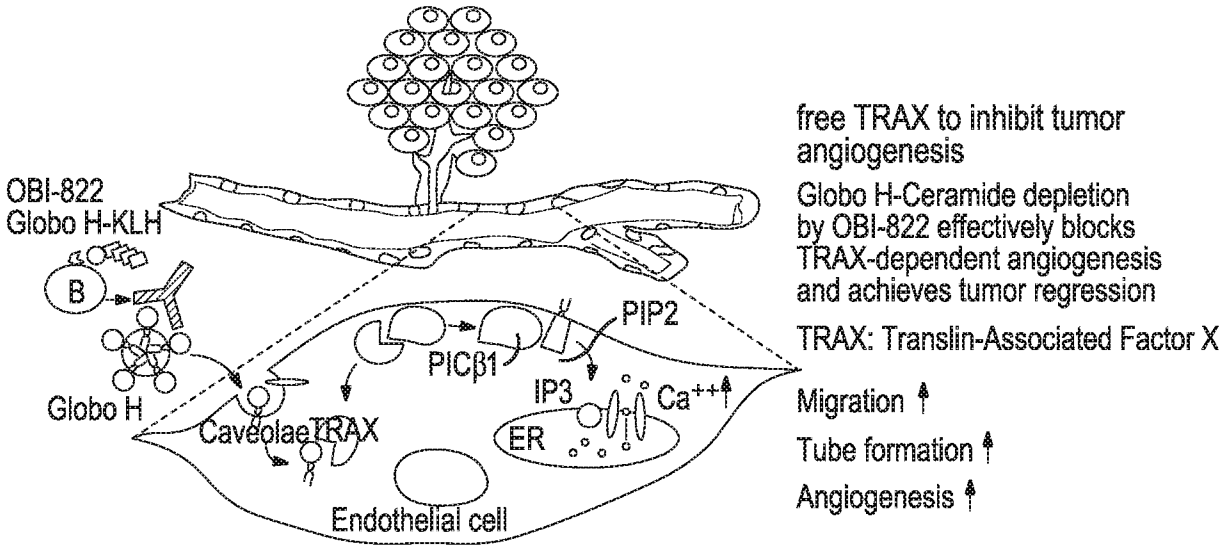

OBI-822
Globo H-KLH
B
Globo H
CaveolaeTRAX
PIP2
PICβ1
IP3
Ca++
ER
Endothelial cell
free TRAX to inhibit tumor angiogenesis
Globo H-Ceramide depletion by OBI-822 effectively blocks TRAX-dependent angiogenesis and achieves tumor regression
TRAX: Translin-Associated Factor X
Migration
Tube formation
Angiogenesis

