

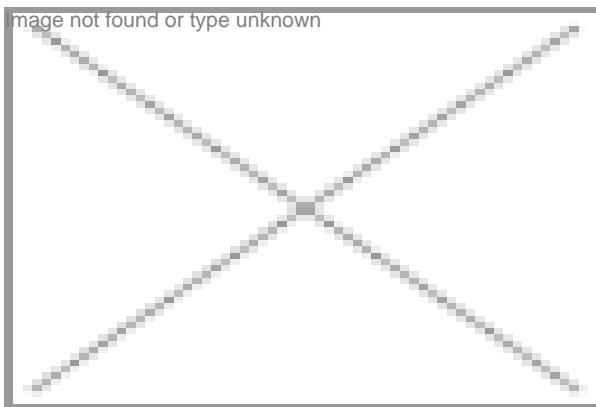
Mission: Recombinant FSH for fertility disorder

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Deriving the maximum benefit from SBIRI funding, Bharat Serum & Vaccines has successfully managed to develop an indigenous product to

Fertility disorders, for centuries, have been the cause of grave concern for women across the globe. Working in this direction, the Mumbai-based Bharat Serums & Vaccines (BSVL) has produced the country's first indigenously developed recombinant follicle stimulating hormone (FSH). This product is used extensively to treat fertility disorders in women. The timely availability of the Small Business Innovation Research Initiative (SBIRI) funding provided the much needed support to the company's in-house efforts and funds for developing and commercializing the product. It also encouraged the company to expand its R&D capabilities and

capacity.

The trademark name of the product is "FOLIGRAF" (r-hFSH), and it is a sterile freeze dried preparation of follicle stimulating hormone in genetically engineered Chinese hamster ovary (CHO) cells. The r-hFSH is a heterodimeric glycoprotein consisting of two non-covalently linked alpha and beta subunits. It is presented in lyophilized form of 75 and 150 IU/vial, intended for subcutaneous injection.

Following intravenous administration, r-hFSH is distributed to the extra cellular fluid space with an initial half-life of around two hours and eliminated from the body with a terminal half-life of about one day. The steady state volume of distribution and total clearance are 10 l and 0.6 l/h, respectively. One-eighth of the r-hFSH dose is excreted in the urine. Following subcutaneous

administration, the absolute bioavailability is about 70 percent. The study reports by the company concluded that r-hFSH is more effective than urinary FSH in terms of a lower total dose and a shorter treatment period needed to achieve pre-ovulatory conditions.

Before the BSVL product was introduced in the market, all the recombinant products used to be imported in the finished form. The FOLIGRAF vial comes in a packing of 75IU *1's and 150IU*1's with a cost of \$41 (1800) and \$79 (3500) respectively. Also the Recombinant FSH provides much better safety than the alternatives. It has an inherent advantage over the urinary derived FSH with no threat of transmission of viruses like HIV, HCV, HBsAg with r-FSH. Besides that the product has batch to batch consistency due to well controlled manufacturing process.

The Way Forward

BSVL's vaccine would help to make the country self sufficient in terms of meeting the domestic requirements. Launched in September 2008, the product is currently available throughout India with an expected revenue of 170 million in 2010-11.

BSVL has developed its competency in the areas of novel drug delivery systems (NDDS) and in development and purification of equine-based therapeutic products. With a focus on biopharmaceuticals, novel drug delivery systems and equine products, the company has made significant progress in R&D activities. To reduce the toxicity of the existing drugs significantly, the company is developing core competency into new drug delivery system. The different products that are in pipeline are liposomal doxorubicin (non pegylated), cisplatin emulsion, amphotericin B emulsion, amphotericin B lipid complex and propofol lipid free. For future growth, BSVL is targeting the regulated markets for its products through technology licensing.

Rahul Koul in New Delhi