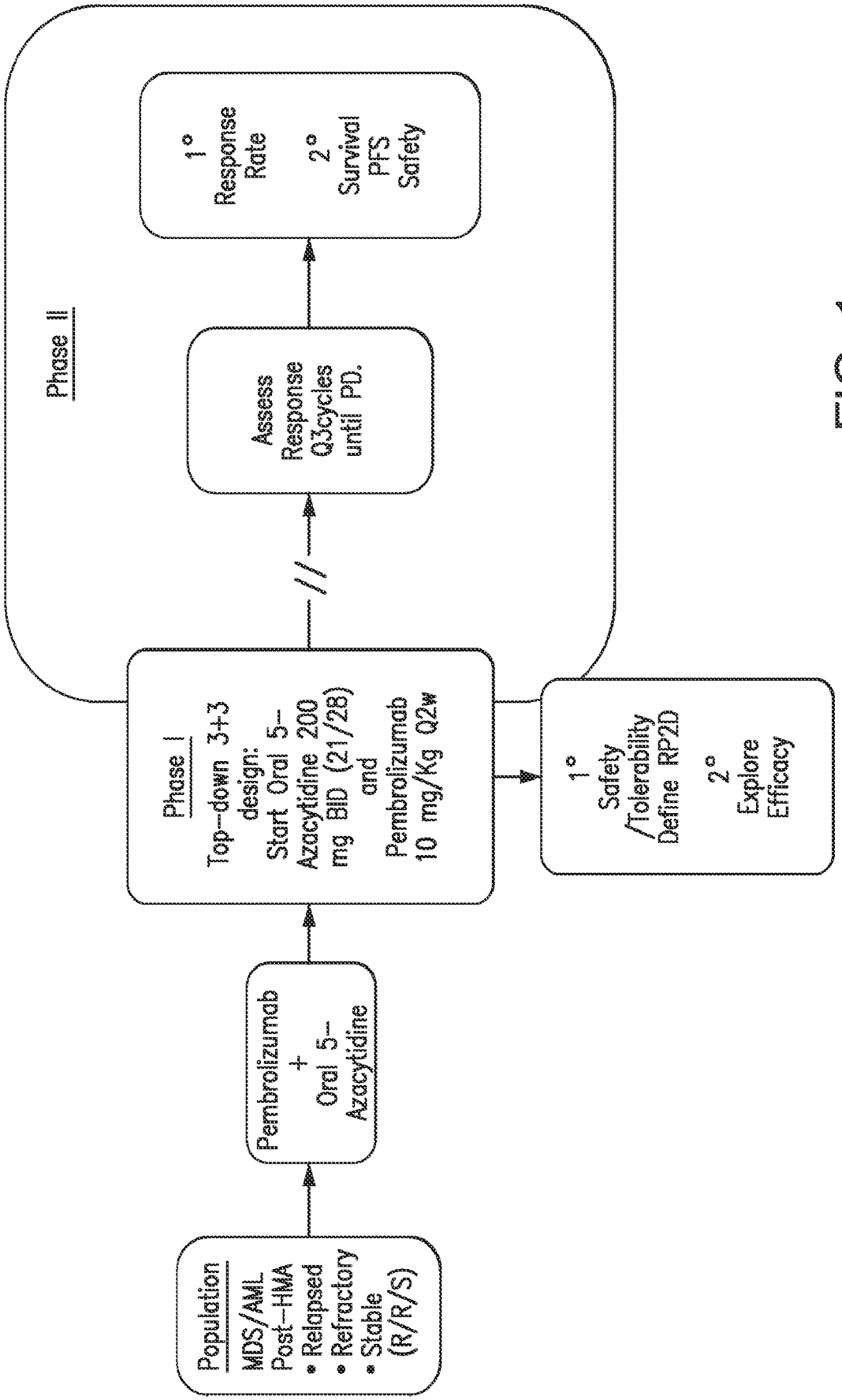

Population
MDS/AML
Post-HMA
• Relapsed
• Refractory
• Stable
(R/R/S)
Pembrolizumab
+
Oral 5-
Azacytidine
Phase I
Top-down 3+3
design:
Start Oral 5-
Azacytidine 200
mg BID (21/28)
and
Pembrolizumab
10 mg/Kg Q2w
1°
Safety
/Tolerability
Define RP2D
2°
Explore
Efficacy
Phase II
Assess
Response
Q3cycles
until PD.
1°
Response
Rate
2°
Survival
PFS
Safety

