Now I invite Dr. Venkatesh Kapur.
Very good afternoon. So after positive sessions so far, I will come to our negative trial.
And I thank my organizers and my mentors Vijay Patil said Kumar sappra promoting this opportunity.
So we will move to the negative part of the afternoon session.
So we all know Pacific Trail which is a standard trail so far, non-resectable patients concurrent, Duralma post CTIT.
So with this motto in the background, so this is a study, Duralma in combination with CTIT.
So we all know Pacific it has done after completion of CTIT and then they have randomized.
But they have done the Pacific too, but during the CTIT they have started Duralma.
So what is the background and what could be the hypothesis or what the,
in Pacific Trail concurrent CTIT followed by 12 months of Duralma resulted in sustained OS and PFS which is gold standard for no.
But 15 to 30% of patients may not be eligible to receive consolidation of Duralma due to various reasons B,
disease progression or because of the toxicity or any other adverse events.
So there is a preclinical evidence which started, which supports that starting IO concurrently with CRT based on hypothesis synergistic effect on concurrent administration of immunotherapy and radiotherapy,
which may provide an opportunity to benefit patients who may progress on CRT alone.
So the patients who have progressed on CRT alone, so is there any possibility by adding IO in early, will there be an early separation of curves or does it benefit to them,
provide an additional benefit to so that 15% or 20% can be avoided and increase the death of responses.
So this is the first phase 3 study designed to assess the efficacy of concurrent IO plus CRT followed by consolidation.
So same, it is a phase 3 randomized double-blinded study, multi-centered global study.
So population of same stage 3, ECOV 0 to 1, stage 3 and 4, the 3A, 3B or the stratification factors at age.
And the randomized 2 to 1 with IO plus CRT with Duralma and CRT and placebo in CRT.
And consolidation, Duralma or placebo.
And the primary endpoints are PFS and secondary endpoints are overall, overall survival and overall response and 2 year overall survival,
PFS, duration of response, safety and toxicities.
And duration of study period is 2018 to 2019 across 106 sites in Asia, Eastern Europe, Americans, and so.
So the other, anyway, we know that it is a negative study.
So we will try to analyze few things, what has went wrong and dash off the things we will discuss in panel discussion.
So median age 63 for both females, 25% and males are 75% and performance status in squamous are 55%.
50% to 55% in both arms and non-scammer are 44.
And PDL1, overall as if you are, okay, EGFR if you see unknown is 45% in the wrong, unknown.
Whereas Pacific has around 22% of EGFR unknown.
But in this study, unknown status is 45%.
And T4 if you see 57.5 or T4 in Duralu-Ham.
And N2 patients nodal button 57% on.
So please remember these points, maybe we will discuss in the panel further in detail.
And so these are the common regimens.
And if you see the last one, who discontinued the dual-member placebo?
So if you see 26% had an adverse event in dual-member and 14% in placebo arm.
So please remember these points.

So PFS, it's a negative, hazard ratio of 0.85 with extremes going and PFS is 13.8 versus 9.4.
And if you see everything is crossing except something like age less than 65, we don't know in female.
But these are just the numbers.
But if you see everything is crossing that midline, so no PFS benefit.
In any of the categories, EGFR positive, negative PDL1 status,
voice also there is no benefit hazard ratio is 1.03, no difference.
And all the voice parameters are in the other end.
Everything is crossing, so no benefit.
And if you see, adverse events leading to discontinuation of dual-map,
0 to less than 4 months, that's the period where they have undergone CTRT regimen.
They are 14% in dual-wolvabum and 5.6% in the placebo arm.
So that could be one as an early, almost like 14% of discontinued, which could have it.
And predominant toxicities are radiation numerates, anemia.
A placebo versus a dual-wolvab study, 28% and 28%.
More or less the radiation numerates is same.
But if you see the discontinuation of more, like 14, 15% in the early phase,
4 months before is a very big number.
And if you see this coming to the mortality deaths, deaths are about 7% in the early phase.
Total deaths are 14% in dual-wolvabum and 10% in the placebo arm.
But in the first 4 months, if you see 7% of 15 deaths,
predominantly are because of infection or infestations.
So that's about 6 patients have died in the early phase of 4 months.
So that's infectious, the primary device which could lead to adverse events.
So in PASVIT 2, IOPLACCT followed by consolidation did not improve PFS,
or there is no OS benefit.
In first 4 months of therapy, high adverse events, as you have seen 15% of 14%,
leading to death, which is not acceptable, properly turned led to the multiple factors,
which are further negative study.
And rates and severity of pneumonitis, though similar between both the groups,
and the safety profile is also consistent between both the groups.
Still, concurrency at followed by dual-wolvab specific, the original specific is the standoff care,
but no more PASVIT 2. Thank you.