



Human trials begin for DesignMedix anti-malarial drug developed to overcome growing drug resistance

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DesignMedix' lead product, experimental anti-malaria medicine DM1157, has begun human clinical trials. DM1157, discovered at Portland State University (PSU) and developed by PSU spin-out DesignMedix, was designed to overcome the serious issue of growing drug resistance among malaria medicines.

"Existing malaria medicines are becoming less effective because of the rise in drug resistance in malaria parasites," said Sandra Shotwell, Ph.D., DesignMedix co-founder and CEO, www.linkedin.com/in/sandrashotwell/. "This new medicine is designed as a first line therapy to overcome drug resistance, and if approved could be used to treat millions of people worldwide, allowing many sickened with malaria to make a complete recovery."

The first cohort of human volunteers has been administered DM1157 at Duke Clinical Research Institute in North Carolina. This Phase I study will assess the drug's safety and its ability to be absorbed in healthy human volunteers as a crucial first step toward gaining approval from the U.S. Food and Drug Administration (FDA) for subsequent testing in patients with malaria and, ultimately, for licensure for widespread domestic and international clinical use.

The clinical trial is being conducted with support from the National Institute of Allergy and Infectious Diseases, part of the National Institutes of Health (NIH) www.nih.gov/, through contract HHSN272201500006I. The research has received ongoing funding from the NIH, as well as support from Medicines for Malaria Venture, the State of Oregon, and private investors.

"It's exciting to see new molecules entering clinical development," said Tim Wells, Ph.D., Chief Scientific Officer of Medicines for Malaria Venture www.mmv.org/. "We are proud to have been able to work with our partner network to verify that DM1157 is active against a wide range of clinical isolates, including newly identified resistant strains. Resistance against current antimalarials is a constant threat and new tools are urgently needed."

Malaria sickens more than 200 million people every year and kills more than 400,000, mainly children under the age of five. In Vietnam alone, more people have died from malaria in the last five years than in the 20 years of the Vietnam War, Shotwell said. Malaria also contributes to significant poverty in countries where the disease is endemic, causing weeks of incapacitating

illness. Shotwell said ideally, the drug would be approved for use in adults as well as those most at risk of death from malaria: pregnant women and children.

The technology underlying the drug's design was first developed in the laboratory of PSU chemistry professor David Peyton, Ph.D. www.pdx.edu/~peytond/, DesignMedix's co-founder and chief scientific officer. It was then exclusively licensed to DesignMedix. Peyton's original experiments centered on modifying chloroquine, a widely-used malaria drug to which the malaria parasite had developed resistance, so that it no longer worked to cure the disease. Armed with initial data and ongoing collaboration from the Peyton laboratory, DesignMedix led the commercial development of malaria drug DM1157. Additional collaborators in Africa and Asia tested the drug on malaria parasites in blood samples drawn from patients, and found the drug killed the parasites in every sample, no matter how resistant they were to other drugs. Researchers checked whether malaria parasites could become resistant to the drug and found that DM1157 remained effective even with extensive forced evolution of the malaria parasite.

"Professor Peyton and his collaborative work with DesignMedix point to the future of PSU as a nimble research institution," said Mark McLellan, Ph.D., PSU's incoming vice president for research and chair of the FDA's Science Advisory Board. "PSU is extraordinarily proud to be a part of the invention of this antimalarial treatment."

For both DesignMedix and PSU, DM1157 is the first medication to reach this key development milestone of human clinical trials. The product has deep Oregon roots; it was invented at PSU, developed by DesignMedix in Portland, manufactured by Cascade Chemistry in Eugene, and formulated into capsules by Serán Bioscience in Bend.

About DesignMedix, Inc.

DesignMedix, Inc. was founded in 2008 to develop small molecule drugs to overcome drug resistance in treating infectious diseases. This is the first DesignMedix product to reach clinical trials. DesignMedix is housed in the Portland State Business Accelerator, a leading technology incubator and home to more than two dozen dynamic science and technology startups. For more information please visit: <http://www.designmedix.com>.

About Portland State University (PSU)

As Oregon's only urban public research university, Portland State offers tremendous opportunity to 27,000 students from all backgrounds. Our mission to "Let Knowledge Serve the City" reflects our dedication to finding creative, sustainable solutions to local and global problems. Our location in the heart of Portland, one of America's most dynamic cities, gives our students unmatched access to career connections and an internationally acclaimed culture scene. "U.S. News & World Report" ranks us among the nation's most innovative universities.