FIG. 1

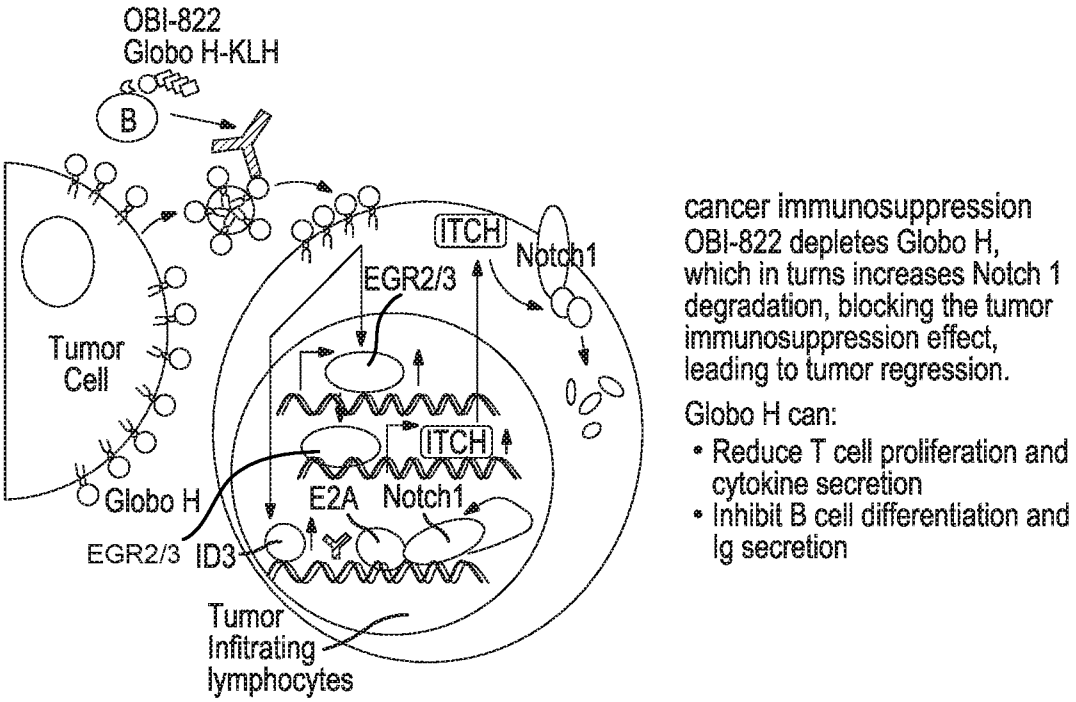

OBI-822
Globo H-KLH
B
Tumor
Cell
ITCH
Notch1
EGR2/3
ITCH
Globo H
E2A
Notch1
EGR2/3
ID3
Tumor
Infiltrating
lymphocytes
cancer immunosuppression
OBI-822 depletes Globo H, which in turns increases Notch 1 degradation, blocking the tumor immunosuppression effect, leading to tumor regression.
Globo H can:
• Reduce T cell proliferation and cytokine secretion
• Inhibit B cell differentiation and Ig secretion

FIG. 2

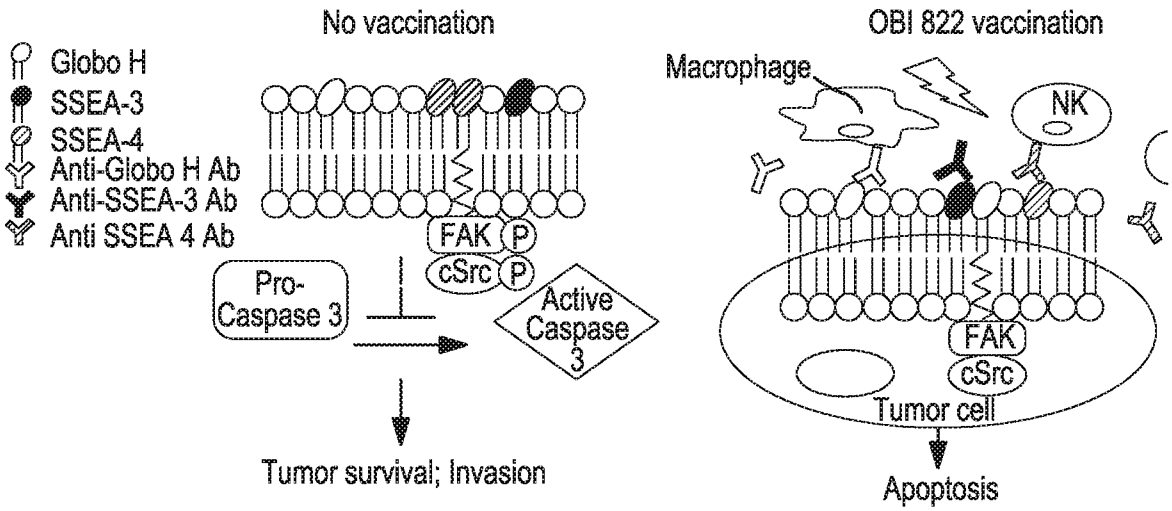

Globo H
SSEA-3
SSEA-4
Anti-Globo H Ab
Anti-SSEA-3 Ab
Anti SSEA 4 Ab
No vaccination
FAK
P
cSrc
P
Pro-Caspase 3
Active Caspase 3
Tumor survival; Invasion
OBI 822 vaccination
Macrophage
NK
FAK
cSrc
Tumor cell
Apoptosis

