ESP Pharma
Excellence in Specialty Pharmaceuticals

News Release

ESP Pharma Announces FDA Grants Orphan Drug Status to I.V. Terlipressin, a Phase III Development Drug for the Treatment of Life-Threatening Type 1 Hepato-Renal Syndrome

Edison, N.J., November 10, 2004 – ESP Pharma, Inc. today announced that the Food and Drug Administration (FDA) has granted Orphan Drug Designation to I.V. Terlipressin for the treatment of Type 1 hepato-renal syndrome (HRS), providing seven years marketing exclusivity upon the completion of clinical studies and FDA approval of the drug for this indication.

As previously announced, on June 8, 2004, ESP Pharma acquired from Orphan Therapeutics, LLC (Lebanon, NJ) exclusive marketing and distribution rights to I.V. Terlipressin in the U.S., its territories, and Canada. Under the terms of the agreement between the two companies, Orphan Therapeutics (OT) pursued the now granted Orphan Drug Designation. OT also agreed to conduct the pivotal Phase III clinical trial and has initiated patient enrollment.

Type 1 HRS involves acute kidney failure arising from severe liver disease and is typically fatal within a few weeks of onset. The condition may be resolved with the kidneys resuming normal activity once liver function is sufficiently improved e.g., by a liver transplant. In the absence of a U.S. approved drug to treat Type 1 HRS, the development of I.V. Terlipressin for this indication targets an important unmet medical need, potentially extending the life of afflicted patients awaiting a liver transplant.

About ESP Pharma, Inc.

ESP Pharma is committed to Excellence in Specialty Pharmaceuticals and is dedicated to helping physicians improve patient outcomes and survival in the acute-care setting. Under the leadership of a highly experienced management team, the Company focuses on its **Buy and Build, Search and Develop** strategy of identifying opportunities to selectively acquire and enhance the market potential of novel, commercially available therapeutics and late-stage development compounds to fulfill unmet market needs. Opportunities for ESP Pharma to acquire product marketing, manufacturing, and development rights are the result of several factors, including industry consolidation and the fact that many existing and developmental drugs cannot meet the increasing revenue thresholds of large pharmaceutical companies. ESP Pharma, a privately held company, has investment support from leading healthcare venture capital and private equity firms: Domain Associates, LLC (http://www.domainvc.com/), Apax Partners, Inc. (http://www.apax.com), New Enterprise Associates (http://www.nea.com), and Thoma Cressey/Equity Partners (http://www.thomacressey.com/). Additional information about ESP Pharma is available on the internet at http://www.ESPPharma.com

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2035 Lincoln Highway | Suite 2150 | Edison, NJ 08817
TEL (732) 650-1377 | FAX (732) 650-1387

About Orphan Therapeutics, LLC

Orphan Therapeutics is a privately held drug development company founded in 2003 with the initial purpose to develop and seek approval from the Food and Drug Administration for intravenous terlipressin to treat type 1 hepato-renal syndrome. The company focuses on licensing drugs not available in the United States and pursues the development of these drugs for FDA approval under Orphan Drug Protection. Additional information is available at http://www.OrphanTherapeutics.com

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Contacts:

ESP Pharma, Inc.
Stuart Z. Levine, Ph.D.
Director, Corp. Communications
Phone: 1 - 732 - 650 - 1ESP (1377)
Fax: 1 - 732 - 650 - 1387
Stu.Levine@ESPPharma.com

Orphan Therapeutics, LLC
Peter Teuber, Ph.D.
President
Phone: 1-908-849-4805
Fax: 1-908-849-4806
Peter.Teuber@OrphanTherapeutics.com