

# CU Cancer Center opens phase I clinical trial of anti-cancer stem cell agent OMP-54F28

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The University of Colorado Cancer Center, together with other participating academic medical centers, recently opened a phase I human clinical trial of the drug OMP-54F28 in patients with advanced solid tumor cancers. OMP-54F28, a candidate investigational drug discovered by OncoMed Pharmaceuticals, targets cancer stem cells (CSCs), also known as tumor-initiating cells, which many researchers believe are at the root of tumor occurrence and growth. These CSCs are notoriously resistant to existing chemotherapies and so may survive current treatments to repopulate a tumor, leading to relapse and metastasis.

"It's a terrific opportunity to put a drug targeting cancer [stem cells](#) in the clinic, especially a drug with as much promise in [preclinical studies](#) as this one," says Antonio Jimeno, MD, PhD, investigator at the CU Cancer Center, director of the university's Cancer Stem Cell-Directed [Clinical Trials](#) Program, and principal investigator of the clinical trial at the CU Cancer Center site. "It is a privilege to work with such a science-focused partner, whose vision totally aligns with ours: bringing to the clinic cutting-edge drugs and ideas that are supported by robust scientific data. In the context of the collaboration between the Gates Center for [Stem Cell Biology](#) and the CU Cancer Center this will be the second clinical trial we will be offering to our patients with the specific intent to target the CSCs in their tumors."

Specifically, OMP-54F28 is an antagonist of the [Wnt pathway](#), a key CSC signaling pathway that regulates the fate of these cells. The Wnt pathway has been intensively studied and is now known to be

inappropriately activated in many major tumor types, including colon, breast, liver, lung and pancreatic cancers, and is thought to be critical for the function of CSCs. Because of this extensive preclinical validation, the Wnt pathway has been a major focus of anti-cancer drug discovery efforts. OMP-54F28 and a sister compound also developed by OncoMed, OMP-18R5, are believed to be two of the first therapeutic agents targeting this key pathway to enter clinical testing. Both OMP-54F28 and OMP-18R5 are part of OncoMed's Wnt pathway strategic alliance with Bayer Pharma AG.

In multiple preclinical models, OMP-54F28 has shown its effectiveness in reducing CSC populations, leading to associated anti-tumor activity, either as a single agent or when combined with [chemotherapy](#).

The Phase I clinical trial of OMP-54F28 is an open-label dose escalation study in patients with advanced solid tumors for which there is no remaining standard curative therapy. These patients are assessed for safety, immunogenicity, pharmacokinetics, biomarkers, and initial signals of efficacy. The trial is being conducted at Pinnacle Oncology Hematology in Scottsdale, Arizona, the University of Michigan Comprehensive Cancer Center, Ann Arbor, Michigan, and the CU Cancer Center under the direction of Principal Investigators Dr. Michael S. Gordon, Dr. David Smith and Dr. Antonio Jimeno, respectively.

"We all hope and expect this drug to live up to its preclinical potential," Jimeno says. "And if it does, we will have a powerful new therapy, exploiting a novel pathway to target this most dangerous subpopulation of cancer cells."

Provided by University of Colorado Denver

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