Fig 1. Study design

Key Inclusion Criteria
- Advanced NSCLC pts who had clinical benefit from prior PD-1/L1 inhibitor (+/- chemo) and progressed
- ≥ 60 days from the last dose of PD-1/L1 inhibitor
- With measurable lesion per RECIST ver. 1.1
- PS 0-1
- Asymptomatic brain metastases allowed

Endpoints and stats
- Primary endpoint: Overall response rate (ORR)
  Hypothesis and statistical consideration
  • Re-challenge of nivolumab will improve ORR from 10% to 20%
  • 60 patients are required to ensure a statistical power of 0.79 at a one-sided alpha error of 0.05.
- Secondary endpoints: Progression-free survival (PFS), overall survival (OS) and adverse events (AEs)

Enrollment and analyzed patients
- Between October 2017 and February 2020, 61 patients were enrolled. One was withdrawn before study treatment and another patient was excluded from efficacy analysis due to insufficient adequate eligibility.
- Among 59 patients who were analyzed for efficacy, median follow-up time was 19.5 months (range, 2.2-30.7 months).

Table 1. Patients characteristics

<table>
<thead>
<tr>
<th>N = 59</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age-median (range)</td>
</tr>
<tr>
<td>Male / Female-no.</td>
</tr>
<tr>
<td>Never / (ex-) smoker-no.</td>
</tr>
<tr>
<td>EGCG performance status 0 / 1-no.</td>
</tr>
<tr>
<td>Non-Sq / Sq-no.</td>
</tr>
<tr>
<td>Clinical stage IIIB-C / IV / post-operative relapse-no.</td>
</tr>
</tbody>
</table>

Prior chemotherapy lines-mediated, range

| N = 60 |

Median PFS was 2.6 months (95%CI: 1.6 to 2.8 months), while five responders had 11.1 months of median PFS.

Fig 2. (a) Waterfall plot and (b) Forest plot for ORR

- ORR was 8.5% (95%CI: 2.8-18.7%).
- DCR was 50.9% (95%CI: 37.5-64.1%).
- Any clinical backgrounds were not predictive for ORR.

Fig 3. (a) Kaplan-Meiyer Curve of PFS and (b) Swimmer’s plot

- Median PFS was 2.6 months (95%CI: 1.6 to 2.8 months), while five responders had 11.1 months of median PFS.

Fig 4. Adverse events

- Common adverse events were skin disorders (23%), malaise (20%) and hypoalbuminemia (15%).
- No TRD was observed.

Conclusion
- Our selection criteria did not work for Nivolumab rechallenge, however, small fraction had clinical benefit.
- Development of predictive biomarker is warranted.