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Celgene gets approval for Revlimid in China

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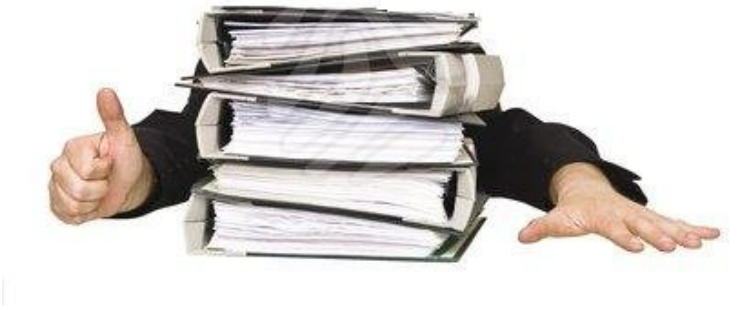

Singapore: Celgene has been granted full approval, which includes an Import Drug License by the China State Food and Drug Administration (SFDA) for use of Revlimid (lenalidomide) in combination with dexamethasone as a treatment for patients with relapsed or refractory multiple myeloma who have received at least one prior therapy.

The approval of Revlimid is based upon the safety and efficacy results of multiple pivotal randomized phase III international clinical trials in patients with relapsed or refractory multiple myeloma. Results from a large, phase II bridging study (MM-021) of lenalidomide and low-dose dexamethasone in 159 Chinese patients, who had relapsed or refractory multiple myeloma, also supported the submission and approval.

Multiple myeloma is the second most commonly diagnosed blood cancer. According to the International Myeloma Foundation, there are an estimated 750,000 people with multiple myeloma worldwide.

Revlimid will be available only through a proprietary distribution program developed by Celgene. The company is working to supply Revlimid to the China market as soon as possible. Certain standard government processes must be followed prior to launch. Celgene expects Revlimid to be available to patients late in the second quarter of 2013.

Celgene's application for Revlimid in patients with relapsed or refractory mantle cell lymphoma (MCL) after prior therapy that included bortezomib has been accepted by the US Food and Drug Administration. The agency has assigned a priority review to the application and has set a Prescription Drug User Fee Act date of June 5, 2013.