Meeting Abstract | 2022 ASCO Annual Meeting I

LUNG CANCER—NON-SMALL CELL LOCAL-REGIONAL/SMALL CELL/OTHER THORACIC CANCERS

Consolidation nivolumab plus ipilimumab or nivolumab alone following concurrent chemoradiation for patients with unresectable stage III non-small cell lung cancer: BTCRC LUN 16-081.

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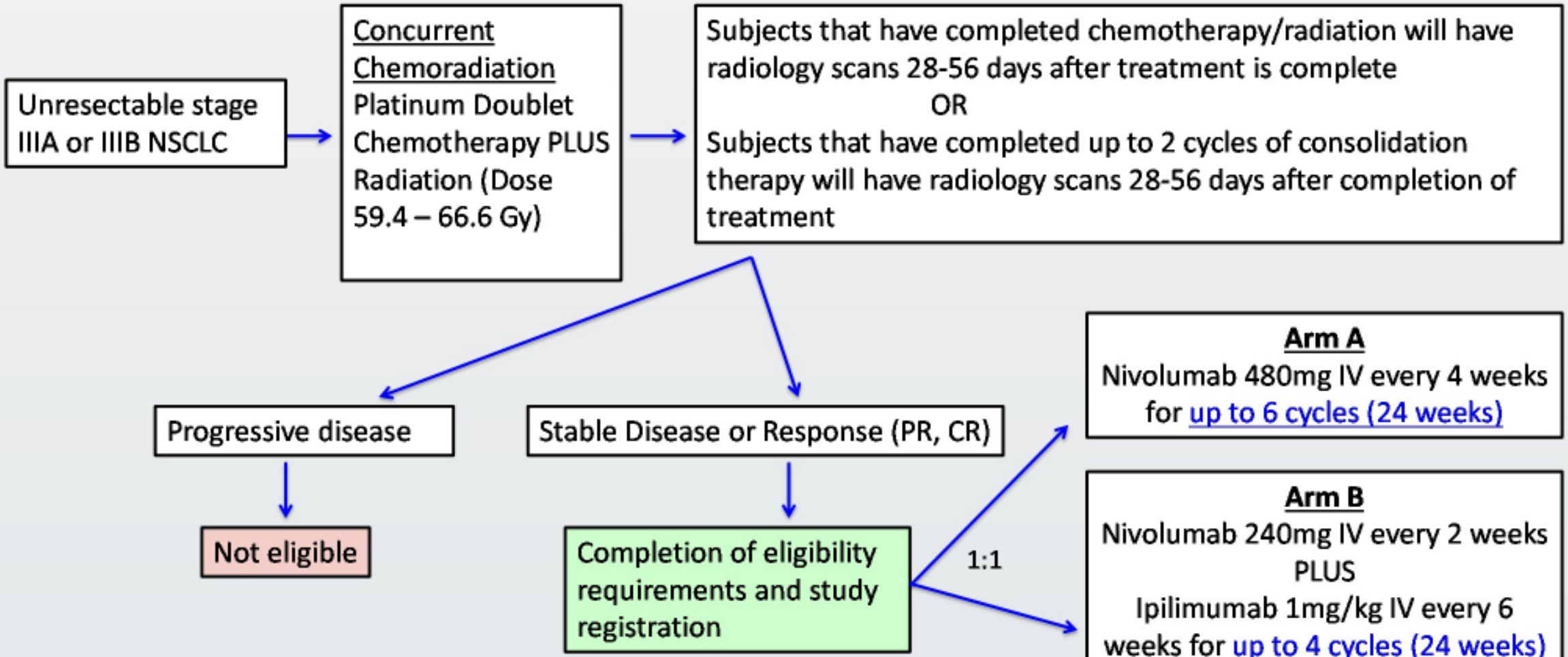
Background

- The PACIFIC trial demonstrated that a year of consolidation PD-(L)1 inhibition - improves overall survival (OS).
- The optimal duration of consolidation IO therapy in this setting is undefined.
- This trial evaluated the use of combination Nivolumab (N) plus Ipilimumab (IPI) or N alone for up to 6 months in unresectable stage III NSCLC after concurrent CRT.

