



PROLOR BIOTECH RECEIVES FDA CLEARANCE FOR A PHASE II TRIAL OF ITS LONG-ACTING HUMAN GROWTH HORMONE IN THE U.S.

Nes-Ziona, Israel– August 24, 2010 – PROLOR Biotech, Inc. (NYSE Amex: PBTH), a company developing next generation biobetter therapeutic proteins, today announced that it has received regulatory clearance from the U.S. Food and Drug Administration (FDA) to conduct a Phase II clinical trial in the U.S. of its longer-acting version of human growth hormone, hGH-CTP. The regulatory clearance followed PROLOR's submission of an Investigational New Drug (IND) application for hGH-CTP that included preclinical and Phase I clinical data, as well as plans for additional animal studies that the company intends to complete prior to initiation of Phase III trials. The hGH-CTP Phase II clinical program is currently ongoing in various clinical centers in Europe.

"The FDA regulatory clearance for conducting a Phase II trial of hGH-CTP in the U.S. is an important milestone for PROLOR," said Dr. Abraham Havron, CEO of PROLOR. "This Phase II trial, which is underway at centers in a number of European countries, is an integral part of a comprehensive and coordinated clinical development program that has been carefully designed to generate the data that we anticipate will be necessary to obtain future marketing authorization in the U.S. and Europe, as well as in other localities. We currently do not plan to include sites in the U.S. in this Phase II trial, but the FDA clearance helps ensure that we will be fully in sync with regulatory requirements in key territories, including the U.S., allowing us to utilize the hGH-CTP European Phase II program as the basis for our anticipated submission of applications to conduct Phase III trials in both the U.S. and Europe."

PROLOR is developing hGH-CTP to provide growth hormone deficient adults and children with growth hormone therapy that requires only once-weekly or bi-monthly injections, rather than the multiple injections per week required by current hGH regimens. The hGH-CTP Phase II clinical program follows a successful Phase I trial that suggested that hGH-CTP, in addition to meeting all safety and tolerability endpoints, could potentially be effective when injected just twice per month.

The hGH-CTP Phase II trial is a randomized, open-label, dose-finding study to evaluate the safety, tolerability, pharmacokinetics and pharmacodynamic properties of hGH-CTP injected either weekly or twice-monthly in patients with growth hormone deficiency who currently receive daily injections of growth hormone. The trial is being conducted at up to 14 sites in six countries.

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.

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.*

PROLOR CONTACT:
Shai Novik, President
PROLOR Biotech, Inc.
Tel: +1 866 644-7811

Email: shai@prolor-biotech.com

MEDIA CONTACT:
Barbara Lindheim
GendeLLindheim BioCom Partners
+1 212 918-4650