First-in-class drug BBI608 tested in patients with advanced cancer

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Researchers at Boston Biomedical, Inc., are working to develop a novel first-in-class cancer drug that works by targeting the stem like properties of some cancer cells, and so far, results of an ongoing Phase I clinical trial demonstrate early signs of a strong safety profile and clinical activity.

"Cancer stem cells arguably represent one of the hottest frontiers in cancer research today," said Chiang J. Li, M.D., chairman and chief executive officer of Boston Biomedical, Inc., Norwood, Mass., who led the research discovery. "If the cancer stem cell hypothesis is proven to be correct, it should be possible to fundamentally advance treatment for patients with a wide variety of cancers because these highly malignant cell populations are inherently resistant to conventional therapies."

Updated data will be presented during the late-breaking clinical trial symposium at the AACR 101st Annual Meeting 2010, held April 17-21.

Li and colleagues took an unconventional line of attack by developing BBI608, a first-in-class cancer cell stemness inhibitor that can target highly malignant cancer stem cells as well as other heterogenous cancer cells.

"Current debates or controversies regarding the cancer stem cell hypothesis are less relevant to our approach since we believe it is crucial to target all malignant cells," said Li.

The Phase I study of BBI608 was designed to determine its safety and to establish a dose regimen for Phase II trials in adult patients with various advanced cancers. The study is being conducted at the Segal Cancer Center, Montreal, Quebec, Canada; the Juravinski Cancer Center, Hamilton, Ontario, Canada; and the Karmanos Cancer Center, Detroit, Mich.

As of March 26, 2010, 18 cancer patients with various solid tumors were enrolled in the study.

Treatment with BBI608 consisted of twice-daily, oral administration for four-week cycles. Dose escalation of BBI608 has reached a daily regimen of 600 mg, and the blood concentration of BBI608 has exceeded the level required to kill cancer stem cells and heterogeneous cancer cells in the laboratory.

Patients have tolerated the escalating doses of BBI608 very well with no significant drug-related side effects. To date, nine patients were evaluated for antitumor activity, of which six have achieved stable disease for at least two months with early signs of tumor regression and prolonged stable disease.

"We are encouraged by the early clinical data which supports our further efforts targeting cancer cell stemness," Li said. "Through incredible team effort and hard work we have accomplished the discovery of BBI608, and its translation from bench to bedside in less than 24 months, which, to our knowledge, sets a record pace for translational medicine. We are very excited about our novel approach and the therapeutic potential of cancer cell stemness inhibitors."

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