

BIBITEC produces clinical supplies for biomimetic immune hormone

BIBITEC, Bielefeld, Germany, September 11 2009 – BIBITEC GmbH, specialized in the production of recombinant proteins, monoclonal antibodies and APIs for use in clinical trials up to phase III, has been assigned to develop a new cell cultivation process for Immunservice's lead product. The assignment also includes GMP-compliant production of the product for use in clinical trials phases I and II as well as process analytics.

The lead product, that has been developed by Immunservice, Hamburg, Germany, received Orphan Designation from the EMEA (European Medicines Agency) for advanced renal cell carcinoma, a quickly fatal disease, and a "Public Summary of Positive Opinion" for completed clinical studies has been published. Clinical trials with a novel cell culture process developed by BIBITEC shall help to elucidate its use for other indications.

The drug substance is an immune-relevant cytokine that has been developed according to biomimetic principles. Biomimetic approaches mimic and imitate the natural structure and mode of action of immune hormones, to develop highly effective and marketable drugs that improve survival and quality of life in patients.

Prof. Dr. Dr. Edith Huland, General Manager of Immunservice GmbH comments: "BIBITEC is a CMO with a proven track record and matches all our requirements to further develop our lead product. Only recently, BIBITEC successfully completed the process development and optimization as well as GMP-compliant production of EPO for use in clinical trials. The entire production and purification process was successfully transferred to large-scale production and market supply."

Prof. Dr. Dirk Lütkemeyer, General Manager of BIBITEC comments: "The biomimetic approach of Immunservice fundamentally improves the therapeutic potential and safety of immune hormones as it considers the biological rationale and principles. We are very pleased to support Immunservice in the development and production of its highly promising drug candidate."

About BIBITEC - www.bibitec.de

BIBITEC GmbH is GMP-certified and specializes in the production of recombinant proteins, monoclonal antibodies and APIs for use in clinical trials up to phase III using mammalian cells. The activities comprise the areas development and optimization of production processes, protein analytics and quality assurance. The fermentation capacity in mammalian cells is up to 100 L. Protein purification is located in clean rooms class C. BIBITEC was founded in 2001 by internationally recognized experts at the University of Bielefeld, Germany, and has since then cooperated with various pharmaceutical and biotechnology companies.

About Immunservice - www.immunservice.com

Immunservice is a biopharmaceutical company addressing orphan disease indications as well as large market indication areas, especially those of high unmet medical need.

Immunservice's unique biomimetic approach translates natural systems involving key immune hormones into well tolerated highly effective therapeutic innovations to improve survival and quality of life in patients.

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