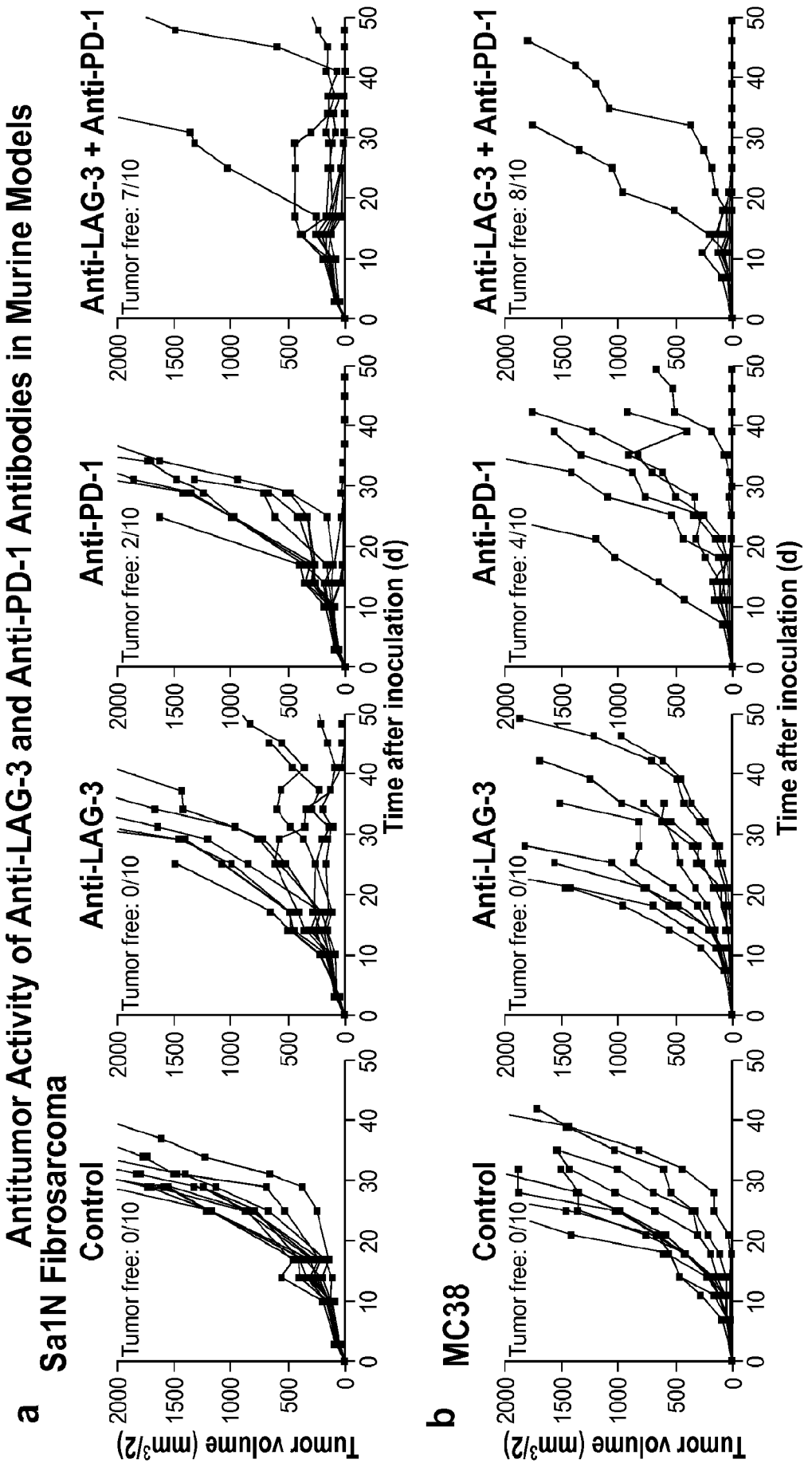

Antitumor Activity of Anti-LAG-3 and Anti-PD-1 Antibodies in Murine Models
a
Sa1N Fibrosarcoma
b
MC38
Control
Anti-LAG-3
Anti-PD-1
Anti-LAG-3 + Anti-PD-1
Tumor free: 0/10
Tumor free: 0/10
Tumor free: 2/10
Tumor free: 7/10
Tumor free: 0/10
Tumor free: 4/10
Tumor free: 8/10
Tumor volume (mm3/2)
Time after inoculation (d)
0
500
1000
1500
2000
0
10
20
30
40
50

Fig. 1

ICMARs = immune cell-modulating antibody regimens (such as, but not limited to, ipilimumab, tremelimumab, anti–PD-1, anti–PD-L1, anti–PD-L2, anti-KIR, anti-CD137, and/or anti-OX40 antibodies)