METHODS

- Schema of BTCRC-LUN16-081 (multi-center, randomized, phase II trial)



- In this planned interim analysis, the safety of the first 50 patients (25 per arm) is assessed.

From September 2017 to September 2019, the first 50 patients were accrued.

Table 1. Baseline Clinical Characteristics

Characteristic	Arm A (N=25)	Arm B (N=25)
Median Age (years)	64	62
Male sex – No. (%)	13 (52)	15 (60)
ECOG performance-status score – No (%)		
0	11 (44)	11 (44)
1	14 (56)	14 (56)
Stage – No. (%)		
Stage IIIA	17 (68)	16 (64)
Stage IIIB	8 (32)	9 (36)
Histology – No. (%)		
Squamous	11 (44)	12 (48)
Non-squamous	12 (48)	11 (44)
NSCLC, NOS	2 (8)	2 (8)
Median Concurrent Radiation Dose (Gy)	60	61.5
Concurrent Chemotherapy Regimen – No. (%)		
Cisplatin + Etoposide	3 (12)	5 (19.2)*
Cisplatin + Pemetrexed	4 (16)	2 (7.7)
Carboplatin + Paclitaxel	18 (72)	19 (73.1)*

* One patient received two different concurrent chemotherapy regimens

Table 2. Summary of Treatment Received

Event	Arm A (N=25)	Arm B (N=25)
Planned total duration of therapy – Weeks (cycles)	24 (6)	24 (4)
Median number of cycles completed – No. (range)	6 (1-6)	4 (1-4)
Completed 24 weeks of treatment- No. (%)	19 (76)	14 (56)

Table 3. Summary of Adverse Events

Adverse Event	Arm A (N=25)		Arm B (N=25)	
	Any Grade	Grade 3-4	Any Grade	Grade 3-4
	number of patients (%)			
Any event	25 (100)	8 (32)	25 (100)	11 (44)
Treatment-related AE leading to discontinuation	4 (16)¶	2 (8)	10 (40)¶	7 (28)
Treatment-related AE leading to death	0	0	0	0
Occurred in ≥ 10% of patients in either group				
Fatigue	6 (24)	0	9 (36)	1 (4)
Cough	3 (12)	0	4 (16)	0
Dyspnea	3 (12)	0	9 (36)	0
Musculoskeletal pain	3 (12)	0	3 (12)	0
Diarrhea	1 (4)	0	5 (20)	1 (4)
Immune-mediated				
Any	11 (44)	4 (16)	15 (60)	8 (32)
Pneumonitis	4 (16)	1 (4)	5 (20)	4 (16)
Rash	5 (20)	3 (12)	3 (12)	1 (4)
Colitis	0	0	0	1 (4)^
Pancreatitis	0	0	0	1 (4)*
Amylase/lipase elevation	0	0	4 (16)	2 (12)*

¶ Treatment-related AE leading to discontinuation in Arm A were from grade 2 pneumonitis (in 2 patients) and from grade 3 pneumonitis and grade 3 rash (in 1 patient each). Treatment-related AE leading to discontinuation in Arm B were from grade 2 pneumonitis (in 2 patients), grade 3 pneumonitis (in 4 patients), and from grade 2 pneumonia, grade 3 colitis, grade 3 pancreatitis, and grade 3 lipase elevation (in 1 patient each). *Occurred in the same patient ^Biopsy-proven colitis

Outcomes

- The 18-month PFS was 62.3% on A ($p < 0.1$) and 67% on B ($p < 0.1$), and median PFS was 25.8 months and 25.4 months, respectively.
- Median OS was not reached on either arm, but the 18- and 24-month OS estimates were 82.1% and 76.6% for A and 85.5% and 82.8% for B, respectively.

Conclusion

- Following concurrent CRT for unresectable stage III NSCLC, both N and N + IPI demonstrated improved 18-month PFS compared with historical controls despite a shortened interval (6 months) of treatment.
- OS data are still maturing but 18- and 24-month OS estimates compare favorably to prior consolidation trials.