

Thank you, organizer. So I'll be talking about new RG event, electinib in potentially resectable stage 3 ALK positive, known as small cell lung cancer. This is the interim analysis of ALENIA, GOREC01-2020 phase 2 trial, led by Alessandro Leonetti from Italy.

So, regarding background additional, as all of us know, neoadjuvant chemo immunotherapy has become now a current standard of care in resectable stage 3 non-small cell lung cancer. However, the role of neoadjuvant TKI in stage 3 non-small cell lung cancer is still unclear.

But the electinib demonstrated relevant good activity for the treatment of ALK-positive non-small cell carcinoma in the metastatic and adjuvant setting. So this trial is a phase 2 study aimed to investigate the near-adjuvant role of electinib in patients with potential dissectable stage 3 ALK-positive non-small cell lung cancer.

The design of this study is all the potentially susceptible locally advanced stage 3 non-small cell lung cancer patients are selected who are candidate for surgical resection after multi MDT discussion. Patient has to have all positive with either IHC, PHIS or NGS method with no previous treatment and patient should have a ECOG performance score of 0 to 1.

and the primary endpoint was the major pathological response and pathological complete response

So, they gave a new adjuvant electinib 600 mg/d for two cycles that is two months and then they took for surgery within less than four weeks after completing the second cycle and then less than eight weeks after surgery they took for adjuvant phase that electinib 600 mg/d for 24 cycles.

So out of 30 patients they screened, 25 patients completed near adjuvant phase out of which 21, that is 84% of the total patients underwent surgery and out of which 20 patients, 95% of the patients completed adjuvant phase. However, only 18% sorry.

18% that is 72% of the total patient included in the primary endpoint interim analysis. 4% did not go under surgery as 2 patients refused and 1 due to clinical decision and 1 patient has got progression of disease. So if you talk about the stage, most of the patients are stage 3A and stage 3B with histopathological variation of adenocarcinoma.

And most of the patients are female patients with smoking of almost 11 former smokers, 11 patients, whereas 14 patients were never smokers. If you see the primary endpoint results, 39% of total patients, that is 7% achieved major pathological response. However, only 3 patients, that is 17% achieved pathological complete response and then

18 patients underwent surgery with R0 resection and out of which most of the patients underwent lobectomy. So they received adjuvant electinib with a median interval of after surgery 4.5 weeks.

New adjuvant treatment was well tolerated with grade 1, 2 toxicity in almost 56% of the cases. However, no grade 3 toxicity treatment related to acute events were observed. After median follow-up of 10.8 months, a total of 159 adjuvant courses of adjuvant

electinib were administered and treatment appeared to be well tolerated. So to conclude, the neoadjuvant electinib appeared to be very effective as major pathological response was achieved in 39% patient whereas PCR was achieved in 17% of the total patients and it is well tolerated in potentially susceptible stage 3 ALK positive non-small cell lung cancer patients.

the results of first stage internal analysis allowed investigator to continue the accrual of the more patients to reach the total of 33 patients

So, if you see a drawback, the sample size is very small, it is only 25 patients. So, to establish the role of kidney RGV and electropneumonia, more number of patients will be required. Final analysis is expected to come in later of this year. Thank you so much.