FIG. 3

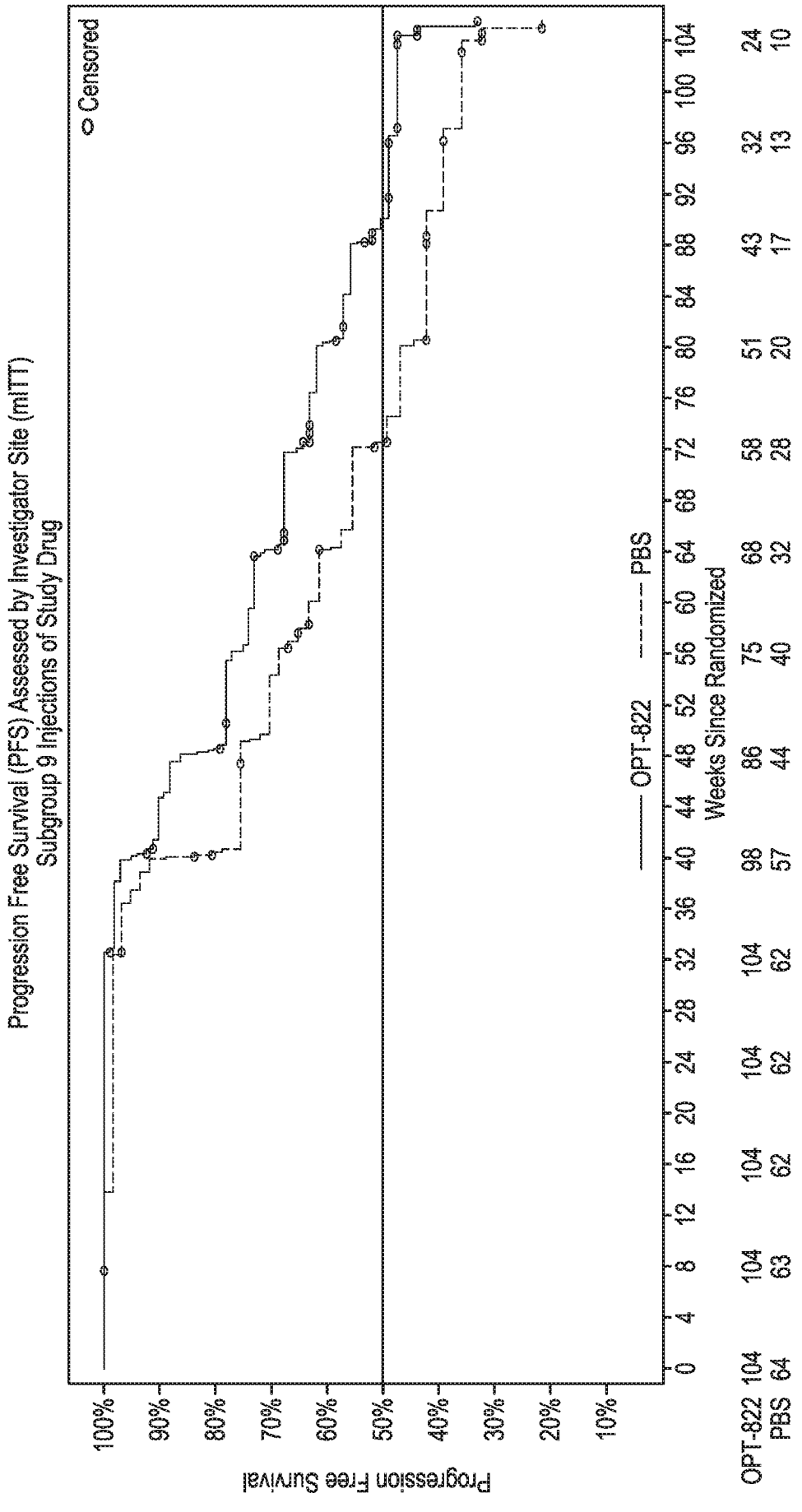

Progression Free Survival (PFS) Assessed by Investigator Site (mITT)
Subgroup 9 Injections of Study Drug
Censored
Progression Free Survival
100%
90%
80%
70%
60%
50%
40%
30%
20%
10%
OPT-822
PBS
Weeks Since Randomized
0 4 8 12 16 20 24 28 32 36 40 44 48 52 56 60 64 68 72 76 80 84 88 92 96 100 104
OPT-822 104 104 104 104 104 98 86 75 68 58 51 43 32 24
PBS 64 63 62 62 62 57 44 40 32 28 20 17 13 10
Stratified Log-rank Test, P=0.0542

