BioSpectrum the business of Bio & Health Sciences ASIA EDITION

Celgene halts phase III trial of cancer drug Revlimid

19 July 2013 | Regulatory | By BioSpectrum Bureau

Singapore: Celgene has discontinued treatment with Revlimid (lenalidomide), prescribed for for multiple myeloma, in open-label, phase III ORIGIN trial, which enrolled 450 patients in over 100 sites in 26 countries due to imbalance in the number of deaths in patients treated with lenalidomide versus patients treated with chlorambucil.

The FDA placed the Origin study on clinical hold on July 12, 2013, with the discontinuation of lenalidomide treatment. All clinical investigators in ongoing chronic lymphocytic leukemia studies using lenalidomide will be officially advised of this action and instructed to inform their patients accordingly.

Based on an imbalance in deaths, specifically 34 deaths out of 210 patients in the lenalidomide arm compared to 18 deaths out of 211 patients in the chlorambucil arm, FDA placed the study on clinical hold. No specific causality for this imbalance has been identified to date.

Revlimid is approved in combination with dexamethasone for the treatment of patients with multiple myeloma who have received at least one prior therapy, in nearly 70 countries, encompassing Europe, the Americas, the Middle-East and Asia, and in combination with dexamethasone for the treatment of patients whose disease has progressed after one therapy in Australia and New Zealand.