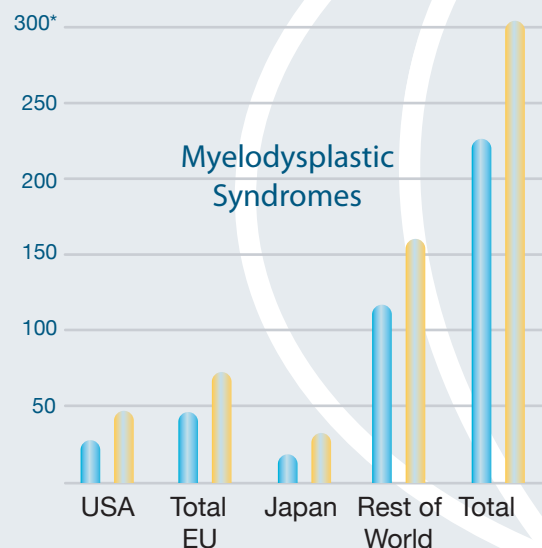
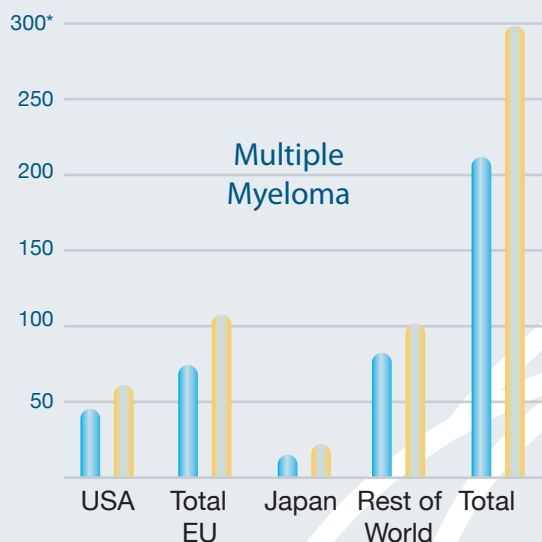


# REVLIMID®

## Offers “Transforming Potential” in Hematological Cancers

~ Being evaluated in more than 30 blood cancers and solid tumors ~

### Global Market Opportunity



Prevalence: 2005 2010

\* Patients in 1,000's

“Multiple myeloma was an illness with an ‘abysmal’ prognosis. With advances such as this novel biotherapy, it is becoming in my view a chronic illness in a majority of patients.”

**Paul Richardson, M.D.**  
Dana Farber Cancer Institute

**REVLIMID®** is the first of Celgene’s new class of cancer drugs called IMiDS®. These immuno-modulatory agents, taken orally as capsules, have unique multiple mechanisms of action that involve the micro-environment of the cancer cell, not just the malignant cell itself. **REVLIMID** modifies cytokines and other growth factors, it blocks the growth of new blood vessels that support tumors, and it amplifies the body’s natural immune response against cancer cells.

### Pharmacogenomics

**REVLIMID** also generates an additional *cytogenetic* response in a subset of patients with a pre-leukemia called MDS. When patients with a chromosome defect linked to MDS called the 5q deletion were treated with **REVLIMID**, in 83% of them the chromosome defect disappeared. [List, *et al.* see next page]

**REVLIMID’s unique mechanism and clinical findings to date support the potential of this new class of drugs.**

### Emerging Regimen for Multiple Myeloma

Before current treatments, patients diagnosed with multiple myeloma lived an average of 33 months. Today lives are being saved, extended and enhanced. As patients live longer there is a growing need for more treatment options. **REVLIMID**, along with a deep pipeline of Celgene’s other IMiDs, is being tested alone, in combination, and in combination with other new treatment regimens to help fill this need.

MARCH 2005: Interim analysis of **REVLIMID** pivotal Phase III trials in relapsed or refractory multiple myeloma patients exceeds pre-established efficacy endpoints. Independent Data Monitoring Committee recommends moving all patients enrolled out of the placebo arm and into the **REVLIMID** arm of the studies.

