Biovest Conducts Meeting with EMA Advancing Process to Seek EU Approval for Cancer Vaccine

The Associated Press

TAMPA, Fla. & MINNEAPOLIS--(BUSINESS WIRE)--Sep 20, 2012--Biovest International, Inc. (OTCQB: BVTI), a majority-owned subsidiary of Accentia Biopharmaceuticals, Inc. (OTCQB: ABPI), today reported milestone achievements advancing BiovaxID™, Biovest's personalized cancer vaccine for the treatment of non-Hodgkin's lymphoma, including a recently conducted regulatory meeting with the European Medicines Agency (EMA) and the appointment of a key contributor to the Human Genome Project to its Scientific Advisory Board.

Biovest reported that it recently conducted a regulatory meeting with the EMA in London, at which the EMA provided Biovest with information to help finalize Biovest's pending Marketing Authorization Application (MAA) seeking EU marketing approval for BiovaxID. The meeting addressed legal, regulatory, and scientific matters for the planned MAA in order to facilitate subsequent validation and assessment of the application. The Company believes that the meeting with the EMA was favorable and will support final preparation and filing of the MAA anticipated for early next year. Based on the meeting, Biovest anticipates that the filing and review of the application will proceed in a timely and customary manner. Next steps in the pre-submission process will include upcoming meetings planned with the Rapporteur and Co-Rapporteur.

The Rapporteur and Co-Rapporteur are members of the EMA's Committee for Medicinal Products for Human Use (CHMP). They are supported by a team of assessors from their National Authority. The Rapporteur and Co-Rapporteur have been assigned with the primary responsibility of preparing and delivering an approvability evaluation report under the EMA's Centralized Procedure. Under this procedure, a registration of BiovaxID throughout all EU-member countries can be obtained simultaneously via a single application. Upon approval, BiovaxID would be the first cancer vaccine available in Europe for lymphoma patients.

In other news, Biovest announced that it appointed David J. States, M.D., Ph.D., to the Company's Scientific Advisory Board. Dr. States is a systems biologist and leader who helped to established the discipline of bioinformatics. He received his M.D. and Ph.D. from Harvard University and clinical training in internal medicine at the University of California, San Diego and the National Institutes of Health in Bethesda, Maryland. He is board certified in internal medicine and is a Fellow of the American College of Medical Informatics. Dr. States has been a leader in establishing bioinformatics as a field including work on molecular modeling, genome mapping and sequencing and proteomics. Notably, Dr. States has been involved in the Human Genome Project from its inception and helped to establish the NIH National Center for Biotechnology Information (NCBI).

About Biovest International, Inc. Biovest International, Inc. develops active immunotherapies (cancer vaccines) which treat and diminish the aggressiveness of B-cell non-Hodgkin's lymphoma, a cancer of the immune system. The Company's lead personalized cancer vaccine product candidate, BiovaxID™, has been evaluated in three clinical trials conducted in collaboration with the U.S. National Cancer Institute (NCI) demonstrating that BiovaxID increases the duration of cancer remission following chemotherapy and induces immune responses which correlate highly with long-term survival. Biovest is currently in the process of pursuing European and Canadian marketing approvals for BiovaxID.

Headquartered in Tampa, Florida with its bio-manufacturing facility based in Minneapolis, Minnesota, Biovest is publicly-traded on the OTCQB™ Market with the stock-ticker symbol "BVTI", and is a majority-owned subsidiary of Accentia Biopharmaceuticals, Inc. (OTCQB: "ABPI").

For further information, please visit: Forward-Looking Statements: Statements in this press release that are not strictly historical in nature constitute "forward-looking statements." Such statements include, but are not limited to, statements about Biovest and its product candidate, BiovaxID™ and any other statements relating to products, product candidates, product development programs, the FDA, the EMA, Health Canada or clinical study process including the commencement, process, or completion of clinical trials or the regulatory process. Such statements may include, without limitation, statements with respect to the Company's plans, objectives, expectations and intentions, and other statements identified by words such as "may," "could," "would," "should," "believes," "expects," "anticipates," "estimates," "intends," "plans," or similar expressions. In particular (and without limitation), statements regarding the timing of anticipated filing of a Marketing Authorization Application for BiovaxID with the EMA or a New Drug Submission for BiovaxID with Health Canada, pre-filing meetings with the FDA or other jurisdictions and/or commercial plans reflect current expectations but are subject to inherent risks of delay in compilation and finalization of all components of the licensing application. Such forward-looking statements involve known and unknown risks, uncertainties, and other factors that may cause the actual results of Biovest to be materially different from historical results or from any results expressed or implied by such forward-looking statements. These factors include, but are not limited to, risks and uncertainties related to the progress, timing, cost, and results of clinical trials and product development programs; difficulties or delays in obtaining regulatory approval for product candidates; competition from other pharmaceutical or biotechnology companies; and the additional risks discussed in filings with the Securities and Exchange Commission. All forward-looking statements are qualified in their entirety by this cautionary statement, and Biovest undertakes no obligation to revise or update this news release to reflect events or circumstances after the date hereof. The product names used in this statement are for identification purposes only. All trademarks and registered trademarks are the property of their respective owners.
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