



## **PROLOR BIOTECH GRANTED EU GMP CERTIFICATION FOR LEAD CANDIDATE HGH-CTP, A PRE-CONDITION FOR ITS PHASE II CLINICAL TRIAL**

**Nes-Ziona, Israel– June 29, 2010** – PROLOR Biotech, Inc. (NYSE Amex: PBTH), a company developing next generation biobetter therapeutic proteins, today announced that it has received formal Good Manufacturing Practice (GMP) certification for hGH-CTP, the company's proprietary biobetter version of human growth hormone. GMP certification is required by the European Union (EU) clinical trials legislation as a precondition for conducting clinical trials in EU member countries.

Article 13 of 2001/20/EC of the EU clinical trials legislation was established to ensure, prior to the initiation of a clinical trial study in any EU member country, that the drug product to be used in such clinical trial study has been manufactured in accordance with EU GMP regulations and meets the conditions of the clinical trial authorization and the product specification file. PROLOR's facilities for working with hGH-CTP, as well as those of the contract manufacturing organizations for the drug substance and drug product, were inspected and audited as part of the assessment process.

"EU GMP certification is a rigorous process that we are delighted to have completed successfully," said Abraham Havron, Ph.D., CEO of PROLOR. "Preparation for the manufacturing audit process and the audit itself were a top priority for the company and a critical milestone for the first half of 2010. This certification allows PROLOR to move forward with our hGH-CTP Phase II clinical trial, which we expect to initiate later this summer."

### **ABOUT hGH-CTP**

hGH-CTP is PROLOR's proprietary biobetter version of human growth hormone. hGH is used for the long-term treatment of children and adults with growth hormone deficiency due to inadequate secretion of endogenous growth hormone. It is also sometimes used to counter involuntary weight loss and certain physical manifestations of aging. Currently available forms of hGH must be injected daily. In contrast, hGH-CTP is expected to require only bi-monthly or weekly injections. Current global sales of human growth hormone products are estimated at about \$3 billion annually.

### **ABOUT PROLOR BIOTECH**

PROLOR Biotech, Inc. is a biopharmaceutical company applying unique technologies, including its patented CTP technology, primarily to develop longer-acting, biobetter, proprietary versions of already approved therapeutic proteins that currently generate billions of dollars in annual global sales. The CTP technology is applicable to virtually all proteins, and PROLOR is currently developing long-acting versions of human growth hormone, which is in clinical development, and interferon beta, factor VII, factor IX and erythropoietin, which are in preclinical development, as well as GLP-1 and other therapeutic peptides. For more information on PROLOR, visit [www.prolor-biotech.com](http://www.prolor-biotech.com).

**Safe Harbor Statement:** *This press release contains forward-looking statements, which may be identified by words such as “expects,” “plans,” “projects,” “will,” “may,” “anticipates,” “believes,” “should,” “would”, “intends,” “estimates,” “suggests” and other words of similar meaning, including statements regarding the results of current clinical studies and preclinical experiments and the effectiveness of PROLOR’s long-acting protein programs, which are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Investors are cautioned that forward-looking statements involve risks and uncertainties that may affect PROLOR’s business and prospects, including the risks that PROLOR may not succeed in generating any revenues or developing any commercial products, including any long-acting versions of human growth hormone, erythropoietin, interferon beta, GLP-1 and other products; that the long-acting products in development may fail, may not achieve the expected results or effectiveness and/or may not generate data that would support the approval or marketing of these products for the indications being studied or for other indications; that ongoing studies may not continue to show substantial or any activity; that the actual dollar amount of any grants from Israel’s Office of the Chief Scientist is uncertain and is subject to policy changes of the Israeli government, and that such grants may be insufficient to assist with product development; and other risks and uncertainties that may cause results to differ materially from those set forth in the forward-looking statements. The results of clinical trials in humans may produce results that differ significantly from the results of clinical and other trials in animals. The results of early-stage trials may differ significantly from the results of more developed, later-stage trials. The development of any products using the CTP platform technology could also be affected by a number of other factors, including unexpected safety, efficacy or manufacturing issues, additional time requirements for data analyses and decision making, the impact of pharmaceutical industry regulation, the impact of competitive products and pricing and the impact of patents and other proprietary rights held by competitors and other third parties. In addition to the risk factors described above, investors should consider the economic, competitive, governmental, technological and other factors discussed in PROLOR’s filings with the Securities and Exchange Commission. The forward-looking statements contained in this press release speak only as of the date the statements were made, and we do not undertake any obligation to update forward-looking statements, except as required under applicable law.*

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