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Celgene drug promises activity in solid tumors

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Celgene has demonstrated in a Phase I trial that its lead pipeline drug,the immunomodulator Revimid (CDC501), is safe and has some efficacy in the treatment of solid tumors. Revimid is a small-molecule analog of thalidomide, which Celgene markets as Thalomid for an inflammatory complication of epilepsy (Marketletters passim) and which has shown promise in other indications, including some forms of cancer, and will be filed for multiple myeloma later this year.

Revimid has been designed to improve upon the safety and and efficacy of Thalomid, which achieved sales of $62 million last year, and has already shown preliminary activity in multiple myeloma. Analysts have predicted that a safer version of the drug would have a high sales potential, given the number of indications in which thalidomide may be a therapeutic option. Thalomid is also being tested in renal cell, colorectal, bone and prostate cancer.

The latest trial of Revimid involved 20 patients with solid tumors, including 13 with metastatic melanoma, two with pancreatic cancer, two with non-small cell lung cancer, two with breast cancer and one with metastatic renal cancer. The patients were treated with 5mg, 10mg, 25mg and 50mg/day of Revimid. No laboratory abnormalities were noted in the study at any dose, and the only side effect was numbness in one hand of the renal cancer patient.

A total of 13 patients had evidence of disease stabilization while on Revimid therapy and are continuing to receive the drug on a named-patient basis in an extension of the study. Eight patients in this group of responders had melanoma, and six of them had evidence of disease regression. Celgene has suggested that, if all goes well in future trials, Revimid could be on the market in 2003/2004.

Files IND for breast cancer therapy

Meantime, Celgene has also filed an Investigational New Drug application with the US Food and Drug Administration to start an open-label, dose-escalation Phase I trial of SPC8490, a selective estrogen receptor modulator-alpha, to identify the maximum tolerated dose effective in the treatment of patients with metastatic breast cancer.

Previous animal studies of SPC8490 showed that it was orally effective in treating breast cancer and demonstrated equal or superior efficacy to AstraZeneca's anti-estrogen therapy Nolvadex (tamoxifen). In addition, the compound was active in tamoxifen-resistant tumor cell lines and one hormonally-responsive ovarian cancer cell line.

Alpha · AstraZeneca · Nolvadex · Prolastin · tamoxifen · Thalidomide · Thalomid

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