Fig. 2A

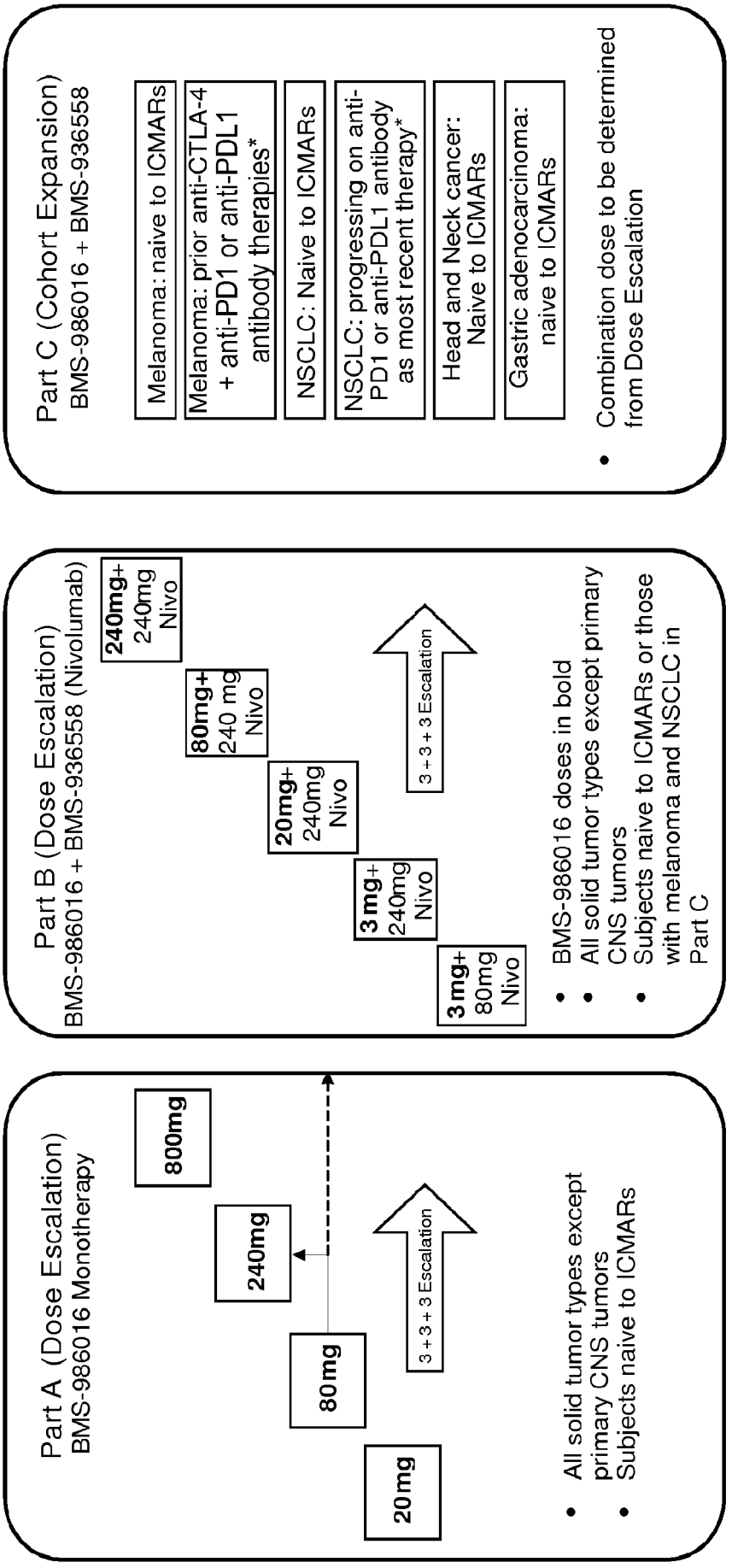

Study Schematic
Part A (Dose Escalation)
BMS-986016 Monotherapy
20mg
80mg
240mg
800mg
3 + 3 + 3 Escalation
All solid tumor types except primary CNS tumors
Subjects naive to ICMARs
Part B (Dose Escalation)
BMS-986016 + BMS-936558 (Nivolumab)
3mg+ 80mg Nivo
3mg+ 240mg Nivo
20mg+ 240mg Nivo
80mg+ 240 mg Nivo
240mg+ 240mg Nivo
3 + 3 + 3 Escalation
BMS-986016 doses in bold
All solid tumor types except primary CNS tumors
Subjects naive to ICMARs or those with melanoma and NSCLC in Part C
Part C (Cohort Expansion)
BMS-986016 + BMS-936558
Melanoma: naive to ICMARs
Melanoma: prior anti-CTLA-4 + anti-PD1 or anti-PDL1 antibody therapies*
NSCLC: Naive to ICMARs
NSCLC: progressing on anti-PD1 or anti-PDL1 antibody as most recent therapy*
Head and Neck cancer: Naive to ICMARs
Gastric adenocarcinoma: naive to ICMARs
Combination dose to be determined from Dose Escalation
ICMARs = immune cell-modulating antibody regimens (such as, but not limited to, ipilimumab, tremelimumab, anti–PD-1, anti–PD-L1, anti–PD-L2, anti-KIR, anti-CD137, and/or anti-OX40 antibodies)