FIG. 4

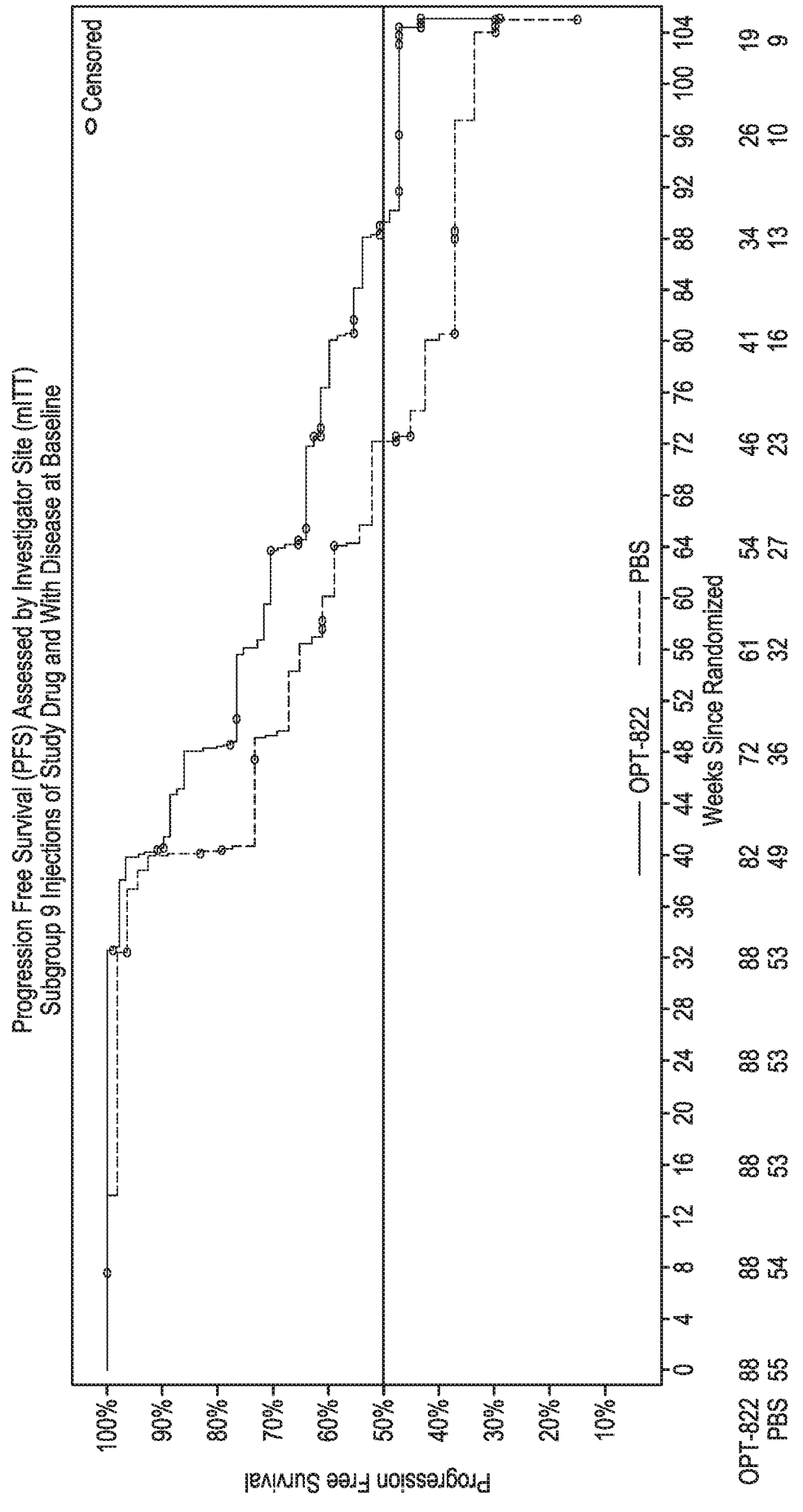

Progression Free Survival (PFS) Assessed by Investigator Site (mITT)
Subgroup 9 Injections of Study Drug and With Disease at Baseline
Censored
Progression Free Survival
100%
90%
80%
70%
60%
50%
40%
30%
20%
10%
OPT-822
PBS
Weeks Since Randomized
0 4 8 12 16 20 24 28 32 36 40 44 48 52 56 60 64 68 72 76 80 84 88 92 96 100 104
OPT-822 88 88 88 88 88 82 72 61 54 46 41 34 26 19
PBS 55 54 53 53 53 49 36 32 27 23 16 13 10 9
Stratified Log-rank Test, P=0.0362

