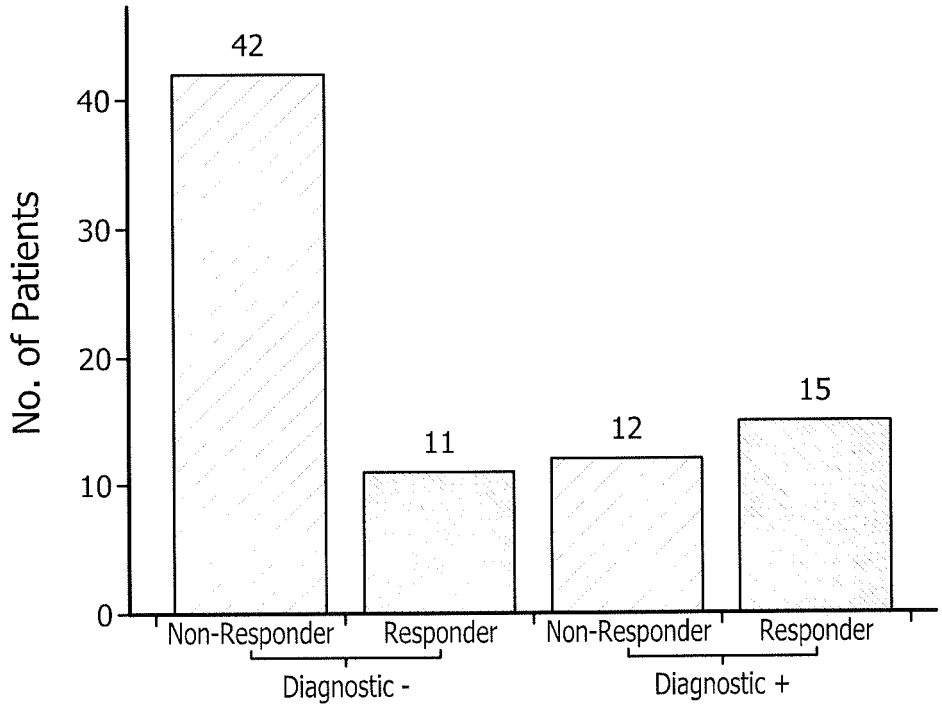

No. of Patients
0
10
20
30
40
42
11
12
15
Non-Responder
Responder
Non-Responder
Responder
Diagnostic -
Diagnostic +

FIG. 1

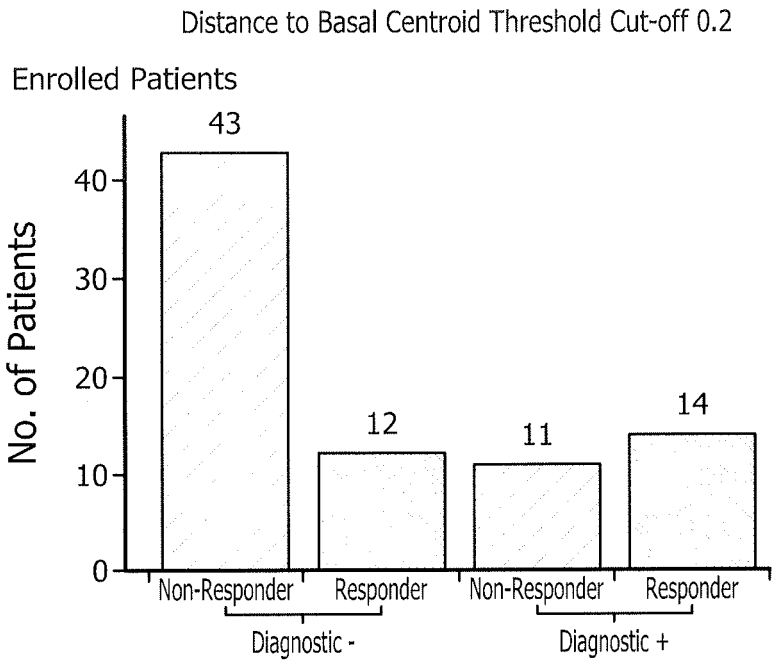

Distance to Basal Centroid Threshold Cut-off 0.2
Enrolled Patients
No. of Patients
0
10
20
30
40
43
12
11
14
Non-Responder
Responder
Non-Responder
Responder
Diagnostic -
Diagnostic +

