about patient support services, call Biogen's Above MS Program at 1-800-456-2255. Zinbryta is expected to be available by prescription later this fall.

Learn more about **Zinbryta**.