FIG. 5

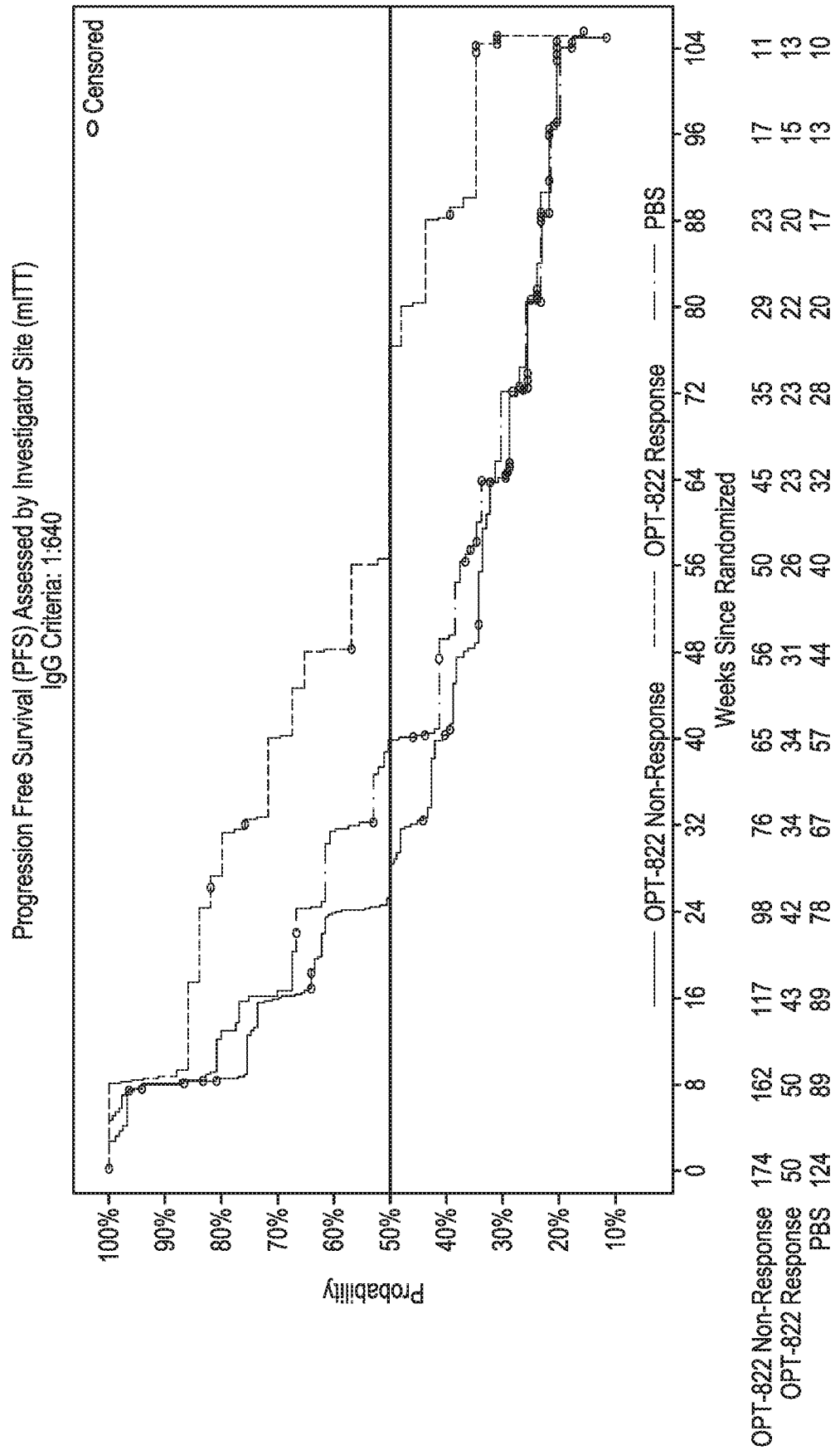

Progression Free Survival (PFS) Assessed by Investigator Site (mITT)
IgG Criteria: 1:640
Censored
Probability
100%
90%
80%
70%
60%
50%
40%
30%
20%
10%
0 8 16 24 32 40 48 56 64 72 80 88 96 104
Weeks Since Randomized
OPT-822 Non-Response
OPT-822 Response
PBS
OPT-822 Non-Response 174 162 117 98 76 65 56 50 45 35 29 23 17 11
OPT-822 Response 50 50 43 42 34 34 31 26 23 23 22 20 15 13
PBS 124 89 89 78 67 57 44 40 32 28 20 17 13 10
Overall stratified Cox Model P=0.0002

