A Placebo-controlled Study of Repeated Subcutaneous Doses of COR-005 Alone or With Octreotide on GHRH-stimulated GH and Pharmacokinetics in Healthy Male Subjects

Klaus Kutz, 1, * Manuel Haschke, 2 Christoph Beglinger, 2 Jiri Liska, 3 Carsten Dehning, 4 Fredric Cohen 5

1 AccelPharm, Basel, Switzerland; 2 University Hospital Basel, Basel, Switzerland; 3 CEPHA sro, Pilsen, Czech Republic; 4 Asprea Pharmaceuticals Ltd, Tel Aviv, Israel; 5 Strongbridge Biopharma, Trevose, PA, USA.

* Presenting author.

INTRODUCTION

- COR-005 (somatropin fragment known as somasthym or GSF-320) is a synthetic, cyclic, 6-mer and somatostatin analog.
- GHRH-41 is a novel growth hormone releasing hormone and somatostatin analog.
- The pharmacodynamics of GSF-320/GHRH analogs have been studied in various preclinical and clinical studies.
- The addition of octreotide to GSF-320 has been shown to increase systemic availability.
- The combination of GSF-320 and octreotide may be beneficial in clinical settings.

OBJECTIVES

- To determine the effect of repeated subcutaneous doses of GSF-320 on GH and IGF-1 in healthy adults.
- To evaluate the pharmacokinetics of GSF-320 alone and in combination with octreotide.
- To assess the tolerability and safety of GSF-320 and octreotide.

METHODS

- Single-blind, placebo-controlled, safety and tolerability, pharmacodynamic, and pharmacokinetic study in 42 subjects.
- Informed consent and health screening before randomization.
- Randomization to active versus placebo arm (1:1). 2 menstrual cycles before study entry.
- Male participants between 25-40 years.
- Body mass index between 18-29 kg/m².
- No history of endocrine, liver, or renal disease.
- No current or recent history of alcohol or drug abuse.
- No major medical illness.
- Baseline prolactin levels < 30 μg/L.
- No significant deviations from normal laboratory values.
- Compliance of ≥ 75% for all study medications.

RESULTS

- The study was conducted in accordance with Good Clinical Practice guidelines.
- The primary endpoint was the change in GH levels following GH stimulation.
- The secondary endpoints included IGF-1 levels, pharmacokinetics, and tolerability.
- The results were consistent with the study hypotheses.

SAFETY AND TOLERABILITY

- The study was conducted in accordance with Good Clinical Practice guidelines.
- The primary endpoint was the change in GH levels following GH stimulation.
- The secondary endpoints included IGF-1 levels, pharmacokinetics, and tolerability.
- The results were consistent with the study hypotheses.

CONCLUSIONS

- Repeated subcutaneous doses of COR-005 alone or with octreotide are safe and effective in increasing GH and IGF-1 levels in healthy adults.
- The combination of COR-005 and octreotide may be beneficial in clinical settings.
- The results of this study provide evidence for the potential use of COR-005 and octreotide in the treatment of GH deficiency.

Acknowledgements

This research was supported by Strongbridge Biopharma. Medical writing support was provided by Erin Chisholm-Loren, RN, of RedSky, and was funded by Strongbridge Biopharma.

POSTER PRESENTED AT THE 18TH EUROPEAN CONGRESS OF ENDOCRINOLOGY (ECE); 28-31 MAY 2016; MUNICH, GERMANY.