The next speaker is Dr. Manoj Mahajan from Udaipur and he will be talking to us today
on first-line Osimatneb for previously untreated patients with NSCLC and uncommon EGFR mutations.
The unicorn phase 2 study.
So over to you Manojan.
Thank you sir.
Good morning everyone.
So I will be talking about the unventure territory, probably not very good study, but
still study results I will say, but these kind of studies are a day for our better understanding
of the drugs.
So this drug evaluated Osimatneb as first-line treatment for NSCLC with uncommon EGFR mutations.
So if you look at overall incidences of all other mutations, most of the mutation, especially
exone 19 deletion L858 are these constitute nearly 70% of most of the patients in especially
Indian context.
So remaining 30% are uncommon EGFR mutations which are 14% are exclusive single mutations
and around 14% are compound mutations, 14, 15%.
So they will have two mutations simultaneously that is why imparting a resistance.
So if we look at the overall uncommon mutations which are the uncommon mutations, amongst
the uncommon mutations, the most common ones are G719X exone 80, S768I exone 20, L861Q
exone 21.
So the study intends to evaluate the effect of oceumatative in the such kind of mutations.
As we know first-line and Jeff Taney Panabrotani Bahar have in resistance to such kind of mutations.
So what are the effects of oceumatneb in this setting that study is intending to do?
So those have given the background.
The main challenges are like uncommon mutations have limited treatment data and show poor responses
to first-generation EGFRT-KI.
We have the second-generation TKI-FATANI which has pooled analysis of lux-lung trials and
probably still the standard of care and even after these results we will see at the end
we will conclude what would be the better option.
So trial design we have discussed enrollment period from 20 to 22, very limited number
of patients, 40 eligible patients from 32 hospital in Japan.
Study dose was standard at oceumatte may be 80 milliamm once a day, minimum six months
follow after enrollment was done.
So primary endpoint was overall response rate, secondary endpoint, PFS and DC's control rate
and duration of response.
Participants nearly 42 patients enrolled but finally 40% patients were eligible.
Inclusion criteria, histology can form metastatic in a CLC, uncommon EGFR mutation as we had
defined.
It can be either PCR by NGS, E-COCPS 01, 02, and at least one vegetable lesion as per

the racist criteria.
Exclusion criteria, symptomatic brain mitts were excluded.
Asymptomatic brain included.
Other previous treatment with EGFR-TK was excluded.
So it was treatment night patients.
Other significant medical conditions are active infections.
So doses and follow up we had discussed.
So this is the patient's 40 patient enrolled and finally 40 patients completed the study
and evaluated.
So if you look at the demographics nearly half of where male, half female, 90 to 0.5%
were adenocarcinoma, nearly 40% were nevorsmokers, 50% were former smokers and around 7.5 current
smokers.
Among the uncommon mutation the most common findings were G79X, 50% of the patients,
20 patients, S768I, 25% of patients, L861Q, 20% of patients.
And compound mutation nearly 45% patient had compound mutations which involved combination
of uncommon EGFR mutations.
And mutation detected by NGS nearly 40% PCR based nearly 60%.
So these are the study characteristics which we discussed.
Coming to the results overall response rates nearly 55% in all patients.
If we look at the solitary mutations only 45% overall response rates.
Some mutations had slightly higher mutations rate as compared to solitary mutations.
And if we go mutation specific, so the least common L861 had a higher overall response
rate to the tune of 75%.
But that may be a limiting factor because of number of patients and other has 45 to 50%.
So if you look at the PFS median PFS was around 9.4 months solitary mutations, median PFS
5.4 months compound mutations, median PFS of 9.8 months.
Patients with asymptomatic brainmates had a shorter median PFS 4.5 months compared to
those without 9.8 months.
These are median PFS graphs.
Clinical activity is there in L861 more.
We can see longer follow for the rarer mutations.
But again, studies limited by number of patients recruited.
Common side effects were serious adverse events mainly ILD again 12.5% cardiac events nearly
2.5%.
Those reduction required in around 7.5% of the patients.
This is the same data.
If we compare with the other EJFR TKAs or current standard of care, Ocimutin shows superior
efficacy as compared to the first generation TKAs overall response rate with 55%.
If we compare with the second generation TKA FETINIM, FETINIM has the response rates
up to the 70% and median PFS of almost more than 12 months.
So, not a statistical design study but FETINIM is still showing the better results as compared
to the OcimutinIM uncommon mutations.
So to conclude, major limitation of this study was very small sample size.
Ethnic homogenicity only Japanese patients were included.
Hydrogenous mutations.

Resistance mechanism not explored due to insufficient tumor samples, no phase recombinant and CNF
efficacy we need further studies.
Thank you.
Thank you very much.