



One Step Closer: Novel Opioid Receptor Compound From Rensselaer Enters Phase I Clinical Trials

For more than 10 years, Rensselaer Chemistry and Chemical Biology Professor Mark Wentland has led a team in the discovery of a family of novel opioid receptor compounds that could be used in treating central nervous system disorders and addiction. In collaboration with licensing partner Alkermes Inc., the team has identified a lead candidate, known as ALKS 33, which entered Phase I clinical trials in early December 2008.

Wentland says that the “eureka” moment occurred with the realization that an opioid drug that his group discovered had triggered significant activity in the targeted area. Until then, most opiates were short-acting. This breakthrough held unusual promise for treating “reward” disorders and a number of diseases because of its long-lasting effect in animal tests.

“The broad goal of a medicinal chemist is to discover a drug that gets widespread use to treat human disease with unmet therapeutic need,” said Wentland, who straddles the boundary between basic and applied research. Having reached the milestone of ALKS 33 entering clinical trials, the team is one very important step closer to realizing that goal. “Medicinal chemistry, foremost among traditional approaches to drug discovery and development, retains its value in a high-tech world,” noted Wentland, who came to Rensselaer from the pharmaceutical industry in 1994.



In September 2006 Rensselaer signed a license agreement granting Alkermes Inc. — a biotechnology company based in Massachusetts — exclusive rights to the compounds discovered by Wentland and his team. In December, Alkermes announced that they had initiated a Phase 1 randomized, double-blind, placebo-controlled study with 16 healthy volunteers to assess safety and tolerability of ALKS 33.

According to Alkermes, the library represents an opportunity for the company to develop important therapeutics for a broad range of diseases and medical conditions, including addiction, pain and other central nervous system (CNS) disorders. Alkermes screened the library of compounds from Rensselaer and is responsible for the continued research and development of any resulting product candidates. The company reported results from the Phase 1 clinical trials during a Research and Development Day meeting held on April 7 in Cambridge, Mass.

According to Alkermes, initiation of the Phase I trial of ALKS 33 was based on recent data from preclinical studies that showed that the Rensselaer compound demonstrated statistically superior oral effectiveness compared to naltrexone — a drug used in the treatment of alcoholism. Specifically, their preclinical studies also suggested that the Rensselaer compound was not readily metabolized by the liver, a unique advantage over existing oral therapies for addiction.

“There are few medications available to help patients struggling to overcome addictions and new treatment options are desperately needed,” said Elliot Ehrich, M.D., chief medical officer of Alkermes. “We believe that the addiction field will evolve in a similar way to other CNS markets, such as mental illnesses, where treatments include both oral and injectable medications. This flexible approach offers patients and doctors the option to build the most appropriate therapies into treatment programs and fit the needs of individual patients.”

“This is a wonderful example of progress under *The Rensselaer Plan* in the areas of biotechnology and technology transfer that demonstrates Rensselaer’s unique strength in its ability to translate scientific discoveries into practical application,” said Ron Kudla, executive director of Rensselaer’s Office of Intellectual Property, Technology Transfer and New Ventures. “Most importantly, this is a testament to the fact that if the results of your research are going to have an impact on the public, it has to be patented in order to be commercialized.”

The license agreement also culminates years of research work by Wentland’s team, which includes more than 20 undergraduate, graduate, and postdoctoral students in chemistry and chemical biology, along with Jean Bidlack, professor of pharmacology and physiology at the University of Rochester, and members of her pharmacology group. Funding is from the National Institutes of Health.

Send comments to:
 Inside Rensselaer, Strategic Communications and External Relations
 1000 Troy Building, 110 Eighth Street, Troy, N.Y. 12180 or to leibat@rpi.edu.

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