BRAF Inhibitor Shows Promising Preclinical Activity Against Melanoma

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Phase III trial currently enrolling
Clear tumor regression seen in preclinical models
No increased toxicity observed

PHILADELPHIA - Preclinical findings recently published in *Cancer Research* [1], a journal of the American Association for Cancer Research, showed RG7204 (PLX4032) inhibited proliferation of tumor cell lines that expressed V600E-BRAF, a mutation found in several human cancers, including melanoma.

The compound also showed partial or complete tumor regression and improved survival in a dose-dependent manner in preclinical efficacy models in rodents, without associated toxicity.

BRAF mutations are found in about 8 percent of all solid tumors but in about 50 percent of melanomas.

"Patients with advanced melanoma currently do not have a lot of options. There are some therapies, but the response rates are very low. Based on this promising preclinical data, we believe this compound merits further study in patients with advanced melanoma," said Dave Heimbrook, Ph.D. [2], global head of discovery oncology at Roche and one of the study authors.

The Cancer Research paper is the first published report of RG7204, which shows tumor regressions in preclinical models. Roche and Plexxikon scientists and their academic collaborators have presented Phase I clinical data at medical meetings.

William Pao, M.D., Ph.D. [3], associate professor of medicine, cancer biology and pathology at Vanderbilt University, said this preclinical research represents a significant step forward in establishing a basis for additional study in melanoma patients.

"This drug will have an impact," said Pao. "The response rates with currently available therapies are only in the 10 percent to 20 percent range, so this represents a large step forward."

Pao, a senior editor with *Cancer Research*, was not involved with the study and has no financial relationship with Roche.

Clinical studies are in progress with RG7204 (PLX4032). A Phase II trial has completed enrollment and a Phase III trial is currently enrolling patients. For this study, Roche is actively recruiting patients who have previously untreated

metastatic melanoma with the V600E BRAF mutation. More information can be found at www.roche-trials.com [4].

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