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MEDIA RELEASE

Major UK Study of Bio Nova's Omniflow II vascular prosthesis

6 July 2011, Melbourne, Australia: Bio Nova International, a Melbourne-based developer and manufacturer of collagen-based medical devices, today announced that its lead product – the biosynthetic vascular prosthesis, Omniflow II – will be studied in a major randomised trial at the St. George's Healthcare NHS Trust in London, UK. The investigator-initiated study "*A Multicentre, Randomised, Controlled, Single Blind Clinical Evaluation of the Omniflow II Vascular Prosthesis for Arteriovenous Haemodialysis Access in the End Stage Renal Disease Recipient*" will compare the performance of Omniflow II to that of currently available synthetic (PTFE) prostheses in dialysis patients.

The study has received final Ethics Committee approval and will enrol patients requiring long-term haemodialysis with a vascular prosthesis and for whom a native fistula is not possible. The primary endpoint is primary patency (flow through the prosthesis). Final results are expected in 2014.

Dr Eric Chemla, Chairman of the Division of Medicine and Cardiovascular Sciences at St George's is the principal investigator, with patients to be recruited from St George's Hospital. Dr Chemla said "Reliable access to the patient's blood circulation is critically important in providing life-saving dialysis for patients with kidney failure. Blockages and infections are two key challenges faced in this area. Given the challenges in maintaining haemodialysis access, we are interested to examine the performance of the Omniflow II prosthesis, particularly in terms of its primary patency and resistance to infection."

Mr Hugh McCormack, Chief Executive Officer at Bio Nova International, said "We are delighted that Dr Chemla and St George's Hospital will be evaluating Omniflow II in a prospective randomised study. The outcomes will be a significant addition to the body of evidence regarding Omniflow II. The study is timely as kidney disease is a growing problem with over 2 million patients worldwide on dialysis."

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Omniflow II for Haemodialysis Access

Haemodialysis access to the patient's blood circulation can be provided by a native fistula (a surgical construction using the patient's own blood vessels), or an implanted vascular prosthesis or an in-dwelling catheter. In cases where a native fistula can be neither constructed nor maintained, and a catheter is not preferred, a vascular prosthesis can be used. As an alternative to synthetic products, Omniflow II is a biosynthetic vascular prosthesis composed of cross-linked ovine collagen and a polyester mesh endoskeleton. Previous studies of Omniflow II use in haemodialysis access have shown good primary patency and low infection rates.

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Bio Nova International is the leading biosynthetic tissue manufacturer in the world, specialising in collagen based medical devices. Bio Nova produces Omniflow II vascular prostheses and patches for surgical bypass of diseased peripheral arteries to avoid amputation, for arteriovenous access (AV access) in haemodialysis patients, and for repair of damaged blood vessels.

Bio Nova's technology is founded on collagen based scaffolds that are used to generate replacement tissue and organs that replicate the form and function of natural tissues and organs. The core technology produces three dimensional collagen based structures ("tissue scaffolds") for use in a wide range of implantable medical devices for the treatment of defective tissues and organs.

Bio Nova International is privately-held and is head-quartered in Melbourne, Australia. Bio Nova develops products using its proprietary technology and sells the Omniflow II product range via its global network of distribution partners in over 30 countries – including most of Europe, Australia, Canada, parts of Latin America and Asia.

For more information, visit www.bionova.com.au