



## **PROLOR BIOTECH REPORTS POSITIVE TOP-LINE RESULTS FROM PHASE I STUDY OF ITS LONGER-ACTING VERSION OF HUMAN GROWTH HORMONE**

***—Data Show PROLOR’s Biobetter Form of hGH has Potential to Reduce Required Dosing Frequency from One Injection Per Day to Two Injections Per Month—***

***—Phase I Safety and Tolerability Endpoints Met—***

**Nes-Ziona, Israel – February 2, 2010** – PROLOR Biotech, Inc., (OTCBB: PBTH) today reported positive top-line results from a Phase I study of its longer-acting version of human growth hormone (hGH). The study was designed to measure the potential durability (half-life), overall drug exposure (AUC) and biological efficacy, as well as the safety and tolerability of PROLOR’s longer-acting CTP-modified human growth hormone (hGH-CTP).

The Phase I study enrolled 24 healthy adults who were randomized to receive one of three doses of hGH-CTP (4mg, 7mg, or 21mg) or placebo. The study results showed that safety and tolerability endpoints were met at all doses in all participants. The potential clinical efficacy of hGH-CTP was assessed by measuring the extent to which hGH-CTP induced insulin-like growth factor-1 (IGF-1) in subjects. This biomarker is the clinically accepted primary indicator of hGH biological activity and is used by endocrinologists to optimize dosing for hGH-deficient adults. Based on this measure, the study results suggest that the daily injections required by patients using conventional hGH could potentially be replaced with just two monthly injections of hGH-CTP.

“We believe that the results from this first human clinical trial of a PROLOR CTP-modified drug are very encouraging and exemplify the promise of biobetter therapeutics,” said Dr. Avri Havron, CEO of PROLOR Biotech. “Our hGH-CTP appears to be a safe and highly potent version of commercially available human growth hormone. Replacing the daily injections required by current hGH users with just two injections per month could dramatically improve the quality of life for patients receiving growth hormone therapy. Based on these Phase I results, we anticipate moving forward rapidly with the planning and execution of a Phase II study of hGH-CTP.”

### **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, 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,” “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 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](mailto:shai@prolor-biotech.com)

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