



AVESTHAGEN's first biosimilar molecule AVDESP™ completes Clinical Batch Manufacturing in Malaysia, to move to Clinical Trials

Bangalore, November 30, 2010: AVESTHAGEN LIMITED, a leading knowledge based life sciences company pioneering the convergence between Food, Pharma and Population Genetics, today announced the completion of manufacturing of the clinical grade material of its first biosimilar molecule- AVDESP™ (biosimilar to Darbepoetin alfa), which will now be moving into Clinical Trials. Inno Biologics, Malaysia's biopharma Contract Manufacturing Organization has successfully developed Drug Substance batches for AVDESP™ that will be used by AVESTHAGEN for conducting clinical trials after formulation of the Drug Product in India. Avesthagen has also signed a Letter of Intent with Inno Biologics for the commercial manufacture of the two biosimilars- AVDESP™ and AVENT™.

AVDESP™ is used in the treatment of specific types of anemia, like anemia associated with chemotherapy/dialysis, where treatments are long drawn out. The recombinant erythropoietin (EPO) which is currently available as a treatment for anemia is administered 2 to 3 times weekly. Darbepoietin alfa has a longer biological half-life as compared to recombinant erythropoietin allowing a reduction in frequency of injections necessary to maintain the desired levels of systemic haemoglobin.



Darbepoietin is an EPO analogue with additional carbohydrate chains which confers a greater metabolic stability and hence the greater half-life than EPO (approximately three fold). This also means that the overall treatment cost is reduced significantly.

Dr. Viloo Morawala-Patell, Founder & CMD, AVESTHAGEN complimented Inno Bio for timely execution of the project and said, "AVESTHAGEN has a rich pipeline of biosimilars, four of which are already through the RCGM (Indian Regulatory body) for conducting clinical trials. We foresee Inno Biologicals playing an important role in meeting Avesthagen's goals

in getting biosimilars quickly to the market. We are aware that Malaysia provides a conducive environment for biotech ventures hence we look forward to be a part of the Malaysian mission. We will certainly explore ways to deepen and widen our partnership with Inno Biologicals and other Malaysian Government bodies which would be mutually rewarding in the long term.”

Avesthagen has indigenously developed several biosimilar drug molecules in its R&D Labs at Bangalore. Avesthagen has a very strong pipeline of biosimilars including the most sought-after biologics. Biosimilars reduce the cost of treatment of diseases drastically as they are often cheaper to produce. AVDESP™ will potentially reduce the financial burden as well as frequency of injections taken by the patients by 40-50%. Darbepoetin alfa clocked sales of USD 2.871 billion in 2009 and with high incidence rates of anemia in India -both due to chemotherapy and Chronic Kidney Disease; it is expected to have a significant market size.

For development of Darbepoetin alfa biosimilar Avesthagen worked on a cell line to efficiently produce the protein molecule. Avesthagen presented to the RCGM, a Govt. of India regulatory body, its data and conclusions on the toxicity and efficacy study of AVDESP™. RCGM approved the results and has directed Avesthagen to approach DCGI for conducting clinical trials.

Dato’ Dr Mohd Nazlee Kamal, Group Managing Director, Inno Bio Ventures Sdn Bhd, said, “The award of a letter-of-intent to undertake commercial manufacturing of biosimilars on the heels of our maiden project reinforces the trust and confidence of global Clients such as Avesthagen in our ability to secure such prized and complex projects and most importantly, deliver. The accomplishment by the company’s subsidiary was a reflection of the propensity and capacity of the Group to pioneer Malaysia’s foray into the global biotechnology arena”.

As a biopharma contract manufacturing organisation, Inno Bio focuses on manufacturing specific quantities of clinical grade material from cell cultures provided by its Clients to conduct drug testing in the preliminary stages before the drug goes into full commercial production. Cell culture is the process by which plant or animal cells are grown under laboratory conditions.

About AVESTHAGEN LIMITED

Avesthagen Limited is India’s leading integrated systems biology platform company that focuses on achieving convergence of food, pharma and population genetics leading to predictive preventive and personalized healthcare.

Avesthagen Limited has four strategic business units: bioPharmaceutical, bioNutrition, bioAgriculture and Science & Innovation, Its partners include multiple top 10 global companies in each of its fields of research. Since its inception Avesthagen has grown into one of India’s leading healthcare biotech companies in addition to its agri-biotechnologies product pipeline, development of clinically validated botanical bioActives, derived from Indian medicinal plants, as well as the development of a pipeline of bio-similar drugs.

Headquartered in Bangalore, India, the company employs 450 people worldwide.

About Inno Biologics

Inno Biologics Sdn Bhd is a subsidiary company of Inno Bio Ventures Sdn Bhd, a Ministry of Finance Incorporated Company, with a close affiliation with the Ministry of Science, Technology and Innovation.

Inno Biologics' services encompass gene cloning and expression using mammalian cell expression system, bioprocess development and cGMP biopharmaceutical manufacturing.

Inno Biologics is part of the Boehringer Ingelheim CMO (Contract Manufacturing Organization) network, member of Massachusetts Institute of Technology- Centre of Biomedical Innovation (CBI) Biomanufacturing Alliance and strategic partners with CEVEC GmbH and CIMAB SA.

For further information please contact:

Anil Ram Chauhan, anilram@avesthagen.com
Ishaan Khanna, ishaan.khanna@avesthagen.com