

Phase 1 clinical trial of CUDC-101 'throws kitchen sink' at head and neck cancer

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Head and neck cancer is among the few solid tumors whose incidence is increasing in the U.S. and outcomes have been slow to improve. Results of a phase 1 trial of the drug CUDC-101 with radiation and chemotherapy were reported by the University of Colorado Cancer Center and 6 other U.S. cancer centers in the journal *Clinical Cancer Research*. CUDC-101, currently being developed by Curis, Inc., works by inhibiting two growth factors and an enzyme that effects DNA expression - EGFR, Her2 and HDAC - all of which are overexpressed in many cancers, including the target of this trial: the common type of especially aggressive head and neck cancer that is not caused by the human papilloma virus (HPV-) but rather by tobacco or alcohol.

"We pretty much threw the kitchen sink at it," says Antonio Jimeno, MD, PhD, the clinical trial's senior author and director of the University of Colorado School of Medicine's Head and Neck Cancer Clinical Research Program. In the phase 1 trial CUDC-101 was combined with the standard of care for treatment of [head and neck cancer](#), which includes the chemotherapy drug cisplatin and radiation.

"Substantial technological advances in how we deliver radiation and chemotherapy are now enabling the addition of targeted agents to improve the cure rates and functional results in our patients," Jimeno says.

Specifically, the study was performed in 12 medium- to high-risk head and [neck cancer](#) patients. At 18 months median follow up, one patient's

cancer had worsened, two had died, and nine remained free of disease. Testing of blood and tumor samples showed that CUDC-101 had indeed inhibited the action of EGFR, HDAC and Her2.

"By analyzing the molecular correlates obtained from our very motivated and generous patients we saw that the drug was doing what it was supposed to be doing. The fact that this complex trial was feasible and didn't significantly add to the toxicity of chemotherapy and radiation that was given along with the study drug makes everybody more excited about pursuing further trials," Jimeno says.

"This is one of the most complex studies undertaken by the Head and Neck Cancer program at the CU Cancer Center to date. We are proud to have led patient enrolment to complete the trial, which defined the proper dosing for this new drug. As much as the results, the trial mechanics themselves contributed to our ability to publish these findings in the leading journal for this kind of research with a trial of only 12 patients," Jimeno points out.

"Multidisciplinary care and access to clinical [trials](#) such as this one are probably among the factors that contribute to higher cure rates in dedicated, specialized Head and Neck Cancer Programs such as ours," Jimeno says.

More information: *Clinical Cancer Research*,
www.ncbi.nlm.nih.gov/pubmed/25573383

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