FIG. 6

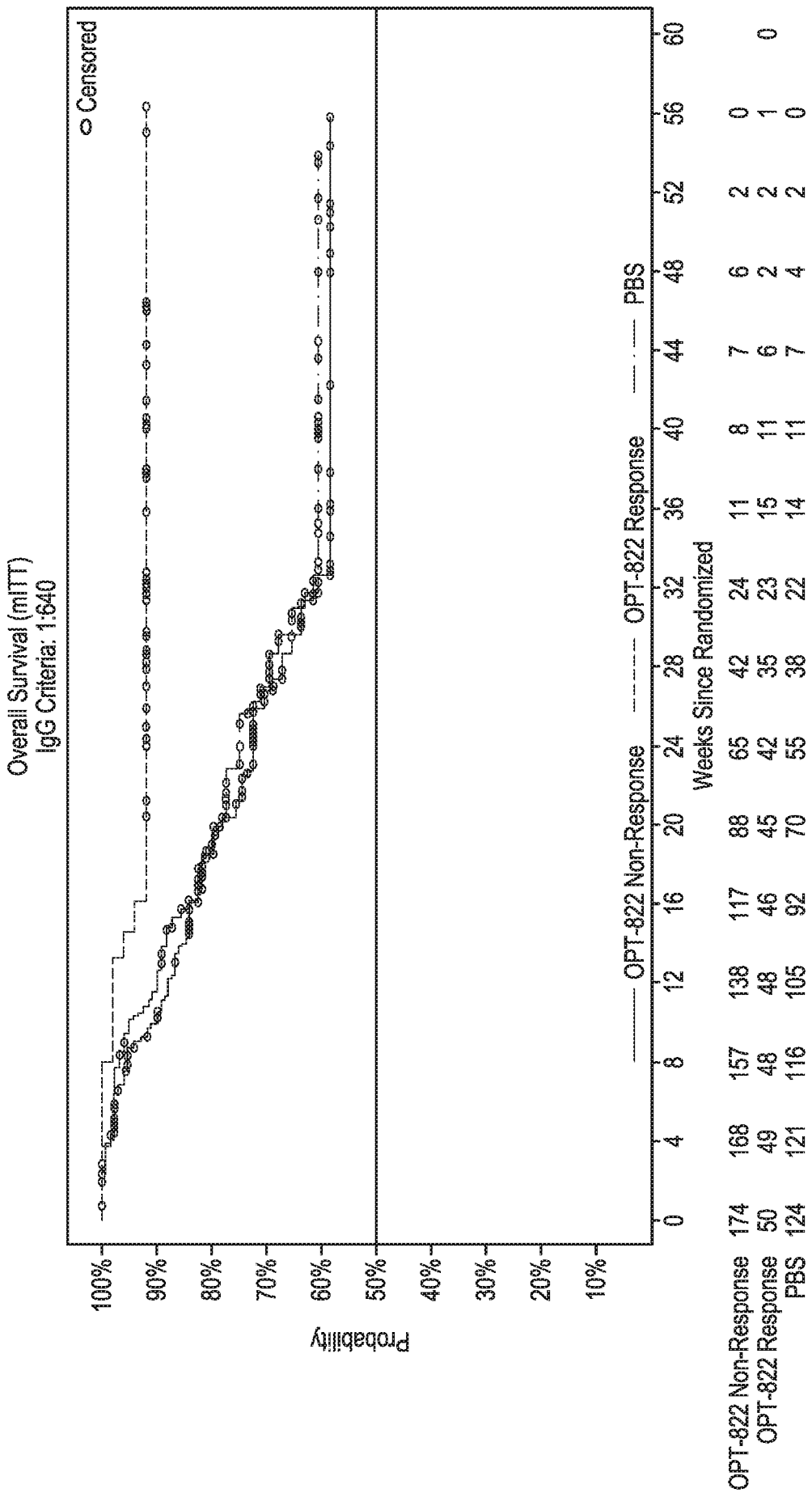

Overall Survival (mITT)
IgG Criteria: 1:640
Censored
Probability
100%
90%
80%
70%
60%
50%
40%
30%
20%
10%
0
4
8
12
16
20
24
28
32
36
40
44
48
52
56
60
Weeks Since Randomized
OPT-822 Non-Response
OPT-822 Response
PBS
OPT-822 Non-Response 174 168 157 138 117 88 65 42 24 11 8 7 6 2 0
OPT-822 Response 50 49 48 48 46 45 42 35 23 15 11 6 2 2 1 0
PBS 124 121 116 105 92 70 55 38 22 14 11 7 4 2 0
Overall stratified Cox Model P=0.0492

