



PROLOR BIOTECH ANNOUNCES POSITIVE TOP-LINE RESULTS FROM PHASE II TRIAL OF ITS LONG-ACTING HUMAN GROWTH HORMONE THAT ACHIEVED ALL KEY STUDY GOALS

--Trial of hGH-CTP in Growth Hormone Deficient Adults Achieved Key Efficacy and Safety Endpoints--

--Positive Results Set Stage for Initiating Phase III Trial Expected to Begin in 2012--

Nes-Ziona, Israel – August 4, 2011 – PROLOR Biotech, Inc. (NYSE Amex: PBTH) today reported positive results from a Phase II clinical trial of its long-acting CTP-modified version of human growth hormone (hGH-CTP) in growth hormone deficient adults. The data show that a single weekly injection of hGH-CTP has the potential to replace seven consecutive daily injections of currently marketed human growth hormone (hGH).

"The findings from the Phase II trial are very promising for adults in need of growth hormone therapy and their physicians," said Dr. Avri Havron, Chief Executive Officer of PROLOR. "The results show that hGH-CTP can potentially provide an exceptional therapy for adults with growth hormone deficiency when given once weekly, while demonstrating an excellent safety and tolerability profile across all doses and for all patients in the trial. The Phase II trial results have enabled us to identify the most suitable dose range of hGH-CTP for our planned Phase III trial, and we look forward to its anticipated initiation in 2012."

"Based on these positive results, PROLOR is offering patients who participated in the Phase II trial the opportunity to continue treatment with single weekly injections of hGH-CTP for an additional four months," noted Shai Novik, President of PROLOR. "Based on feedback from patients and their physicians, we expect that the majority of patients who completed the Phase II study will elect to participate in the four-month extension period, which we view as a powerful endorsement of hGH-CTP in view of the fact that those patients who elect to participate will have to undergo continued clinical monitoring requirements such as routine blood collections. We expect that information from the voluntary extension period will provide additional data enabling us to further verify the anticipated doses and titration schedule of hGH-CTP for the planned Phase III trial."

The objectives of the randomized open-label, multicenter Phase II trial were to measure the safety and tolerability of hGH-CTP in growth hormone deficient adults and to assess dose ranging and dose response in order to identify the dose range that will be targeted in the planned Phase III trial.

Design of the Phase II Trial

The three main cohorts in the trial received a single weekly dose of hGH-CTP for a period of four weeks, containing 30%, 45% or 100% of the equivalent cumulative commercial hGH dose these patients would usually inject each day over the course of seven days (referred to as the "30%," "45%" and "100%" cohorts, respectively.) The top-line data reflect results from 39 patients, with 13 patients in each cohort comprised of 11 males and two females.

In addition to the three main cohorts, PROLOR researchers are also enrolling growth hormone deficient adults in an experimental fourth cohort, which is being conducted outside of the formal Phase II trial. The patients in the experimental fourth cohort are receiving a single injection of hGH-CTP once every two weeks that contains 50% of the cumulative commercial dose of hGH that they would usually inject each day during a two-week period. Enrollment in this experimental cohort is ongoing.

Efficacy for the three main cohorts receiving a single weekly injection of hGH-CTP is defined by measuring daily insulin-like growth factor 1 (IGF-1) levels within the desired therapeutic range over a period of seven days during the last week of treatment in the study. The desired therapeutic range is defined as an IGF-1 level that is between +2 standard deviations through -2 standard deviations from the average IGF-1 levels expected in a normal population stratified by age group and gender. In addition, the trial measured IGF-1 levels within a narrower range of +/- 1.5 standard deviations from the average normal population IGF-1 levels, for the purpose of learning more about the variance of patients within the normal range.

Phase II Trial Top-Line Data Analysis

As shown in the table below, the study data show that patients in all three cohorts (the “30%,” “45%” and “100%” cohorts) achieved average IGF-1 levels that were within the normal range on 100% of the days when they were assessed. In addition, the data show that patients in each of the cohorts achieved average IGF-1 levels within the narrow definition of the normal range on many or most of the days when they were assessed, indicating a favorable variance profile within the normal range.

hGH-CTP demonstrated excellent safety and tolerability in all patients across all trial cohorts, with no apparent issues. In addition, there were no indications that hGH-CTP can induce excessive levels of IGF-1 in patients above the normal range when used in high doses.

Cohort	% Days Within Normal Range (+/- 2 SD)	Avg. Cmax (preferred below +2 SD)	Variance Measure: % Days Within Narrow Normal Range (+/-1.5 SD)
30%	100%	-0.9	57%
45%	100%	0.1	100%
100%	100%	0.4	86%

- The table shows the average percent of days within the normal therapeutic range (+/- 2 SD), average percent of days within a narrower normal therapeutic range (+/- 1.5 SD), and average Cmax (highest concentration level) of IGF-1 for males, measured during the last treatment week, expressed in standard deviations from the mean IGF-1 levels expected in the normal population.
- The incremental average elevated levels of IGF-1 of the two females included in each cohort during the last treatment week were dose proportional. The small number of females in each cohort does not allow for a statistical analysis, yet provides a positive indication of response.

Based on the Phase II study results, PROLOR researchers estimate that 2mg per week of hGH-CTP, containing 50% of the cumulative weekly hGH dose that an adult patient would usually be prescribed as the initial treatment dose, has a high likelihood of being defined as the starting dose for males and females in the adult Phase III trial.

ABOUT PROLOR

PROLOR Biotech, Inc. is a clinical stage 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 Phase II clinical development, as well as Factor VII, Factor IX, interferon beta, erythropoietin, an anti-obesity peptide and agents for atherosclerosis and rheumatoid arthritis, which are all in preclinical development. For more information, 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,” “has the potential to” 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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