Study drug LOXO-101 shows tumor regression in varied cancers

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A phase I study of the drug LOXO-101 appears to significantly reduce tumors in patients with varied types of genetically defined cancer, according to a study led by The University of Texas MD Anderson Cancer Center.

The results of the study, which followed patients with unique proteins called tropomyosin receptor kinase fusions (TRKs), were presented at the American Association for Cancer Research's annual meeting held April 16-20 in New Orleans.

"We saw efficacy with significant tumor regression in all six TRK fusion patients enrolled in the study," said David Hong, M.D., associate professor of Investigational Cancer Therapeutics. "We were surprised by the fact that the study demonstrated efficacy in every one of the TRK fusion-positive patients."

Out of 43 patients enrolled in the study, the six with TRK gene fusions had tumors representing cancers such as sarcoma, thyroid, salivary gland, gastrointestinal and non-small cell lung. Five demonstrated partial responses to LOXO-101 and the sixth recorded a 17 percent tumor regression. All six of these patients remain on study, with the longest out past one year and all of them into at least their seventh cycle. A seventh patient with a TRK gene fusion more recently enrolled for the study.

"We are currently enrolling all solid tumor types with TRK fusions for a phase II trial," said Hong. "Over time, we anticipate that the list of tumor types will continue to grow. In published literature, TRK fusions have been found in nearly every tumor type. The phase II study is important not only for generating additional data about LOXO-101 in patients with TRK fusion cancer, but we anticipate it will further broaden the range of tumor types that we've tested thus far."

The phase I study revealed that LOXO-101 has been well tolerated at various once-daily and twice-daily doses. Common side effects included fatigue, constipation, and dizziness. The planned phase II trial, which will include only patients tested positive for TRK gene fusions, will use a dosage of 100 mg twice daily, for patients who responded previously.

Hong believes comprehensive genomic profiling is key to further unlocking information about TRK gene fusions.

"It's fundamentally important that we adopt comprehensive genomic profiling as a field," he said. "In the case of this Phase I trial, many of the TRK fusion patients were detected as part of genomic testing, and I am encouraged to see that labs around the world are increasingly including TRK fusions in their routine testing menu."

Hong's findings are an update to study results presented at last year's AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics.

Provided by University of Texas M. D. Anderson Cancer Center