



Avesthagen starts Clinical Trials for its leading biosimilar- AVDESP™

Bangalore, March 3, 2011: AVESTHAGEN LIMITED, a leading knowledge based life sciences Company pioneering the convergence between Food, Pharma and Population Genetics today announced that its leading biosimilar molecule- AVDESP™ is moving into clinical trials.

AVDESP™ is Avesthagen's biosimilar to Darbepoietin alfa. AVDESP™ is used in the treatment of specific types of anemia, like anemia associated with chemotherapy and 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. In 2010, it clocked global sales of USD 2.5 billion.

Clinical Batch Manufacturing for the molecule was completed at Inno Biologics, Malaysia. Avesthagen has contracted Quintiles to conduct the trials and the trial which will be carried out in India is being designed by global experts to ensure that the entire process-right from the study protocol, patient recruitment to the primary, secondary end-points as well as the safety and efficacy end-points are all based on international norms. The trial will be carried out for both the indications for which Darbepoietin alfa has been approved- anemia due to Chronic Kidney Disease and anemia associated with Chemotherapy.

Commenting on this development Dr. Viloo Morawala-Patell, Founder and CMD, AVESTHAGEN said, "This is a significant milestone in the lifecycle of our biosimilar program. Avesthagen has a rich pipeline of biosimilars through which we intend to provide cost-effective healthcare solutions to patients across the globe."

Avesthagen has a strong pipeline of biosimilars under development, starting with AVDESP™ which it has positioned for the global markets. For development of Darbepoietin 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 directed Avesthagen to approach DCGI for conducting clinical trials.

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