Chemoradiation Followed by Durvalumab in Poor Risk and/or Elderly Patients with Stage III NSCLC

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Statistical Methods/Sample Size Determination/Data Analysis:

For the primary endpoint of completion rate of chemotherapy/split course chest radiation, where we anticipate 80% completion, a sample size of n=30 provides power of about 0.8 in a non-inferiority test with non-inferiority margin of 0.18 and alpha =0.05. This will allow estimation of the completion rate within ±0.13 using a 90% confidence interval (normal approximation) or within a total width of 0.30 (using exact Binomial interval).

For the endpoint of completion of durvalumab post-chemoradiation, we estimate post-chemoradiation n of 24 (assuming 80% completion of chemoradiation). This will allow estimation of durvalumab completion rate within ±0.13 using a 90% confidence interval (normal approximation) or within a total width of 0.30 (using exact Binomial interval).

For the secondary endpoints, with n=30 subjects, we estimate 70% power to detect improvement in PFS for adding Durvalumab and 55% power to detect improvement in OS, each at a liberal 0.10 level of significance and without adjusting for multiplicity. (Without Durvalumab, the median survival is known to be 20 months in this patient population; we expect that adding Durvalumab in the treatment regimen will improve the median survival to 30 months. Without Durvalumab, the median progression free survival (PFS) is known to be 11 months in this patient population; we expect that adding Durvalumab in the treatment regimen will improve the median PFS to 17 months.)