So I will be discussing about another Chinese trial, another Chinese drug used in the
recitable lung cancer and this is about the rational 315 which discuss about the event
free survival and overall survival of an newer joint Tisseli Zumab which is an anti-pideon
antibody plus chemotherapy versus adjoint atisseli Zumab in recitable non-small cell lung cancer.
So we all know that surgery offers the highest likelihood of cure in poor patient with
recitable early stage NSLC. However, the five-year tumor recurrence rates can be as high as 67%
and in recent years the management of recitable NSLC has evolved rapidly with emerging evidence
of a clinical benefit of perioperative PD-1 PD-L1 monoclonal antibodies.
This trial talks about the use of Tisseli Zumab in this setup.
So this was the study design as we can see the eligibility criteria first was the recitable
stage 2 through 3A NSLC as per the AGCC-8 th edition.
Patients should have a performance status of 0 or 1, patients should be EGFR-ALC wild type.
They were stratified into based on the histology squamous versus non-scammas, DC stage and as well
as video expression. There were two arms randomized in one-is-to-one fashion.
The newer joint phase consisted of 3 to 4 cycles of immunotherapy drug along with a platinum
doublet, the first-camera spackle-daxle was used and for non-scammas, pemetic state was used along with the platinum.
The surgeon was offered after 3 to 4 cycles and then a joint phase consisted of doing the
immunotherapy drug every 6 weeks, 400 mg along with or placebo in the comparator arm.
The primary end points were to look for a major pytholic rate by blinded independent
pathological river and EFS by BICR. The key secondary end points were to look for the PCR,
the other secondary end points were OS, EFS by investigator and the safety.
This was the patient disposition. We can see two arms, two 26 patients were exposed to the
immunotherapy drug, though two 27 the placebo arm, almost all patients received a newer
joint treatment in the TIS arm and almost 99.6 in the new joint, placebo arm.
84% patient did receive the definitive surgery in the immunotherapy arm versus 76, so more
patient received surgery in the immunotherapy arm. Along with that, the adjunct TIS was able to
administer it to almost 75% patient versus 65% in the placebo arm.
In the intent, looking at the demographics, we can see the baseline characteristics were
matched in both the groups, be it the age of the patient, the sex, the eco-performed status,
the smoking status. As we can see, again in this trial, almost 80% of the scammers'
histology was involved compared to almost 20% of the non-scammers, the nodar status and
the pediatric expression, they were all matched in both the groups.
Again, significant improvement in the MPR, the major pathological response, we can see
a difference of 41.1% favoring the immunotherapy drug and in the PCR rate, as well, we can

see a staggering difference of 35% with almost 40% of PCR we are achieving with this help
of this drug. Again, talking about the event-free survival, at the two years, we can see there
is significant difference between the two curves, 68.3% of EFS in the immunotherapy drug arm versus 51.8% in the placebo arm, and it was statistically significant.
Talking about the substrate analysis, all subgroups irrespective of the age, the sex, the performance
status, histological type, PDO expression, or stomachs, smoking status, everyone did benefit
with the use of addition of this drug to the chemotherapy. Again, talking about the histology variation response as per the histology, again, we can see there is a significant
improvement for the EFS, for the B, the scammers or non-scammers, and I can see the scammers
doing better in this population with the help of this drug.
Talking about the staging, again, both the stage 2, resectable and stage 3 are resectable,
both had an improvement in the EFS at the end of two years as we can see in this chart.
About the OS, there was a benefit trend which was observed, and I think as we give more
time for the trial to evolve, we will get the difference a bit more.
Talking about the safety, the safety was quite manageable, the grade 3 side effects were
almost similar in both the subgroups, and there was no new safety signals.
Again, talking about the most commonly frequently adverse events, where mainly, I think, was
more because of the chemotherapy itself, and they were all quite matching in both the subgroups.
Again, obviously, we expect more immune-meditary adverse events in the immunotherapy arm, but
then the most common reactions were skin adverse reaction, and very less, that is less than 10% of the
patient experience, more than grade 3 immune-related adverse events.
So, they concluded as this trial demonstrated clinically meaningful and statistically significant
benefit of EFS with the perioperative TIS plus new adjoint chemotherapy.
The NPR and PCR rates were significantly improved with the new adjoint immunotherapy drug.
The OS benefit trend favoring a perioperative TIS was observed with the interim analysis,
and the trial will continue to assess the OS.
The safety profile was quite well manageable, and taken together the statistically clinically
significant EFS, NPR and PCR benefits, and thus, managed with safety profile, they supported
the use of perioperative TIS in this population.
So, my take would be that trial shows that there is an impressive benefit, particularly
in the group of patients with gamma-cystology.
Typically, we see that this population is under-presented and generally, they are less favorable outcomes.
There was no significant delay in the surgery, the toxic profile was as expected.
Obviously, the studies about the Chinese patient, and we should consider having additional data on this.
Thank you.
Thank you.