FIG. 2A

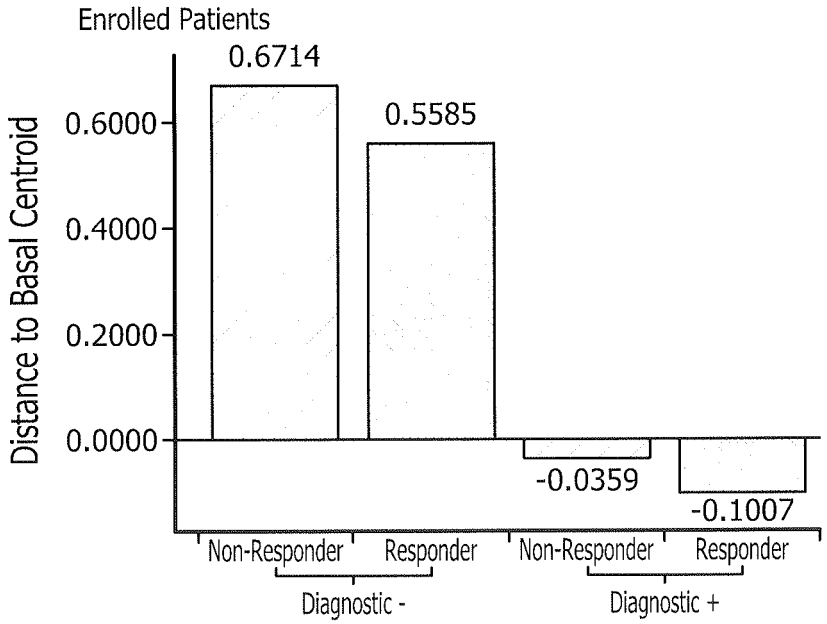

Enrolled Patients
Distance to Basal Centroid
0.0000
0.2000
0.4000
0.6000
0.6714
0.5585
-0.0359
-0.1007
Non-Responder
Responder
Non-Responder
Responder
Diagnostic -
Diagnostic +

FIG. 2B

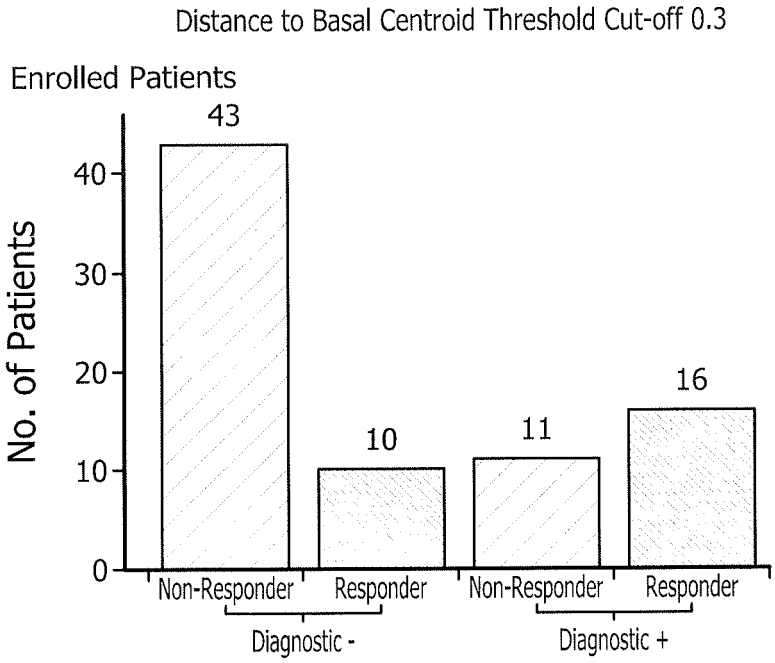

Distance to Basal Centroid Threshold Cut-off 0.3
Enrolled Patients
No. of Patients
0
10
20
30
40
43
10
11
16
Non-Responder
Responder
Non-Responder
Responder
Diagnostic -
Diagnostic +

