C46

Lanreotide Depot/Autogel in Intestinal and Pancreatic Neuroendocrine Tumors According to Body Mass Index: Subgroup Analyses from the CLARINET Study

Edward M. Wolin MD[1]; Martyn E. Caplin DM[2]; Marianne E. Pavel MD[3]; Jarosław B. Ćwikła MD PhD[4]; Alexandria T. Phan MD[5]; Markus Raderer MD[6];Eva Sedláčková MD[7]; Guillaume Cadiot MD PhD[8]; Jaume Capdevila MD[9]; Lucy Wall MD[10]; Guido Rindi MD PhD[11]; Alison Langley MSc[12]; Edda Gomez-Panzani MD[12]; Philippe B. Ruszniewski MD PhD[13]
on behalf of the CLARINET Study Group

[1]Markey Cancer Center, Lexington, KY, USA;
[2]Royal Free Hospital, London, UK
[3]Charité University Medicine Berlin, Berlin, Germany
[4]University of Varmia and Masuria, Olsztyn, Poland
[5]The Methodist Hospital, Houston, TX, USA
[6]University Hospital, Vienna, Austria
[7]First Faculty of Medicine and General Teaching Hospital, Prague, Czech Republic
[8]Robert-Debré Hospital, Reims, France
[9]Vall d'Hebron University Hospital and Vall d'Hebron Institute of Oncology, Barcelona, Spain
[10]Western General Hospital, Edinburgh, UK
[11]Università Cattolica del Sacro Cuore, Rome, Italy
[12]Ipsen, Les Ulis, France
[13]Beaujon Hospital, Clichy, France

Background: CLARINET showed antitumor effects with lanreotide Autogel (Depot in USA) 120 mg in metastatic intestinal/pancreatic neuroendocrine tumors (NETs). Here, we characterize treatment effects within subgroups defined *post hoc* by baseline body mass index (BMI).

Methods: CLARINET was a 96-week randomized trial of patients with metastatic grade 1/2 (Ki-67 <10%) nonfunctioning intestinal/pancreatic NETs (NCT00353496). Patients received lanreotide Autogel 120 mg (n=101) or placebo (placebo; n=103) every 4 weeks. Patient subgroups were based on well-known WHO BMI categories. Median progression-free survival (PFS) [95% confidence interval (CI)] was determined by Kaplan–Meier analysis, and hazard ratios (HRs) and CIs by using a Cox proportional hazards model with a single term for treatment (both on the intent-to-treat population); summary statistics were used for adverse events (AEs; safety population). PFS analyses investigated only the consistency of treatment effects across subgroups as the study was not otherwise powered for such analyses.

Results: In the lanreotide group median PFS was not reached in any BMI subgroup (vs 13–24 months for placebo); HRs favored lanreotide and were generally consistent with the overall population (Table). Incidences of AEs overall were similar across BMI and treatment groups; the most common AE was diarrhea (Table).

Conclusions: CLARINET subgroup analyses suggest that lanreotide has antitumor effects and a favorable safety/tolerability profile regardless of patient BMI.

Reference

Caplin ME, Pavel M, Cwikla JB, et al. Lanreotide in metastatic enteropancreatic neuroendocrine tumors. N Engl J Med. 2014;371(3):224-33. doi:10.1056/NEJMoa1316158