Fig. 2B

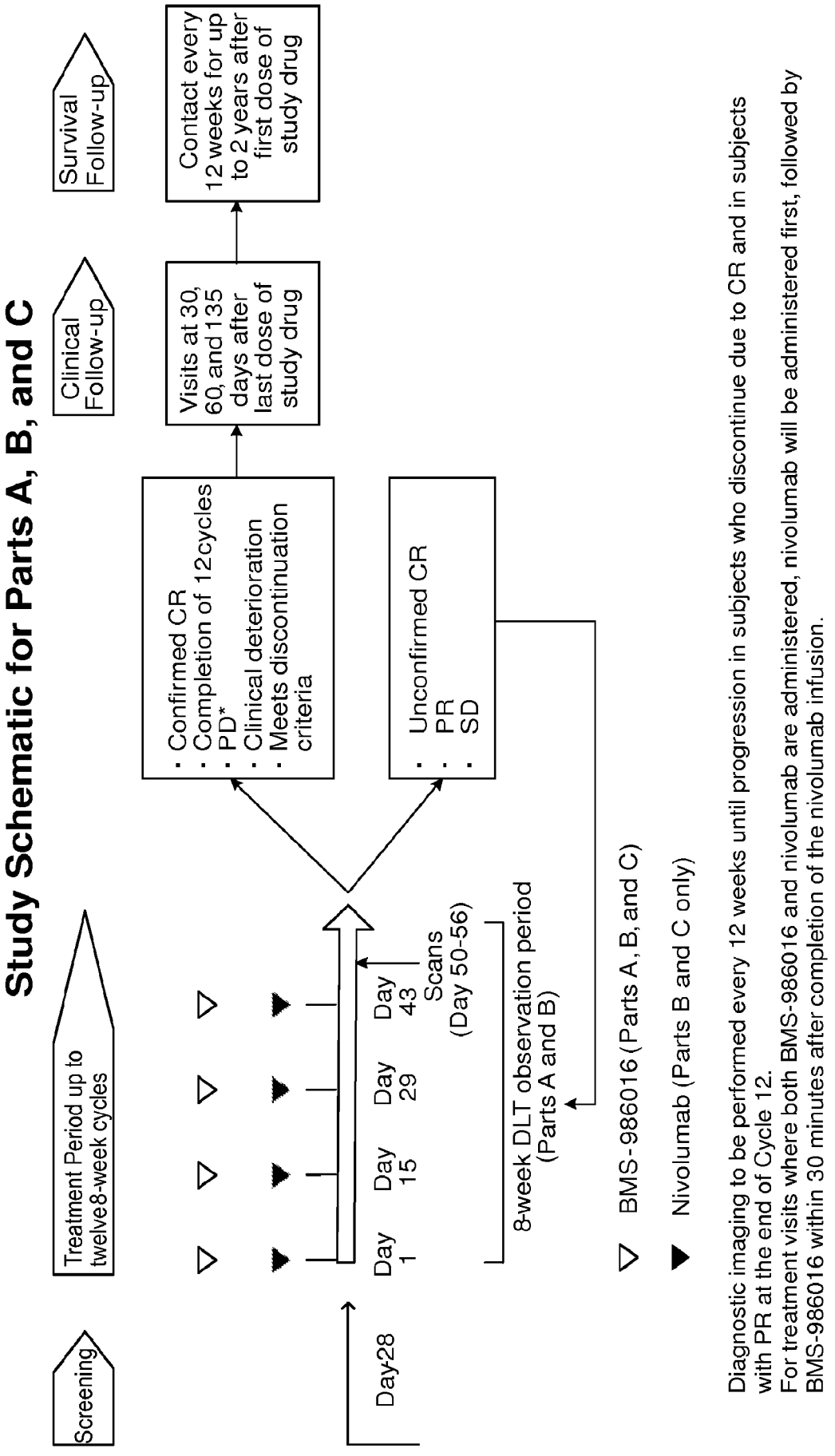

Study Schematic for Parts A, B, and C
Screening
Treatment Period up to twelve8-week cycles
Clinical Follow-up
Survival Follow-up
Day-28
Day 1
Day 15
Day 29
Day 43
Scans (Day 50-56)
8-week DLT observation period (Parts A and B)
· Confirmed CR
· Completion of 12cycles
· PD*
· Clinical deterioration
· Meets discontinuation criteria
· Unconfirmed CR
· PR
· SD
Visits at 30, 60, and 135 days after last dose of study drug
Contact every 12 weeks for up to 2 years after first dose of study drug
BMS-986016 (Parts A, B, and C)
Nivolumab (Parts B and C only)
Diagnostic imaging to be performed every 12 weeks until progression in subjects who discontinue due to CR and in subjects with PR at the end of Cycle 12.
For treatment visits where both BMS-986016 and nivolumab are administered, nivolumab will be administered first, followed by BMS-986016 within 30 minutes after completion of the nivolumab infusion.

Fig. 3