

Bharat Biotech's REVAC-B⁺™ – Hepatitis B Vaccine Crosses 150 million Mark

New Revac-Bmcf The First Vaccine in the World to be manufactured free of Thiomersol (Mercury) and Cesium Chloride

Hyderabad, October 30th, 2008 – Bharat Biotech International Limited (BBIL/Bharat Biotech) the multi-dimensional biotechnology company specializing in product-oriented research, development and manufacturing of vaccines and bio-therapeutics announced today that it has crossed production and delivery of more than 150 million doses of **REVAC-B⁺™**, recombinant hepatitis B vaccine since its launch in October 1998.

REVAC-B⁺™ has been marketed and sold in more than 30 countries worldwide with manufacturing and quality standards on par with USFDA, EMEA and WHO guidelines. The Vaccine has established an excellent safety and efficacy profile since its launch 10 years ago.

In his comments, Dr. Krishna Ella, Chairman and Managing Director of Bharat Biotech said, "The success of **REVAC-B⁺™** bears testimony to our solid emphasis on R&D to develop vaccines that carry excellent safety and efficacy profiles. The Next Generation **REVAC-Bmcf** (Thiomersol and Cesium Chloride Free^{*}) Recombinant Hepatitis-B Vaccine manufactured by us are cost-effective and address the safety concerns expressed by parents and members of the medical profession." He added.

Bharat Biotech is a major supplier of the Cesium Chloride Free Hepatitis-B Vaccines, It has taken steps to ensure a smooth transition for customers from the traditional Hepatitis-B vaccine to the new preservative-free **REVAC-Bmcf** (Thiomersol and Cesium Chloride Free^{*}) vaccine apart from effectively upgrading and optimizing production technologies to ensure the phasing out of thiomersol as preservative in some of BBIL products.

REVAC-Bmcf (Thiomersol and Cesium Chloride Free^{*}) vaccine contains the same components utilized in BBIL's previous Hepatitis-B vaccine, but now it is supplied preservative-free in a single-dose vial. Bharat Biotech had successfully manufactured a preservative-free pediatric vaccine of a highly reputed MNC on a contract basis and the product was exported to a regulated market in Far East.

- * The preservative thiomersal which contains mercury is used in the production process for many vaccines. There are trace amounts of thiomersol left over from the production process that cannot be removed, but these amounts are so small that Regulatory agencies consider the vaccine to be preservative-free. The Global Advisory Committee on Vaccine Safety of WHO in its July 2006 Statement on thiomersol stated that it does not support concerns over safety of thiomersol. The Immunization Safety Review Committee of the National Academy of Sciences Institute of Medicine, USA, however, recommends for a phase-out of thiomersol as a preservative in vaccines.

About Recombinant Technology

The Hepatitis-B surface Antigen (HBsAg) is produced in genetically engineered yeast cells of *Pichia pastoris* which carry the gene that codes for the major surface antigen protein of the hepatitis-B virus. HBsAg expressed in yeast cells is purified by complex physical, chemical and biochemical processes. The resultant highly purified surface antigen assembles spontaneously into spherical particles of an average diameter of 20-24nm containing non-glycosylated polypeptides in a lipid matrix. An extensive and rigorous R&D processes characterised and confirmed that these 20-24nm spherical particles resemble the natural HBsAg protein in their antigenic properties. The efficacy and safety of the formulated **REVAC-Bmcf** is ensured through stringent adherence to the highest standards of bio-process control and consistent Quality Assurance measures. No substance of Human origin is used in the manufacture of HBsAg protein.

Safety Information

There are risks associated with all vaccines, including **REVAC-Bmcf** (Thiomersal and Cesium Chloride Free) Recombinant Hepatitis-B Vaccine for Paediatric Use). **REVAC-Bmcf** has proven low reactogenicity and is well tolerated. Open and comparative trials did not show adverse reactions in the vaccines. Inflammation at the site of injection or a febrile reaction may be observed in some subjects.

In rare cases of post-vaccinal hypersensitivity, the common symptoms that are quickly recognised by the physician are dizziness, headache, nausea, abdominal pain, rash, pruritis, urticaria, arthralgia, myalgias and similar associated symptoms and side effects. As with any vaccine, vaccination with **REVAC-Bmcf** vaccine may not protect 100% of individuals.

For full prescribing information, visit www.bharatbiotech.com

About Bharat Biotech International Limited

Bharat Biotech is a multi-dimensional biotechnology company specialising in product-oriented research, development and manufacturing of vaccines and bio-therapeutics. It is the first bio- Pharma company in the country to be audited and approved by Korean Food & Drugs Administration and has set a new benchmark in quality standards that epitomizes the tremendous progress of Indian biotechnology in the global arena. For more information, visit: www.bharatbiotech.com

Important information about forward-looking statements

Certain statements in this press release may be considered "forward-looking". Such forward-looking statements are based on current expectations, and, accordingly, entail and are influenced by various risks and uncertainties. The Company therefore cannot provide any assurance that such forward-looking statements will materialize and does not assume an obligation to update or revise any forward-looking statement, whether as a result of new information, future events or any other reason. Additional information concerning risks and uncertainties affecting the business and other factors that could cause actual results to differ materially from any forward-looking statement is contained in the prospectus.

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