FIG. 3A

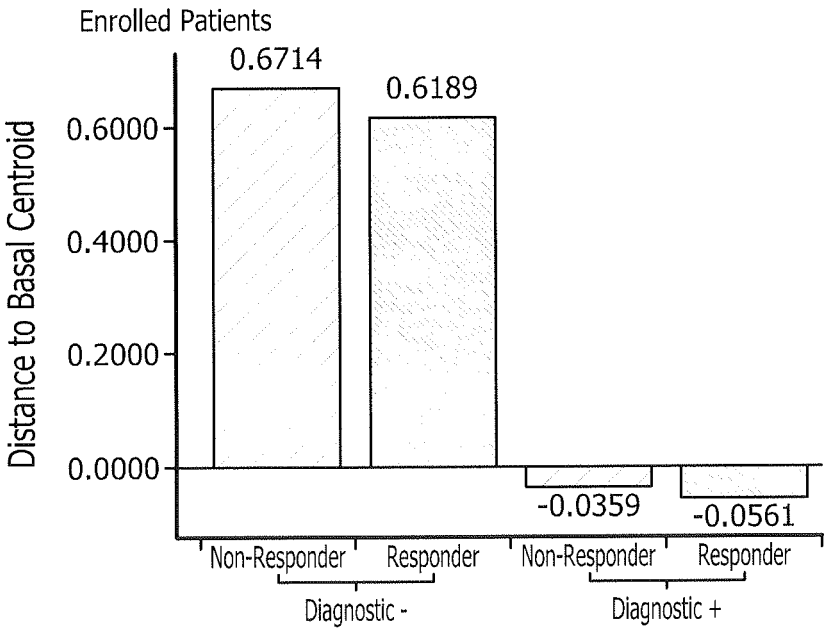

Enrolled Patients
Distance to Basal Centroid
0.0000
0.2000
0.4000
0.6000
0.6714
0.6189
-0.0359
-0.0561
Non-Responder
Responder
Non-Responder
Responder
Diagnostic -
Diagnostic +

FIG. 3B

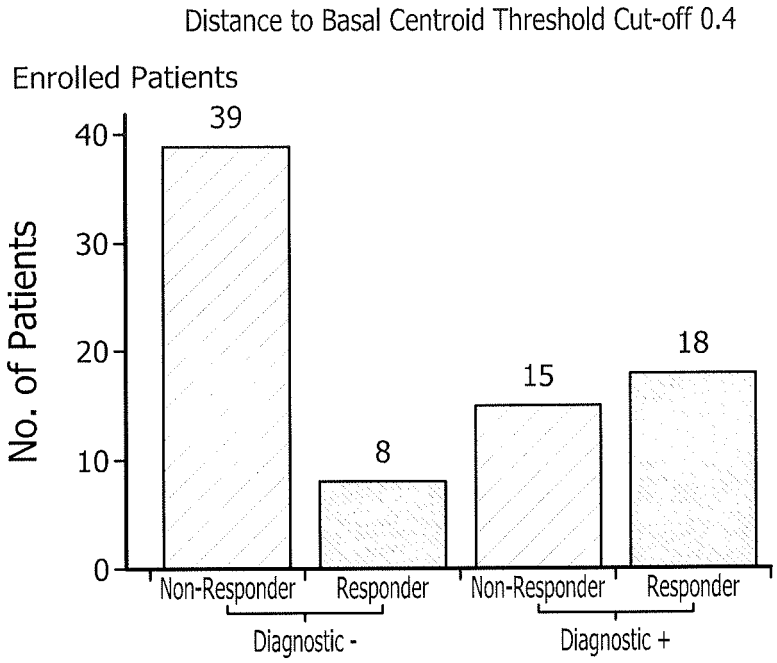

Distance to Basal Centroid Threshold Cut-off 0.4
Enrolled Patients
No. of Patients
0
10
20
30
40
39
8
15
18
Non-Responder
Responder
Non-Responder
Responder
Diagnostic -
Diagnostic +

FIG. 4A

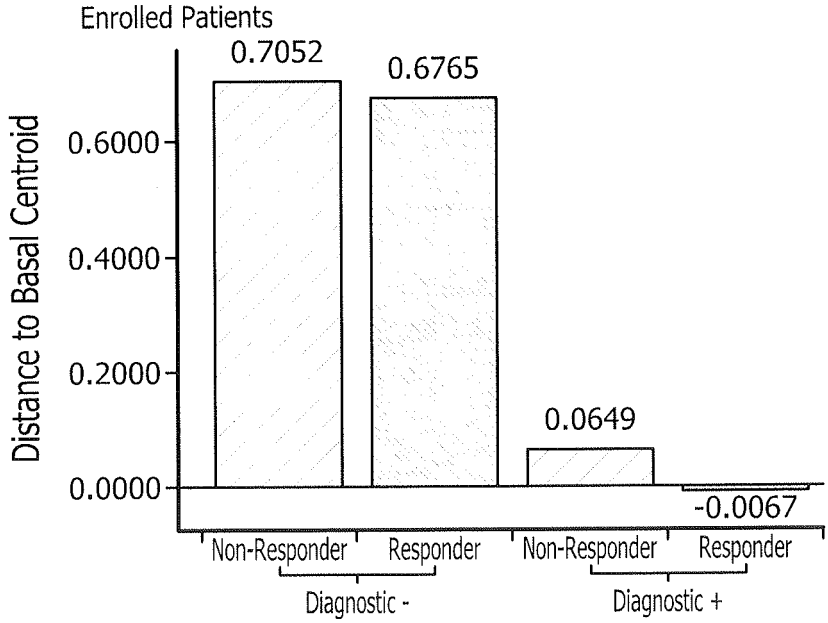

Enrolled Patients
Distance to Basal Centroid
0.0000
0.2000
0.4000
0.6000
0.7052
0.6765
0.0649
-0.0067
Non-Responder
Responder
Non-Responder
Responder
Diagnostic -
Diagnostic +