FIG. 7

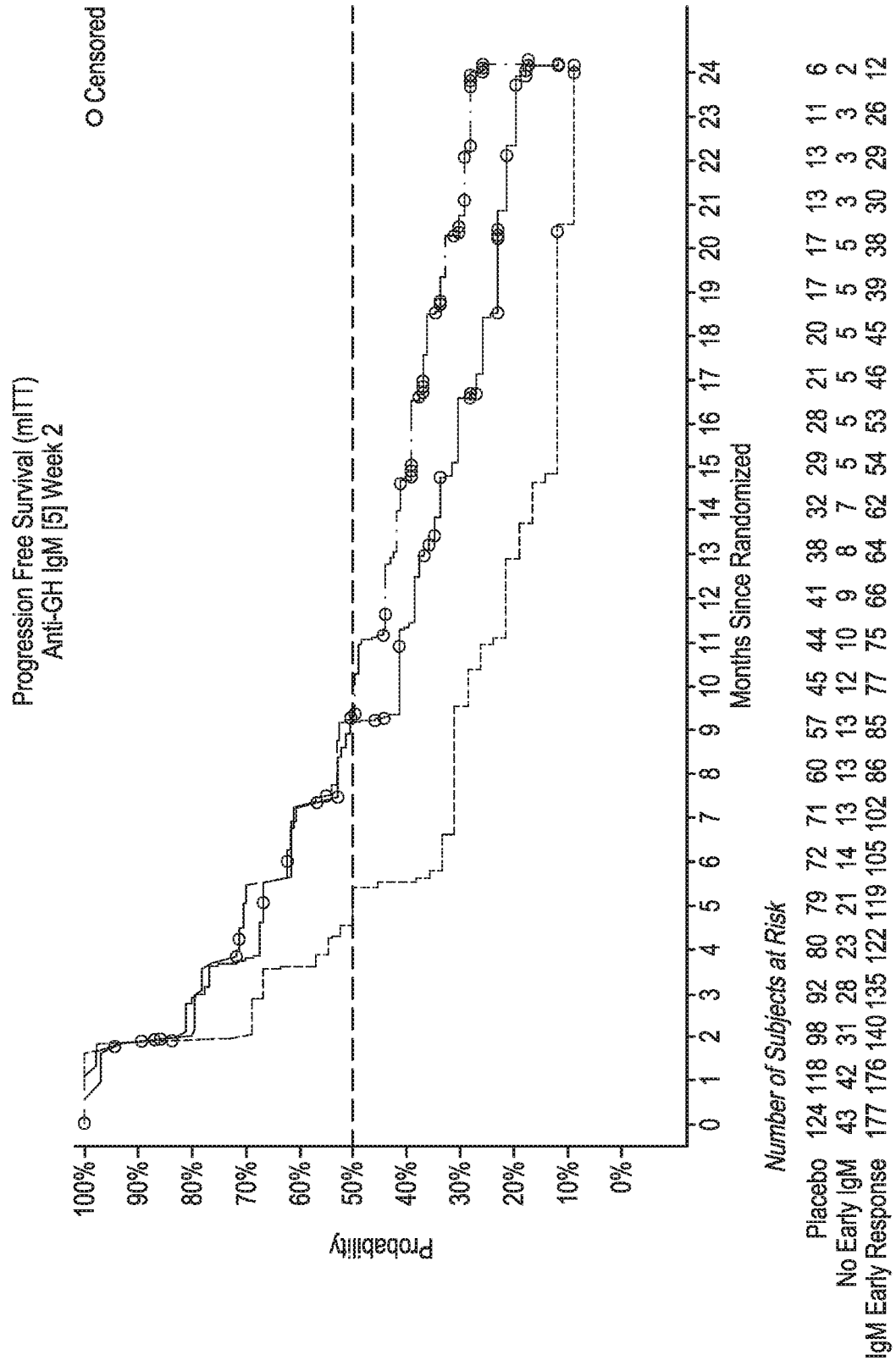

Progression Free Survival (mITT)
Anti-GH IgM [5] Week 2
O Censored
Probability
100%
90%
80%
70%
60%
50%
40%
30%
20%
10%
0%
0 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24
Months Since Randomized
Number of Subjects at Risk
Placebo 124 118 98 92 80 79 72 71 60 57 45 44 41 38 32 29 28 21 20 17 17 13 13 11 6
No Early IgM 43 42 31 28 23 21 14 13 13 13 12 10 9 8 7 5 5 5 5 5 3 3 3 3 2
IgM Early Response 177 176 140 135 122 119 105 102 86 85 77 75 66 64 62 54 53 46 45 39 38 30 29 26 12

FIG. 8

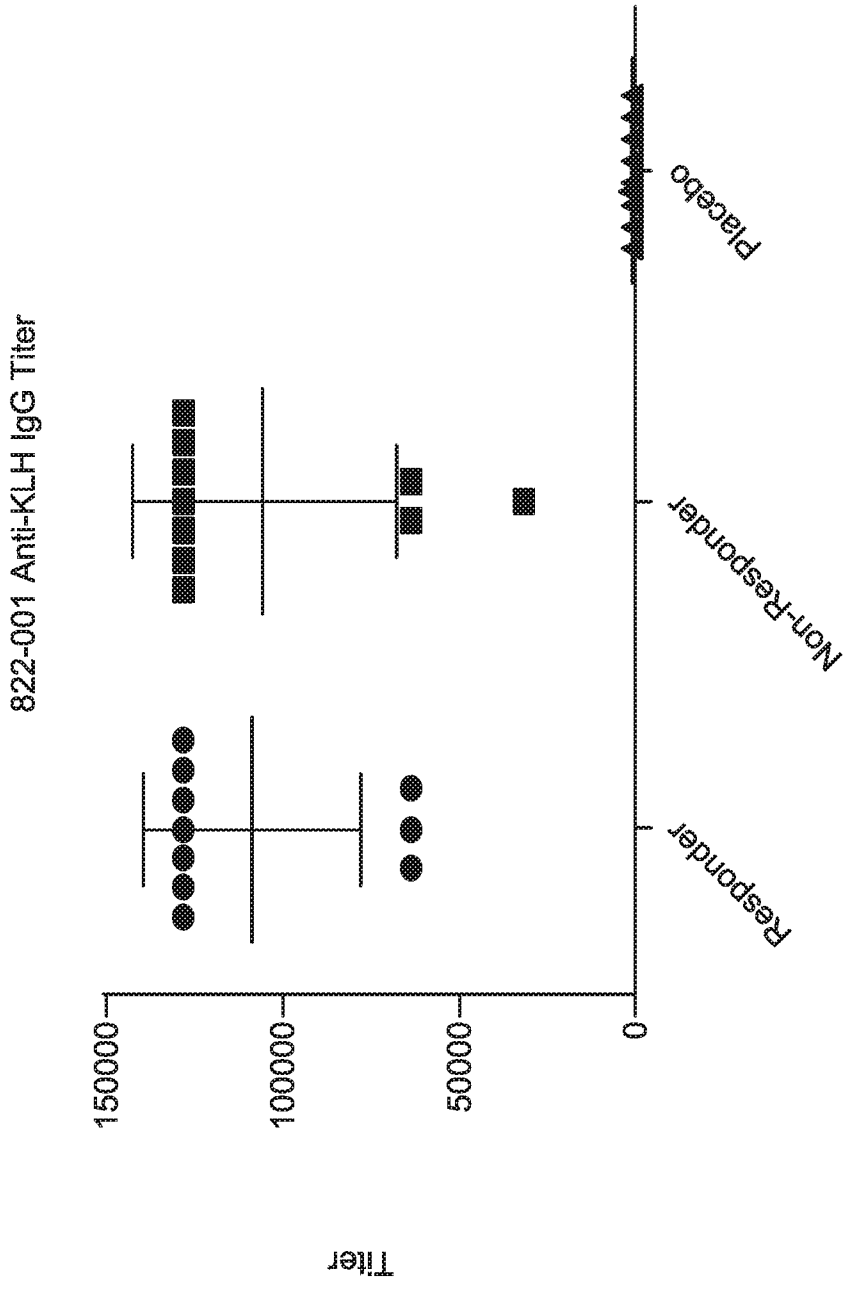

822-001 Anti-KLH IgG Titer
Titer
150000
100000
50000
0
Responder
Non-Responder
Placebo