### REVLIMID Anticipated Near-term Milestones

Date	Indication	Event
2Q:05	MDS/5q-	Completed rolling NDA submission
2Q:05	MM & MDS/5q-	Results presented at ASCO
1H:05	MDS/5q-	Initiate Phase III trials in Europe
2H:05	MDS/5q-	Potential approval and launch
3Q:05	MM	sNDA filing

## MDS Study

**Myelodysplastic syndromes (MDS) are a group of hematologic, pre-leukemic malignancies that affect approximately 300,000 people worldwide.**

According to the American Cancer Society 10,000 to 20,000 new cases of MDS are diagnosed each year in the United States, with mean survival rates ranging from approximately six months to six years for the different MDS classifications. The total number of cases is expected to grow as the population ages. MDS patients must often rely on blood transfusions to manage symptoms of anemia and fatigue until they develop life-threatening iron overload and/or toxicity, thus underscoring the critical need for new therapies targeting the cause of the condition rather than simply managing its symptoms.



“**[REVLIMID]** is the biggest thing we have ever had for this disease... It actually changes the bone marrow itself and makes it work effectively, like a normal bone marrow... In 20 years of dealing with patients with myelodysplasia, we have never had anything with this magnitude of benefit for individuals that can cause a remission, particularly with just a pill.”

**Alan List, M.D.**, Moffitt Cancer Center, quoted in *Medical Breakthroughs, Cardiovascular Health Channel*

In February 2005, the *New England Journal of Medicine* published an important study validating Celgene's expectations for **REVLIMID**. Dr. Alan List, leader of the Hematologic Malignancies Program at the **H. Lee Moffitt Cancer Center & Research Institute** in Florida, conducted a Phase I/II trial that demonstrated **REVLIMID**'s promise as an innovative way of treating patients with MDS. Administered orally as a capsule, **REVLIMID** has shown the ability to simultaneously block the growth of new blood vessels that nourish tumors and stimulate the immune system to fight cancer cells.

## Regulatory Strategy

**REVLIMID** has received both “Orphan Drug Status” and “Fast Track” designation from the Food and Drug Administration (FDA) based on unmet medical needs both in MM and MDS/5q deletion patients. Celgene has completed the submission of the **REVLIMID** rolling New Drug Application with the FDA in the second quarter of 2005, for the use of **REVLIMID** in a sub-group of MDS patients with the 5q deletion chromosomal abnormality. If approved, **REVLIMID**'s use in treating this debilitating form of blood cancer may have a positive effect on the lives of tens of thousands of patients around the world and on the company itself.

## Centers of Excellence See Value in Studying REVLIMID as an Emerging Oncology Regimen

- In a Phase II trial, led by Vincent Rajkumar, M.D. at the **Mayo Clinic**, 25 of 30 patients using the combination of **REVLIMID** plus dexamethasone achieved an objective response yielding a response rate of 83% at that point in time.
- Mohammad Hussein, M.D., Director of the **Cleveland Clinic Cancer Center**, reported on a Phase II study of **REVLIMID** as a new therapeutic approach for patients with relapsed/refractory multiple myeloma, showing a clinical benefit based on a response rate of more than 66%.
- **The Southwest Oncology Group (SWOG)** initiated a Phase III randomized, double blind, placebo-controlled trial comparing the combination of **REVLIMID** plus dexamethasone with dexamethasone alone in patients with newly diagnosed multiple myeloma.
- **The Eastern Cooperative Oncology Group (ECOG)** initiated a 3-armed randomized Phase III study of **REVLIMID** plus dexamethasone versus **REVLIMID** plus low-dose dexamethasone in multiple myeloma with thalidomide plus dexamethasone salvage therapy for non-responders.
- **The Cancer and Leukemia Group B (CALGB)** initiated a Phase III randomized, double blind, placebo-controlled study of maintenance therapy with **REVLIMID** or placebo following autologous stem cell transplantation for multiple myeloma.