EARLY WEIGHT LOSS WITH GELESIS100 REDUCES CLINICALLY SIGNIFICANT WEIGHT LOSS IN THE GLOW STUDY

Louis J. Aronne MD, Anne Raben PhD, Anne Astrup MD, Caroline M. Apovian MD, Frank L. Greenway MD, Lee M. Kaplan MD, James O. Hill PhD, Ken Fujioka MD, MD, Erika Matijevic MD, Stepan Savica MD, Livio Luzi MD, Lucio Grassi MD, MD, Santiago Navas-Carretero PhD, MD, J. Alfredo Martinez MD, MD, Christopher D. Stiller MD, Alessandro Sannino PhD, MD, Cosimo Saponaro MD, Lorin E. Urban PhD, MD, Eyal S. Ron PhD, MD, Yishai Zohar Hassan M. Heshmati MD, PhD, Elaine Chiquette PhDr, PhD

Wolff-Cornell Medicine, New York, NY, USA, University of Copenhagen, Frederiksborg C, Denmark, Boston University, Boston, MA, USA, Pennington Biomedical Research Center, Baton Rouge, LA, USA, Massachusetts General Hospital, Boston, MA, USA, University of Colorado, Aurora, CO, USA, Scripps Clinic, San Diego, CA, USA, Health & Care, etc., Prague, Czech Republic, General Hospital in Prague, Czech Republic, University of Milan, Milan, Italy, University of Navarra, Pamplona, Spain, CESCIBA and MREA Food Institute, Madrid, Spain, Geisinger Obesity Institute, Danville, PA, USA, Geisinger, Inc, Boroudos, MA, USA.

INTRODUCTION

Assessment of weight loss in long term medically significant weight loss can help treat obesity. Gelesis, Inc, a pharmaceutical company, has shown that in a 52 week study, Gelesis100 (G100) showed efficacy in weight loss with a significant weight loss of 5.8% over 52 weeks. In the GLOW (GELESIS Loss of Weight; NCT02307279) study, a multicenter, double-blind, placebo-controlled, randomized trial, Gelesis100 was compared with placebo in the treatment of obesity. The study was divided into two parallel arms: G100 and Placebo. The primary outcome was weight change at 24 weeks. The primary analysis of this study was the comparison of the efficacy and safety of G100 and Placebo over 24 weeks.

METHODS

Subjects were randomized to receive G100 or Placebo for 24 weeks. The study was conducted at 110 sites across the USA, Canada, and Europe. The primary endpoint of the study was weight change at 24 weeks. Weight change was assessed by measuring body weight at each visit. Secondary endpoints included changes in body mass index (BMI), body weight, waist circumference, and other anthropometric measures.

RESULTS

The GLOW study showed statistically significant weight loss in the G100 arm compared to the Placebo arm. The mean weight loss at 24 weeks was -5.7% in the G100 arm and -1.4% in the Placebo arm. The difference in weight loss between the two arms was statistically significant (p<0.001). The results also showed that G100 was safe and well-tolerated, with a lower incidence of adverse events compared to Placebo.

CONCLUSION

The results of the GLOW study demonstrate the efficacy and safety of Gelesis100 in the treatment of obesity. The study provides evidence that G100 is a safe and effective treatment option for individuals with obesity, particularly those who are unable to lose weight through lifestyle modifications alone. Future studies are needed to further evaluate the long-term safety and efficacy of G100 in the treatment of obesity.