FIG. 9

Subject No.	Visit	Lesion Assessment	Date of Assessment	Status	Method	Organ	Response
065	Screening	TARGET	2015-03-18	None			
		NON-TARGET	2015-03-18	None			
	Visit 7	TARGET	2015-10-01	None			NA
		NON-TARGET	2015-10-01	None			NA
		NEW	2015-10-01				No
		Overall	2015-10-01				UE

FIG. 10

Subject No.	Visit	Lesion Assessment	Date of Assessment	Status	Method	Organ	Response
035	Screening	TARGET	2014-04-24	None			
		NON-TARGET	2014-04-24	PRESENT	CT SCAN	SUBCENTIMETER MESENTERIC NODES	
	Visit 7	TARGET	2014-11-25	None			NA
		NON-TARGET	2014-11-25	PRESENT	CT SCAN	SUBCENTIMETER MESENTERIC NODES	SD
		NEW	2014-11-25				No
		Overall	2014-11-25				SD
	Visit 10	TARGET	2015-05-12	None			NA
		NON-TARGET	2015-05-12	PD	CT SCAN	SUBCENTIMETER MESENTERIC NODES	PD
		NEW	2015-05-12		CT SCAN	PERITONEUM	Yes
			2015-05-12		CT SCAN	PERITONEUM	
		Overall	2015-05-12				PD

FIG. 11

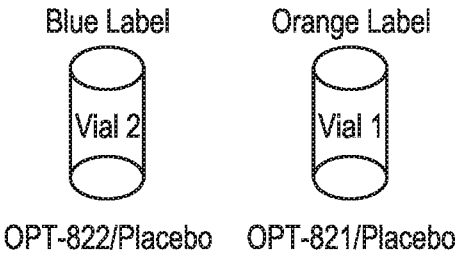
Subject No.	Visit	Lesion Assessment	Date of Assessment	Status	Method	Organ	Response
041	Screening	TARGET	2014-05-22	None			
		NON-TARGET	2014-05-22	PRESENT	CT SCAN	LUNG	
	Visit 7	TARGET	2015-01-08	None			NA
		NON-TARGET	2015-01-08	PRESENT	CT SCAN	LUNG	SD
		NEW	2015-01-08				No
		Overall	2015-01-08				SD
	Visit 10	TARGET	2015-06-25	None			NA
		NON-TARGET	2015-06-25	PRESENT	CT SCAN	LUNG	SD
		NEW	2015-06-25		CT SCAN	SMALL MESENTENIC NODULE	Yes
		Overall	2015-06-25				PD

FIG. 12

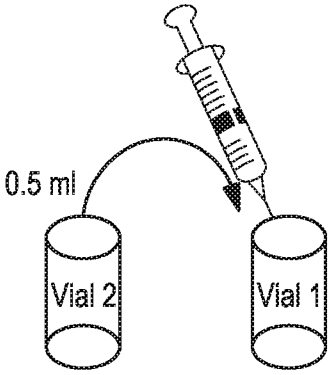
Subject No.	Visit	Lesion Assessment	Date of Assessment	Status	Method	Organ	Response
060	Screening	TARGET	2015-01-06	None			
		NON-TARGET	2015-01-06	PRESENT	CT SCAN	PERITONEUM	
	Visit 7	TARGET	2015-08-17	None			NA
		NON-TARGET	2015-08-17	PRESENT	CT SCAN	PERITONEUM	SD
		NEW	2015-08-17				No
		Overall	2015-08-17				SD

FIG. 13

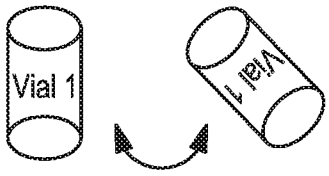
Step 1:Thaw 30 min (Vial 1 & 2).



Step 2:Transfer 0.5 ml from Vial 2 to Vial 1



Step 3:Gently mix Vial 1 by gently
iInverting the vial 4-5 times.



Step 4:Withdraw 0.8 ml from Vial 1
for subject injection within 2 hour.

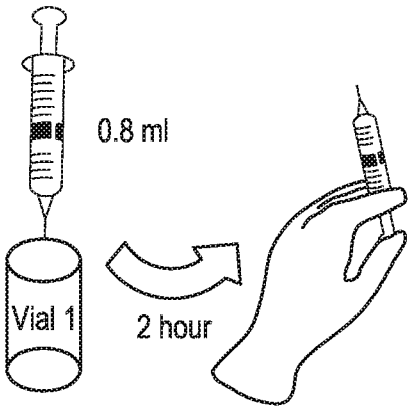


FIG. 14