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UAMS' First Phase 1 Cancer Clinical Trial Testing New Way to Protect Hearts while Treating Cancer

LITTLE ROCK — The drug dexrazoxane has a reputation akin to someone who both fights and sets fires.

On the one hand, this Food and Drug Administration (FDA)-approved drug prevents heart damage caused by doxorubicin, which is used in chemotherapy. On the other hand, dexrazoxane may undermine the cancer treatment, causing many doctors to leave it on the shelf.

UAMS researcher Hui-Ming Chang, M.D., MPH, believes she may have found a way for dexrazoxane to protect the heart without hampering doxorubicin's cancer fighting ability. With the support of a five-year, \$3.5 million National Institutes of Health (NIH) grant, she has begun testing her laboratory findings at the newly opened UAMS Winthrop P. Rockefeller Cancer Institute Phase 1 Cancer Clinical Trial Unit.

Her study is the first phase 1 cancer clinical trial at UAMS. Cancer clinical trials at UAMS were previously limited to phase 2 and 3 studies.

"This is a significant milestone for UAMS and the Cancer Institute," said Michael Birrer, M.D., Ph.D., the institute's director and vice chancellor. "We are especially excited to kick off our phase 1 trials with Dr. Chang's bench-to-bedside research. As a result of her remarkable laboratory findings, there is a real opportunity to protect the hearts of patients while treating their cancer."

Chang named her study the Phoenix Trial, an aspirational reference to the mythical bird that rises from the ashes.

"Very few cancer doctors are treating their patients with dexrazoxane, but I am cautiously optimistic we can bring it back," said Chang, a professor in the College of Medicine departments of Pharmacology/Toxicology and Internal Medicine. "If the trial successfully translates our lab findings to humans, it will revive dexrazoxane for greater use in cancer patients treated with doxorubicin."

Dexrazoxane has been on the market since 2007, and doctors traditionally administered it to cancer patients at the same time as doxorubicin. In the lab, Chang discovered that if she gives dexrazoxane to mice eight hours before doxorubicin, it completely protects the heart from doxorubicin's side effects and does not interfere with doxorubicin's ability to kill cancer cells.

The eight-hour timeframe relates to dexrazoxanes' two-hour half-life, meaning it dissipates from the body within eight hours (four half-lives).

"The earlier infusion of dexrazoxane degrades a protein that would otherwise allow doxorubicin to damage the heart," Chang said. "This protein remains degraded long enough for dexrazoxane to leave the system so that it does not inhibit doxorubicin's beneficial effects."

The phase 1 clinical trial aims to determine the most effective dose and timing for dexrazoxane prior to doxorubicin. The project will evaluate whether the dexrazoxane pre-treatment prevents heart damage caused by doxorubicin in breast cancer patients.

Chang notes that preventing heart damage is especially important given the long-term survival of cancer patients, breast cancer patients in particular.

"Breast cancer is very prevalent among women, and more than 90% will survive," she said. "With such good survivorship, we want them to have a healthy heart, too."

The study is now recruiting 25 healthy women volunteers, ages 18-65. It will also recruit 120 breast cancer patients with non-metastatic, HER2-negative breast cancer.

Women interested in volunteering for the study can email PHOENIX1@uams.edu. Compensation is available.

"If the phase 1 trial is successful, we will move to the Phoenix 2 Trial for breast cancer patients. We can also involve other types of cancers, including sarcoma and pediatric leukemia, later," Chang said.

The Phase 1 Cancer Clinical Trial Unit is part of the Cancer Institute's state-of-the-art infusion center that opened in November 2020. Chang arrived at UAMS the same month, bringing the new Phoenix Trial with her from the University of Missouri School of Medicine.

Phase 1 clinical trials are the first to involve human participants. Almost every cancer treatment offered to patients today has come about because of a clinical trial.

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UAMS is the state's only health sciences university, with colleges of Medicine, Nursing, Pharmacy, Health Professions and Public Health; a graduate school; hospital; a main campus in Little Rock; a Northwest Arkansas regional campus in Fayetteville; a statewide network of regional campuses; and seven institutes: the Winthrop P. Rockefeller Cancer Institute, Jackson T. Stephens Spine & Neurosciences Institute, Harvey & Bernice Jones Eye Institute, Psychiatric Research Institute, Donald W. Reynolds Institute on Aging, Translational Research Institute and Institute for Digital Health & Innovation. UAMS includes UAMS Health, a statewide health system that

encompasses all of UAMS' clinical enterprise including its hospital, regional clinics and clinics it operates or staffs in cooperation with other providers. UAMS is the only adult Level 1 trauma center in the state. *U.S. News & World Report* named UAMS Medical Center the state's Best Hospital; ranked its ear, nose and throat program among the top 50 nationwide; and named six areas as high performing — COPD, colon cancer surgery, heart failure, hip replacement, knee replacement and lung cancer surgery. UAMS has 2,876 students, 898 medical residents and four dental residents. It is the state's largest public employer with more than 10,000 employees, including 1,200 physicians who provide care to patients at UAMS, its regional campuses, Arkansas Children's Hospital, the VA Medical Center and Baptist Health. Visit www.uams.edu or www.uamshealth.com. Find us on [Facebook](#), [Twitter](#), [YouTube](#) or [Instagram](#).

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