



# EnzymeRx

Changing the Treatment  
Paradigm for Refractory Gout

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## **EnzymeRx Announces its IND for Uricase-PEG 20 Becomes Effective FDA Clears the Path for Clinical Trial**

PARAMUS, NJ, September 25, 2009. EnzymeRx, LLC ([www.enzymerx.com](http://www.enzymerx.com)), a clinical-stage biotechnology company, today announced that its Investigational New Drug (IND) application for Uricase-PEG 20, filed with the U.S. Food and Drug Administration (FDA) last month, has become effective.

EnzymeRx filed this IND for intravenous Uricase-PEG 20 in the management of elevated uric acid levels associated with tumor lysis syndrome. Tumor lysis syndrome is a serious condition that can occur during the treatment of certain tumors, and can result in sharply elevated uric acid levels. Uricase-PEG 20 metabolizes poorly soluble uric acid into highly soluble allantoin, and in a prior phase 1 clinical trial, it was shown to lower uric acid levels in gout patients. Because its long half-life may provide for an extended duration of uric acid-lowering after just a single dose, Uricase-PEG 20 may offer a convenient alternative to existing therapies for tumor lysis syndrome. EnzymeRx plans to launch a dose-ranging phase 1 clinical trial of intravenous Uricase-PEG 20 shortly.

Tony Fiorino, MD, PhD, President and Chief Executive Officer of EnzymeRx, remarked: “We are pleased with the FDA’s review of the IND, which allows us begin the clinical development of intravenous Uricase-PEG 20. Our near-term plans include not only launching the intravenous phase 1 study, but also resuming the clinical development of intramuscular Uricase-PEG 20 in gout. The EnzymeRx team is looking forward to a busy fourth quarter.”

### **About Uricase-PEG 20**

Uricase-PEG 20 is a recombinant uricase derived from *Candida utilis*, modified by the attachment of multiple 20 kilodalton molecules of polyethylene glycol (PEG). Uricase-PEG 20 has a prolonged half-life and reduced immunogenicity compared with unmodified uricase, and has been well tolerated in preclinical studies and in a prior phase 1 study in gout patients. EnzymeRx is developing Uricase-PEG 20 for the treatment of refractory gout and the management of hyperuricemia associated with tumor lysis syndrome.

### **About EnzymeRx**

EnzymeRx, LLC is a private, clinical stage biotechnology company founded in 2008 to develop Uricase-PEG 20. For more information about EnzymeRx, uricase or gout, please visit [www.enzymerx.com](http://www.enzymerx.com).