FIG. 1

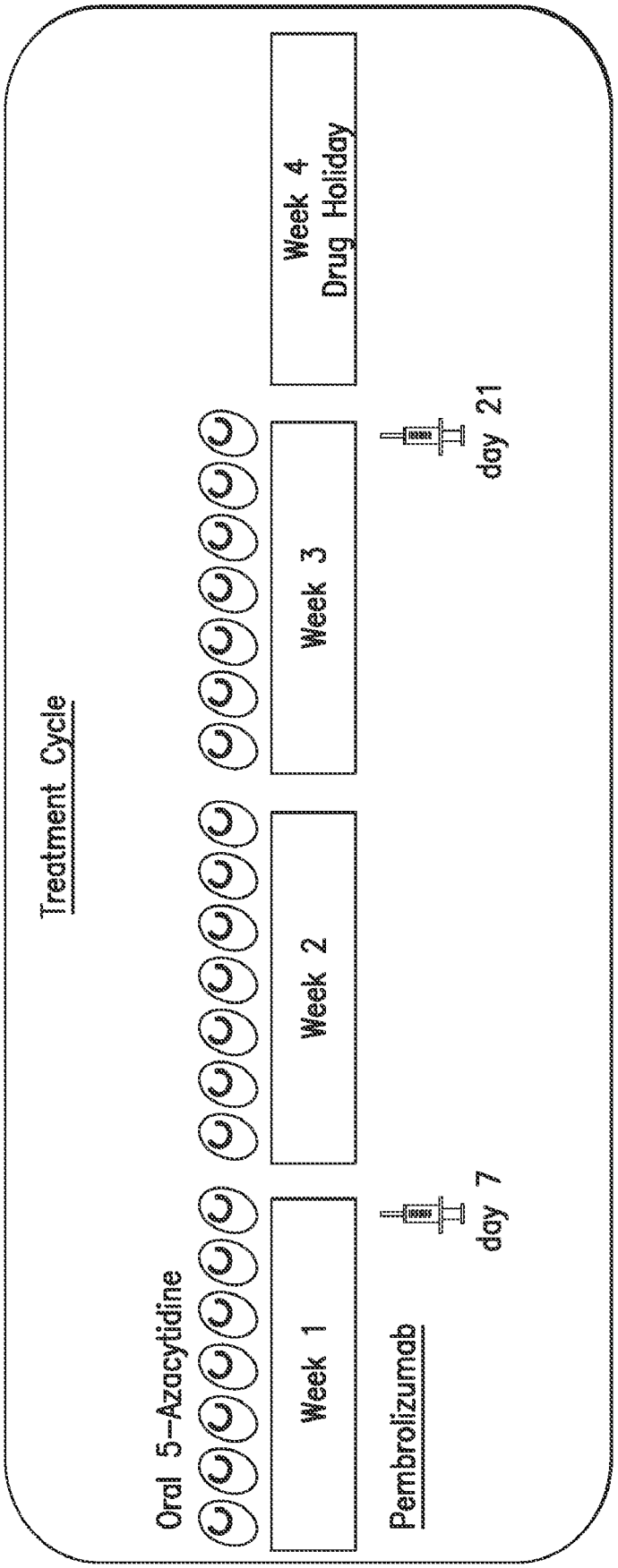

Treatment Cycle
Oral 5–Azacytidine
Week 1
Week 2
Week 3
Week 4
Drug Holiday
Pembrolizumab
day 7
day 21

