So, thank you organizers for the opportunity and this would be the interim analysis from
the galaxies lung 2-1 trial.
So, this is basically phase 2 randomized open label study combining the Bell-Ros-Sturtuck
plus Dostarly map in the patient with PDL1 high that is TPS 50 percent or more in advanced
metastatic NSLC.
Normally, what we see is that whenever we see more than 50 percent PDL1 expression, we
think that that is a good opportunity to offer some immunotherapy drugs and we expect
the good result.
But when we see it carefully from the trial keynote 0-2-4 trial, the response rate was
close to 45 percent and even the overall survival, five year survival was 26 percent.
So, this study tried to analyze whether there can be the results can be improved beyond
this.
So, currently the first line treatment option for this particular subset of patient that
is PDL1 50 percent or more, the one of the treatment option includes single agent pembrolyzumab
but the response rates are usually less than 50 percent which necessitates the new treatment
approaches.
The Dostarly map as we are already aware that it has shown comparable clinical activity
with the pembrolyzumab in first line NSLC in the parallel trial which has was phase 2 study and it was combined with the chemotherapy as versus the standard of care that is pembro
and chemotherapy.
As we were trying to see for the mechanism of resistance to overcome the resistance.
So, this was another this anti-PDL1 where combined with novel anti-teget inhibitory immune checkpoint inhibitor like bell rostrotag.
Normally, this bell rostrotag it has an it is an FCY receptor enamel monoclon antibody,
it modulates the CD2 CD26 pathways.
It will inhibit the regulatory T cell proliferation and ultimately it is also having a higher potency
as compared to other anti-teget monoclonal antibodies.
Apart from that it because of this unique mechanism it will increase the CD8 T cell expression
while it will reduce the regulatory T cell in the patients.
So, this was a study design known patient untreated unresectable locally advanced metastatic
NSLC, PDL1 score high either by the Daco or the Ventana SP263 assay.
No actionable mutation and current or the foremost smokers were included.
A symptomatic even the treated brain metastasis were eligible.
Basically, for this study we can see the sub study one for this particularly for this session
where the pembrozoma was compared with the dose taryllumab along with the combination
of bell rostrotag.
These various different doses of the bell rostrotag were used like 100 milligram, 400
and 1000 milligram.

The primary endpoint for this study was overall response rate while the secondary endpoints
are PFS, OS, duration of the response, safety and the other parameters.
For this particular study total at that data of cut off so total 124 patients were eligible
and the median follow up of 7.3 month.
Then we see the baseline demographic characteristic, majority of the patient were male even the
Asian people were there included mostly from 16 to 30 percent while most of the patient
had excellent performance rates.
We can see the central this PDL1 central testing was available for those patients having PDL1
TPS score of 90 percent or more and even in 38 to 40 percent of the patients.
So, this was a primary efficacy endpoint of overall response rate.
We can see the after a median follow up the overall response rate with dose taryllumab
was 37 percent while with 100 milligram bell rostrotag with dose taryllumab is was 63 percent,
65 percent with a higher dose of 400 milligram bell rostrotag while it was 76 percent with
the 1000 milligram of bell rostrotag.
We can see majority of the patient had a partial response or a stable disease and even the
confirmed overall response rates were also seen.
So, this was a showing the combination also showed a greater reduction in the tumor size
as we can see from the waterfall charts and even the depth of the responses was higher
as compared to the combination treatment versus the dose taryllumab monotherapy.
So, as we see the CTDNA as a biomarker for the molecular testings and the molecular responses,
from this study also when they evaluated the CTDNA reduction in the CTDNA after the treatment
with the median reduction was 65 percent with the dose taryllumab alone while it was 100
mg bell rostrotag with dose taryllumab it was 55 percent versus 94 percent with the 400
milligram bell rostrotag while it was 97 percent reduction in the CTDNA in the 1000 milligram
bell rostrotagum.
So, when coming towards the safety profile this combination has shown that there might
be increase in the immune related adverse event as we can see almost treatment emergent
adverse event in almost 90 to 97 percent of the patient.
But when we see the majority grade 3 or more adverse event they were seen in 60 percent,
16 percent versus 33 percent in 100 milligram while 22 percent and morally with the 1000
milligram bell rostrotagum while grade 4 serious adverse event were uncommon like 7 percent
and 3 percent only while the rates of that treatment discontinuation because of the adverse
event 6 percent with the dose taryllumab while 23 percent in 100 milligram, 16 percent in
the 400 am and the 40 percent in the 1000 milligram bell rostrotagum even similarly the
other adverse event.

So, most common treatment related adverse event where skin and the subcutaneous tissue disorder
and as we are aware that endocrine disorder like hypothyroidism were seen and even the
treatment discontinuation reasons where skin and again subcutaneous disorders and other
thoracic and medicinal disorder while rarely the fatal event were seen like immune mediated
hepatitis, pneumonitis and the myocarditis and this was again we can see the treatment
related adverse event most commonly either the skin subcutaneous tissue or maybe the
hypothyroidism were seen.
So, to conclude the galaxies lung 201 is the largest presented randomized phase 2 study
in the patient who have been previously untreated and resectable locally at one metastatic NSLC
with high PDL1 expression where they have assessed anti-teaset with anti-pedian one combination.
So, bell rostrotag is a differentiated anti-teaset monoclonal antibody with multiple mechanism
of action clinically meaningful improvement in overall response rate was observed in all
combination cohorts compared with the Dostolema monotherapy and the combination regimen had
an increase in the immune related adverse event which but generally manageable.
So, this trial will ongoing recruitment in the reported arms and additional follow up
with better characteristics for the long term safety and efficacy will be needed.
Follow up of this study will inform the future development of the bell rostrotag.
Thank you.