Good afternoon everybody. Today I'm going to discuss about LORA study and this is the
background we all know that almost 20% of our patients do come in stage 3 lung cancer,
non-small cell lung cancer. Out of these 20 to 30% patients, majority of patients, almost
70% patients are and resectable stage 3 lung cancer and out of these almost 30% patients
are EGFR mutated. And what we are going to talk about is that the current standard of
care for these un-resectable stage 3 and SCLC is chemo-current chemo radiation followed
by a dual-mom S consolidation therapy for one year. But based on the specific data,
post-doc subgroup analysis data, we already know that for EGFR mutated patients, the
outcomes are not so great with dual-mom maintenance and there is hardly any difference between
the two groups when we give dual-mom a placeable. And as of now, there was no approved targeted
therapy for un-resectable stage 3 and SCLC. So mostly we end up giving, not giving dual-momables
of such patients and they don't get anything and there is progression. That is where this
trial comes, that is phase 3 LORA study. Basically, Ocibaltinib after definitive CT-RT
in un-resectable stage 3 EGFR mutated NSCLC and this is the primary result of this phase
3 double-blind study. So this was a double-blind study where patients who have responded to
CT-RT with chemo-radiation were randomized into 2 is to 1 with ocemetinib ATMG 1's daily versus
placeable and the treatment duration till progression was given and the primary end point
was PFS which was decided by a blinded central review and secondary end points were OS, CNS,
PFS and safety. The statistical assumptions were that plant sample size was 200 with 2 is to 1
ratio for ocemetinib at placeable and the primary analysis of PFS was to be done with
statistical power of 90 percent to detect the PFS as a ratio of 0.53 at 5 percent significance
level which would lead to a PFS benefit from 8 to 15 months and once this is done with sequential
testing procedures, if OS and CNS PFS were also calculated, will be calculated based on if the
primary results are good. So this is how the patients were given to total 216 patients were
randomized out of which 143 patients received ocemetinib and 73 patients did not receive
they were only placeable out of this 143 patients, 56 percent patients were still receiving ocemetinib
while only placeable only 10 percent patients were still on placeable that is observation.
However, one point to note is that almost 80 percent patients who were on placeable
arm did receive ocemetinib on progression while being one observation only. The median PFS for
ocemetinib on was around 22 months and not PFS the fall off for PFS was 22 months and 5.6
months on the placeable arm. These are the baseline characteristics of both the

groups which was
more or less similar on the both sides. So this is the primary endpoint which is a PFS by a
blinded central review and what we can see is there is a stark difference in the median PFS that
is 39.1 month versus 5.6 month with hazard ratio of 0.16. The one year PFS was also 74 percent versus
22 percent and two year PFS was 65 percent versus 13 percent. So the benefit of ocemetinib
was continued up to 2 years and even beyond. This is the PFS by investigation assessment that
is also similar to the BICR and the hazard ratio here is also 0.19 with significant P value.
If we see the subgroup analysis all the subgroups did benefit with ocemetinib with ocemetinib
in comparison to placeable group. If we look up for the responses the overall response rate was
57 percent on the ocemetinib on versus 33 percent on the placeable arm. These patients these 33
percent patients are those patients who are still having continued to having response
because of previous CTRT. The disease control rate was almost 90 percent versus 80 percent.
Median duration of response was 37 percent months in ocemetinib on versus 6.5 months in the
placeable arm. The overall survival data is of now is immature with only 20 percent events
occurred at the time of analysis and the hazard ratio was in the towards the benefit of ocemetinib
with hazard ratio of 0.81 but we need to follow up this data. If we see for sites of new lesions
we expect that patients on ocemetinib when I have lesser distant metastases but even
lung metastases were also lesser with ocemetinib in comparison to placeable.
When we are giving something versus not giving anything there are there is expected to have
higher toxicities and this is what is seen here that great three toxicities or more were seen in
almost 35 percent patients with ocemetinib in comparison to 12 percent patients. However,
only 13 percent patients required to discontinue the drug in comparison to 5 percent on placeable
if we see for serious side effects which are related to the treatment given 13 percent patients
were seen to have great three or more toxicity with ocemetinib and 1 percent with ILD was
that was a great five toxicity. Same thing seen here the percentage of radiation
pneumonitis is almost 48 percent versus 38 percent diarrhea was more common with ocemetinib
peronichia was more common but all most of these side effects were more common in grade 1 or 2
so they were manageable and did not require treatment discontinuation. The ILD that was seen
in majority of patients was also in grade 1 and grade 2 which was managed well. However,
one patient did expect because of ILD on the ocemetinibum.
So, the conclusion was all the law study ocemetinib is given after CTRT definitely improved PFS
in comparison to placebo in patients with unresectable stage 3, EJFR mutated NSCLC,

the median PFS being almost 39.1 months versus 5.6 months with hazard ratio of 0.16.
Improvement is seen across all subgroups the interim OS which is immature right now it
suggests benefit towards ocemetinib but we need to see the final data.
Safety is manageable with no new safety signal seen and all patients with this tells us that
all our patients with stage 3 or even early state lung cancer should undergo EJFR testing
so that we can give this benefit to our patients. So, ocemetinib should become and has become the
standard of care for our patients of unresectable stage 3 NSCLC who are EJFR mutated. We have not
progressed after definitive CTRT. Thank you. Thank you. Thank you doctor.