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What is multiple myeloma?

Multiple myeloma (also known as myeloma or plasma cell myeloma) is a cancer of the plasma cells in blood. Plasma cells help produce infection and disease fighting antibodies called immunoglobulins. However, most multiple myeloma patients' cells produce a useless form of immunoglobulin called paraprotein (or M protein) that prevent the marrow from forming normal plasma cells and other white blood cells important to the immune system. Multiple myeloma cells can also attach to other tissues of the body, such as bone, and produce tumors. The actual cause of the disease is unknown.

What is the prevalence of multiple myeloma?

Multiple myeloma is the second most common cancer of the blood, representing approximately one percent of all cancers and two percent of all cancer deaths. It is estimated that approximately 45,000 Americans have multiple myeloma with about 14,600 new cases diagnosed each year. Only about 35 percent of multiple myeloma patients survive longer than five years with the disease. Although the average age of patients is 70 years old, recent statistics indicate both increasing incidence and younger age of onset. The disease is also twice as common in African Americans as Caucasians, and affects slightly more men than women.

What are the symptoms of multiple myeloma?

Unfortunately, multiple myeloma does not usually exhibit symptoms until the advanced stage, and when present they are similar to common symptoms of other conditions, including:

- Bone pain in the lower back, hip bones or skull;
- Fatigue and paleness of skin due to multiple myeloma-induced anemia;
- Weakness, fatigue, confusion, constipation, nausea, vomiting, increased thirst and urine production resulting from increased levels of calcium in the bloodstream;
- Kidney failure with or without kidney pain; and
- Frequent recurrent infection such as bacterial pneumonia and urinary-tract infections.

What are the current treatments for multiple myeloma?

A cure for the disease has not yet been found. Disease stage, age and kidney function of the patient are among the many factors that determine the type and dosing level of drug therapy. The primary treatment for multiple myeloma today is chemotherapy, although side effects are common because healthy cells can be damaged by therapy. Multiple myeloma is usually treated by a combination of drug therapies such as melphalan and prednisone. Other chemotherapeutic drugs such as vincristine, cyclophosphamide, carmustine and doxorubicin are also frequently used.

Multi-drug resistance of cancer is one major cause of patient failure on chemotherapy. An alternative treatment is radiation therapy, which is used for areas of bone damaged by myeloma that have not responded to chemotherapy and are causing serious symptoms.

Today, THALOMID®, REVIMID™ and ACTIMID™ are members of a new class of novel immunomodulatory drugs, or IMiDs™, which have demonstrated potent anticancer activity. Multiple pivotal Phase III special protocol assessment (SPA) clinical trials for full approval and multiple Phase II trials for accelerated approvals are evaluating these IMiDs in the treatment of a broad range of conditions, including; multiple myeloma and other hematological cancers and malignant blood cell disorders such as myelodysplastic syndromes (MDS) and solid tumor cancers. REVIMID has received a Fast Track Designation from the FDA both for the treatment of multiple myeloma and the treatment of MDS. The IMiDs are believed to affect multiple biological pathways within the cell, which ultimately may be responsible for the clinical activity observed in more than 200 studies worldwide. The IMiD pipeline is covered by a comprehensive intellectual property estate of U.S. and foreign issued patents and pending patent applications including composition-of-matter and use patents.

THALOMID, REVIMID (CC-5013) and ACTIMID (CC-4047) are not approved by the FDA or any other regulatory agencies as a treatment in multiple myeloma or MDS and is currently being evaluated in clinical trials for efficacy and safety for future regulatory applications.

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