FIG. 2

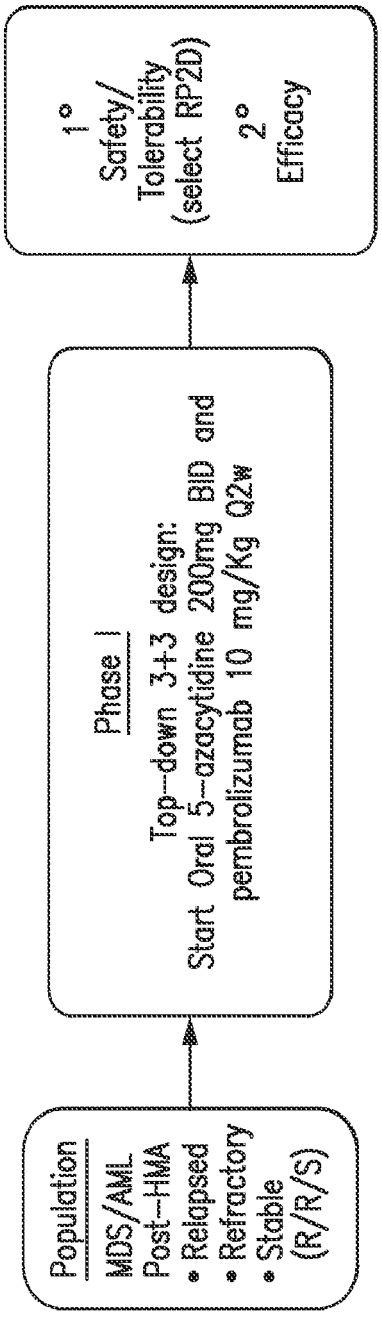

Population
MDS/AML
Post-HMA
• Relapsed
• Refractory
• Stable
(R/R/S)
Phase I
Top-down 3+3 design:
Start Oral 5-azacytidine 200mg BID and
pembrolizumab 10 mg/Kg Q2w
1°
Safety/
Tolerability
(select RP2D)
2°
Efficacy

FIG. 3

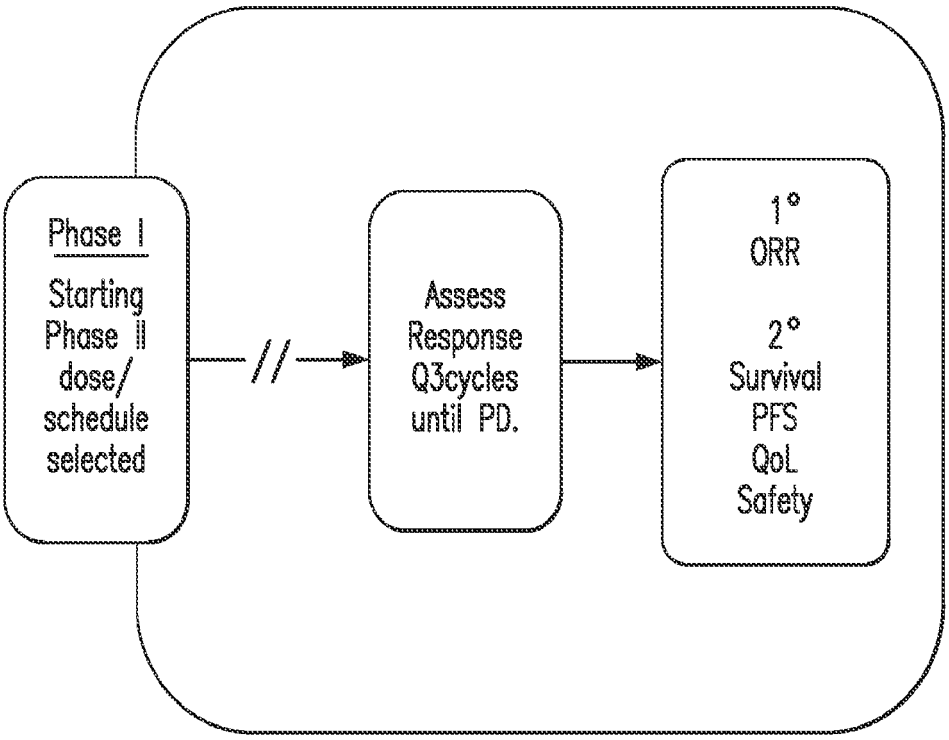

Phase I
Starting Phase II dose/ schedule selected
Assess Response Q3cycles until PD.
1°
ORR
2°
Survival
PFS
QoL
Safety

