

IN EVERY ISSUE

Multiple Myeloma & Thrombocytopenia

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Velcade Gets Second Approval

Data from the VISTA trial were originally presented at last year's American Society of Hematology meeting, but the FDA made its decision using updated data. Velcade, when combined with other forms of chemotherapy and administered before a stem cell transplant, is also yielding good results, according to additional studies in newly diagnosed patients. Common side effects of Velcade include neutropenia (low white blood cell count), nausea, fatigue, and peripheral neuropathy.

Velcade, also approved for mantle cell lymphoma, is a proteasome inhibitor that works by blocking enzymes that affect cell growth and survival. Myeloma is the second most common blood cancer, affecting nearly 20,000 Americans each year. The disease results when abnormal plasma cells (white blood cells that make antibodies) develop in the bone marrow and begin multiplying, crowding out normal blood cells. For more on Velcade, go to www.velcade.com.

New Drugs Stimulate Platelet Production

Patients with thrombocytopenia have low levels of blood-clotting platelets, leaving them vulnerable to life-threatening bleeding. Thrombocytopenia can be caused by cancer, its treatment, or a disorder called immune thrombocytopenia purpura (ITP), which is characterized by small, numerous bruises (called purpura) that appear on the skin and signal broken blood vessels.

ITP is primarily caused by the body's immune system attacking mature platelets or the cells that produce platelets. The disease can also appear in patients with certain blood cancers or graft-versus-host disease (when the donor immune cells view the recipient's body as foreign following an allogeneic stem cell transplant).

Two drugs were recently submitted to the Food and Drug Administration for approval to treat chronic ITP—when the disease lasts longer than six months. Nplate (romiplostim) and Promacta (eltrombopag) both stimulate the production of platelet cells.

Nplate's approval on August 22 was based on two phase III trials published earlier this year in the *Lancet* that showed the agent allowed patients to discontinue or reduce other ITP medications, as well as offered a longer response and reduced the rate of significant bleeding events.

Promacta was granted priority review in March, and if approved, will be available in September. The FDA reviewed data from an international phase III study that showed Promacta, given as a daily pill for up to six weeks, increased platelet counts to a safe level in 59 percent of patients compared with 16 percent taking a placebo.

While ITP is rare in most cancer patients, the approvals may lead to the drugs being used for thrombocytopenia caused by cancer or chemotherapy.