

New drug for metastatic melanoma shows promising results in clinical trial

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A clinical trial of a promising new experimental therapy for metastatic melanoma has shown positive results, including tumor shrinkage in the majority of patients. The positive results support previously reported positive data for the drug known as PLX4032 (RG7204) in a much larger patient population where all responses were confirmed by an independent review committee.

Jeffrey Sosman, M.D., director of the [Melanoma Program](#) at Vanderbilt-Ingram Cancer Center, presented the data from the Phase II clinical trial at the International Melanoma Research Congress of the Society for Melanoma Research in Sydney, Australia.

Melanoma is the most serious type of [skin cancer](#) and is growing at a rate of about 5 percent to 6 percent annually. It is one of the deadliest cancers, with a historical five-year survival rate of less than 15 percent due to the lack of effective treatments.

The new drug, PLX4032, which is being co-developed by Plexxikon and Roche, is a novel, oral, small molecule drug which targets melanoma and other cancers that harbor a mutation known as BRAF V600.

The Phase II trial of the drug is a single-arm study of previously treated metastatic melanoma patients who have the BRAF V600 mutation. The multi-center study enrolled 132 patients and as of Sept. 27, data showed a confirmed response rate of 52 percent, including:

-three confirmed complete responses (CR) (no evidence of disease)

-66 confirmed partial responses (PR) (tumor shrinkage of at least 30 percent)

In addition, 39 patients had stable disease. The median progression-free survival (PFS) was 6.2 months, compared to historical PFS of less than

two months. The median duration of response was 6.8 months. Median overall survival has not yet been reached.

"PLX4032 represents a true paradigm shift in the treatment of melanoma and a real breakthrough in melanoma research," said Sosman, principal investigator for the Phase II trial. "For the first time, we have the possibility of offering a true personalized medicine targeted to melanoma patients who will benefit most from the treatment."

Vanderbilt-Ingram is now routinely testing all melanoma patients for the BRAF mutation as part of its newly launched Personalized Cancer Medicine Initiative.

Provided by Vanderbilt Medical Center

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