18 June 2009

IS Pharma plc ("IS Pharma")

FDA ACCEPTS FINAL SECTION OF NDA FILING FOR LUCASSIN®

IS Pharma plc (AIM: ISPH), the specialist hospital medicines group, is pleased to announce that Orphan Therapeutics, LLC ('Orphan Therapeutics'), it's North American licensee for Variquel®/Haemopressin® (Lucassin® in the US), has been notified that the U.S. Food and Drug Administration (FDA) has accepted the final section of the New Drug Application (NDA) filing by Orphan Therapeutics, LLC and Ikaria Holdings, Inc. seeking marketing approval for Lucassin® (terlipressin for injection) for the treatment of hepatorenal syndrome (HRS) Type 1. Furthermore, Lucassin has been granted Priority Review, as well as Orphan Drug status and Fast Track designation.

Following marketing approval, Orphan Therapeutics will transfer the North American rights to Ikaria Holdings, Inc., which will then be responsible for the manufacturing, distribution, marketing, sales, customer service and post-market development of Lucassin.

Tim Wright, CEO of IS Pharma, said:

"We are pleased that Lucassin has been granted Priority Review by the FDA. This marks an important milestone towards obtaining marketing approval in the U.S. where currently no drug is approved for the treatment of hepatorenal syndrome (HRS) Type 1. HRS Type 1 is the development of kidney failure in patients with late-stage liver cirrhosis in the absence of any other cause. It is characterized by rapid onset of renal failure with a high mortality rate that exceeds 80% within three months."

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About IS Pharma plc (AIM: ISPH)

IS Pharma (International Speciality Pharmaceuticals) is a fast growing, profitable business which develops, acquires and commercialises late-stage pharmaceuticals and medical devices, focusing in critical care, oncology and neurology. Based in the UK, IS Pharma commercialises its portfolio in the UK directly and internationally through a strong network of distributors.

To find out more please go to www.ispharma.plc.uk