FIG. 4

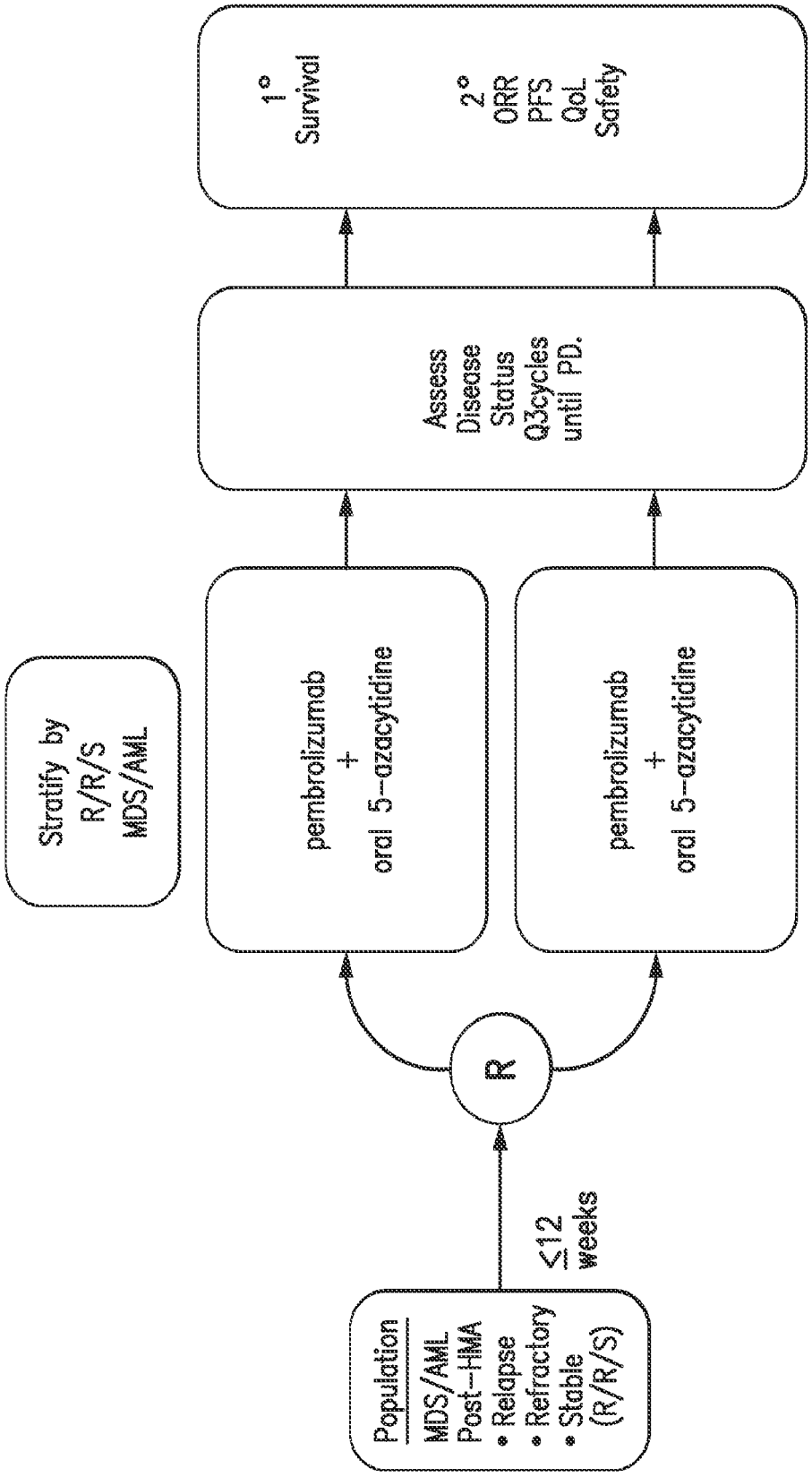

Population
MDS/AML
Post-HMA
• Relapse
• Refractory
• Stable
(R/R/S)
≤12 weeks
R
Stratify by
R/R/S
MDS/AML
pembrolizumab
+
oral 5-azacytidine
pembrolizumab
+
oral 5-azacytidine
Assess
Disease
Status
Q3cycles
until PD.
1°
Survival
2°
ORR
PFS
QoL
Safety

FIG. 5

*≤ 1/3 (33%) subjects with Cycle 1 dose reduction or drug–related discontinuation. Otherwise repeat at reduced dose
†Otherwise repeat with reduced dose of oral 5–azacytidine
Mono = oral 5–azacytidine alone treatment arm
Combo = oral 5–azacytidine + durvalumab combination treatment arm
R = Randomization
SD = Stable Disease
PD = Progressive Disease
FAB = French American British Classification in MDS
HMA = Hypomethylating Agent
ECOG PS = Eastern Cooperative Oncology Group Performance Status

FIG. 6

Mono = oral 5-azacytidine alone treatment arm
Combo = oral 5-azacytidine + durvalumab combination treatment arm
R = Randomization
SD = Stable Disease
PD = Progressive Disease

FAB = French American British Classification in MDS
HMA = Hypomethylating Agent
ECOG PS = Eastern Cooperative Oncology Group Performance Status

FIG. 7