Press release
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Irvine Scientific Receives CE Mark Approval for Human Serum Albumin

Protein supplement for gamete and embryo manipulation in assisted reproduction

SANTA ANA, California – October 05, 2015: Irvine Scientific, a world leader in the innovation and manufacture of Assisted Reproductive Technologies (ART), today announced the receipt of CE Mark approval for its Human Serum Albumin Solution (100 mg/mL) in Normal Saline (HSA). HSA is used in assisted reproductive procedures as a protein supplement for gamete and embryo manipulation.

Irvine Scientific's HSA is manufactured according to current Good Manufactured Practice (cGMP) guidelines and International Standards using only the highest quality, low endotoxin raw materials, in order to meet or exceed regulatory guidelines. Every lot undergoes extensive quality testing including sterility (USP <71>, CFR Title 21 part 610.12, Ph. Eur. 3.2), biocompatibility by Mouse Embryo Assay (MEA), to meet low endotoxin specifications (USP <85> and Ph. Eur. 2.6.14 Bacterial Endotoxins Test) as well as pH (USP <791> and Ph. Eur. 2.2.3) and Osmolality (USP <485> and Ph. Eur. 2.2.35).

"Irvine Scientific is committed to producing consistently high quality products to our customers, and to demonstrate that commitment by meeting the requirements of regulatory bodies worldwide," **said Timothy P. Mullane, Chief Operating Officer, Irvine Scientific.** "We are pleased to be able to offer HSA with the CE Mark, especially for our European customers and network of distributors."

HSA joins a portfolio of CE Marked products Irvine Scientific offers for assisted reproductive procedures. View them at http://www.irvinesci.com/assisted-reproductive-technology

ENDS

Notes to Editors

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About Irvine Scientific

Irvine Scientific, a member of JX Group, is a worldwide leader in the innovation and manufacture of cell culture media, reagents, and medical devices for researchers and clinicians. The company provides unrivalled service and quality to scientists working in cell therapy and regenerative medicine, assisted reproductive technology and cytogenetics, and industrial cell culture for the large-scale production of biotherapeutics and vaccines. Irvine Scientific adheres to both ISO and FDA regulations and operates dual cGMP manufacturing facilities in California, USA and Tokyo, Japan. The company's consultative philosophy combined with expertise in cell culture and compliance provides customers with unique capabilities and support. For over 40 years, Irvine Scientific has remained uniquely flexible and focused on media while becoming a strategic global leader in media products and services.