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INTERCEPT PHARMACEUTICALS ANNOUNCES PUBLICATION OF STUDY DEMONSTRATING ITS LEAD COMPOUND CAN REVERSE LIVER FIBROSIS
--Proof-of-Principle Study Published in *Gastroenterology*--

New York, NY – August 12, 2004 – Intercept Pharmaceuticals, Inc., an emerging specialty pharmaceutical company focused on developing small molecule drugs for the treatment of chronic liver and metabolic diseases, today announced publication in *Gastroenterology* of a major set of studies led by its scientific co-founder, Stefano Fiorucci, M.D., demonstrating that Intercept's lead FXR agonist, INT-747, can stop development of, and perhaps even reverse, liver fibrosis in animal models.

Liver fibrosis is the process of chronic scarring that leads eventually to cirrhosis and liver failure. It affects individuals with alcoholic liver disease, chronic viral infections like hepatitis B and C, and obesity associated non-alcoholic fatty liver disease (NAFLD), making it a major cause of disability and death for tens of millions of people worldwide. There currently are no approved treatments for liver fibrosis, leaving liver transplant as the only option available for those few patients with end-stage disease able to receive a donor organ.

"Publication of this landmark study which confirms the therapeutic rationale underlying our lead compound for liver fibrosis is an important milestone for our company," said Mark Pruzanski, M.D., President and CEO of Intercept Pharmaceuticals. "Until recently, liver fibrosis and cirrhosis have not been considered treatable, yet Dr. Fiorucci and his team have now demonstrated in validated animal models that liver fibrosis may be slowed and perhaps even reversed by Intercept's lead compound. Based on these encouraging results, we plan to advance INT-747 into human clinical trials in early 2005."

Prior work by Intercept's founders and other researchers elucidated the role of FXR, a member of the nuclear hormone receptor family, in the regulation of bile flow and rate of bile synthesis from dietary cholesterol. These studies suggested that FXR agonists may have utility in the treatment of a variety of cholestatic liver diseases which impair enterohepatic bile flow, resulting in progressive damage to the liver. More recently, as reported in the *Gastroenterology* paper, Intercept has uncovered the potential of FXR agonists to directly repress the degenerative processes underlying liver fibrosis.

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"On behalf of the many researchers, clinicians and patients who have been frustrated by our inability to treat liver fibrosis, I am encouraged to report the positive results of our initial work with INT-747," said Stefano Fiorucci, M.D., Professor of Gastroenterology at the University of Perugia in Italy and a well known liver disease researcher and clinician. "Agents like INT-747 for the first time give us the possibility of treating this often fatal condition to preserve adequate liver function and perhaps even restore lost function. I look forward to working with the Intercept team to rapidly advance INT-747 and associated compounds towards human clinical testing."

Intercept's lead compound, a potent, orally bioavailable FXR agonist formerly known as 6ECDCA, was discovered in 2001 through a collaboration between GlaxoSmithKline and University of Perugia scientists. Worldwide intellectual property rights to the compound and to a number of other FXR agonists, antagonists and modulators have been assigned to Intercept. FXR is known to be expressed in the liver, intestine and kidney, and Intercept intends to continue to lead research efforts to fully elucidate the therapeutic potential of this target.

About Intercept Pharmaceuticals

New York City-based Intercept Pharmaceuticals, Inc. is an emerging specialty pharmaceutical company focused on developing small molecule drugs for the treatment of chronic liver and metabolic diseases. The company is currently advancing its lead drug candidate, INT-747(6ECDCA), for the treatment of a group of life threatening fibrotic and cholestatic liver diseases for which there are virtually no effective marketed drugs. The company intends to lead in the advancement of drug candidates acting on FXR in multiple indications through clinical proof-of-concept. As a ligand-regulated nuclear hormone receptor, FXR is a member of a target class that has consistently yielded successful marketed pharmaceuticals in a variety of indications.