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DUR-928 compound continues phase 1 clinical trials

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A therapeutic compound developed at Virginia Commonwealth University, which may have broad applicability in acute organ injuries and in several metabolic diseases such as nonalcoholic fatty liver disease and nonalcoholic steatohepatitis, continues to make strides toward becoming an approved treatment option.

A phase 1 oral single-dose study was completed earlier this year. In March, DURECT Corporation announced it had initiated an oral multidose phase 1 clinical trial. Phase 2 is scheduled to begin next year.

The compound, DUR-928, is the result of a collaborative effort between the VCU Department of Internal Medicine, VCU Medical Center and the McGuire VA Medical Center. DURECT Corporation has helped develop the compound and holds the rights to commercialize DUR-928 and related molecules discovered during the collaboration.

Shunlin Ren, M.D., Ph.D., associate professor in the VCU School of Medicine, has carried out nearly 20 years of discovery research leading to DUR-928.

"This novel regulator has a potential to serve as a novel therapeutic for acute organ injury and chronic metabolic/lipid disorders, and ultimately to save many patients' lives," he said.

DUR-928, an endogenous epigenomic regulator, is an orally bioavailable small molecule that modulates the activity of various nuclear receptors

that play an important regulatory role in lipid homeostasis, inflammation and cell survival.

The first phase 1 trial of DUR-928 was a single-site, randomized, double-blinded, placebo-controlled, single-ascending-dose study that evaluated the safety, tolerability and pharmacokinetics of DUR-928 when orally administered. The 30-subject study evaluated DUR-928 in five cohorts of healthy volunteers receiving DUR-928 (up to 1,000 mg dose).

DUR-928 was well-tolerated at all dose levels, with no treatment-related adverse events reported and no subjects withdrawing from the study.

VCU Innovation Gateway has been an essential component in DUR-928's development. Acting as a liaison to outside companies, Innovation Gateway is a university resource that facilitates commercialization of university inventions and supports research through collaborative agreements.

"The relationship with DURECT is a telling example of our strategy for building strategic industry partnerships," said Ivelina Metcheva, Ph.D. "These connections lead to sponsored research and eventually licensing to enable commercialization of intellectual property at VCU."

DURECT anticipates commencing a phase 1 single-dose, injectable administration trial in healthy subjects in the second half of 2015 as precursor to a multidose phase 1 trial. Assuming no undue safety results from these trials, DURECT would then be positioned to commence one or more phase 2 trials with patients in 2016.

DURECT is evaluating various potential indications for DUR-928 in order to prioritize the development program. Long-term opportunities fall into four broad categories: (a) acute orphan indications, (b) broader acute indications, (c) chronic orphan indications, and (d) broader chronic

indications. DURECT's initial phase 2 studies will be designed to show an efficacy signal in patients suffering from an acute orphan condition such as acute kidney injury and a chronic indication such as nonalcoholic steatohepatitis or one of the orphan liver conditions DURECT is exploring.

"We are very excited about the results of this research," Ren said. "We are constantly finding new clinical applications for DUR-928 and look forward to announcing successful clinical trials for those applications. I hope FDA's future approvals of DUR-928 will give new hope to patients with cardiovascular, liver, kidney and other diseases. It is exciting to have the opportunity to help people and save lives."

Provided by Virginia Commonwealth University