Oggetto: Terapia di mantenimento del Microcitoma polmonare con la Lanreotide ad alte dosi
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Terapia di mantenimento del Microcitoma polmonare con la Lanreotide ad alte dosi

Si apre uno spiraglio nella terapia di mantenimento del Microcitoma polmonare con la Lanreotide ad alte dosi? E' quanto si sta cercando di verificare attraverso questo trial randomizzato di fase III, patrocinato da FONICAP, che verra' presentato al prossimo IASLC 2017 di Tokyo in Giappone
A cura di Antonio Santo (UO Oncologia / GIVOP - AOUI Verona)

Multicenter Randomized Trial exploring Maintenance with Lanreotide (LAN) in SCLC patients (pts) expressing Somatostatine (SST) receptors, after response to upfront therapy: Efficacy results of the G04-2011 trial.
Pilotto S, Bria E, Galetta D, Grossi F, Fasola G, Romano G, Bonanno L, Bearz A, Papi M, Caprioli A, Catino A, Follador A, Rijavec E, Misino A, Surico G, Favaretto A, Giannone L, Tortora G, Giannarelli D, Santo A, on behalf of FONICAP (Forza Operativa Nazionale Interdisciplinare contro il CAncro del Polmone).

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Background. SCLC is characterized by both a rapid response and progression during and after standard upfront treatment. Thus, maintenance strategies have emerged as potential treatment opportunities, although to date all drugs have failed to significantly improve overall prognosis. SCLC cells are featured by a neuroendocrine phenotype, frequently expressing SST receptors. The aim of this study was to investigate the efficacy of the SST analogue LAN, as a maintenance strategy for SCLC pts after response to standard upfront treatment.
Methods. A multicentre, randomized, open-label, no-profit national trial was conducted, randomizing (1:1) SCLC (limited/extended disease, L/ED) pts expressing SST receptors (assessed by SST receptor scintigraphy) with objective response (CR or PR) after upfront platinum-based chemotherapy plus/minus radiotherapy to receive maintenance LAN 120

mg subcutaneously every 28 days, up to progressive disease (PD) for 1 year (Arm A), versus observation (Arm B). Primary end-point was 1-year Progression-Free Survival (PFS), defined as time from inclusion to documented progression or death for any cause. Primary intention-to-treat (ITT) analysis was planned (power: 80%; 2-tailed alpha-error: 5%) after 47 PFS events.

Results. Seventy-one pts (median age 66 [37-82]; male/female 72/28%; L/ED 39/61%; ECOG-PS 0-1/2 97/3%; previous best response CR/PR 6/94%) were randomized in 9 Italian centers. Median time from diagnosis and end-of-1st line to inclusion was 5.7 months (3-160) and 30 days (0-119), respectively. Median number of LAN doses and treatment duration (Arm A) was 4 (1-12) and 83 days (1-392), respectively. With a median follow-up of 9.4 months and 62 events, median PFS was 3.6 (95% CI 3.2-3.9) versus 2.3 months (95% CI 1.7-2.9), for Arm A and B (log-rank p=0.11; HR 1.51, 95% CI 0.90-2.50), with a 1-year PFS of 10.3% versus 7.3%, respectively. At the cox-proportional multivariate modelling, stage (ED versus LD, HR 2.88 [95% CI 1.64-5.04, p<0.0001) and treatment arm (B versus A, HR 1.63 [95% CI 0.97-2.72], p=0.06) were independent predictors for PFS. Median PFS of arm A and B was 7.0 [95% CI <1-13.5] and 3.8 months [95% CI <1-8.6] in LD pts (p=0.21), and 3.0 (95% CI 2.2-3.8) and 2.2 (95% 1.7-2.7) in ED pts (p=0.19). Median OS was 9.5 (95% CI 4.8-14.3) and 4.7 months (95% CI 1.7-16.6), for Arm A and B (log-rank p=0.47), respectively. LAN was extremely well tolerated: serious treatment-related adverse events were grade 3 abdominal pain and electrolyte disorder in overall 2 pts.

Conclusions. Although the primary end-point was not met, the overall efficacy of LAN as a maintenance strategy after response to standard upfront treatment for SCLC deserves future investigations, with a particular regard to pts with limited disease. EUDRACT: 2011-005730-20