FIG. 4B

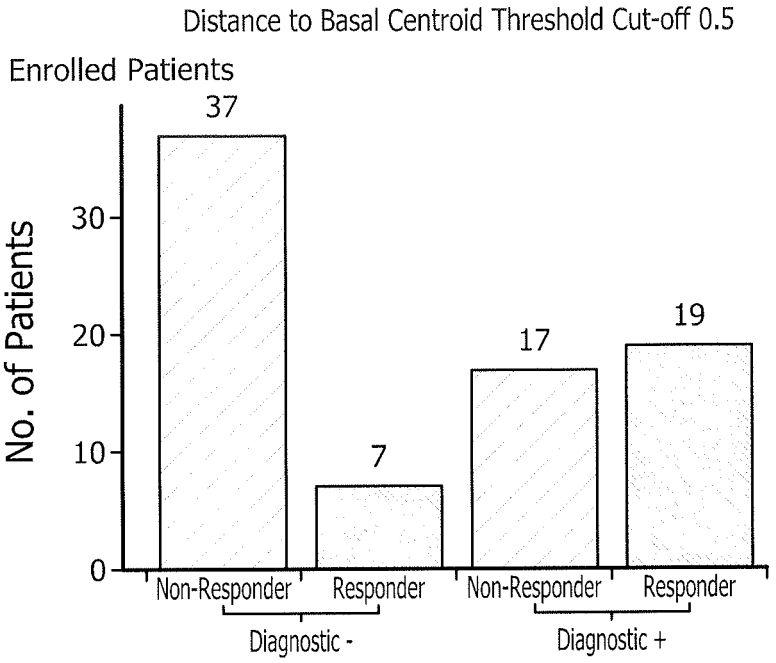

Distance to Basal Centroid Threshold Cut-off 0.5
Enrolled Patients
No. of Patients
0
10
20
30
37
7
17
19
Non-Responder
Responder
Non-Responder
Responder
Diagnostic -
Diagnostic +

FIG. 5A

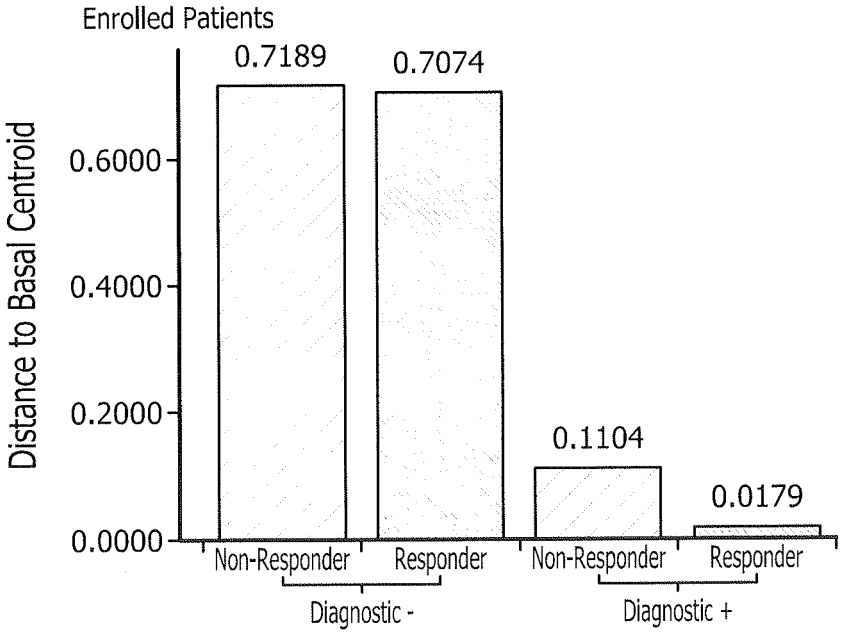

Enrolled Patients
Distance to Basal Centroid
0.0000
0.2000
0.4000
0.6000
0.7189
0.7074
0.1104
0.0179
Non-Responder
Responder
Non-Responder
Responder
Diagnostic -
Diagnostic +

FIG. 5B

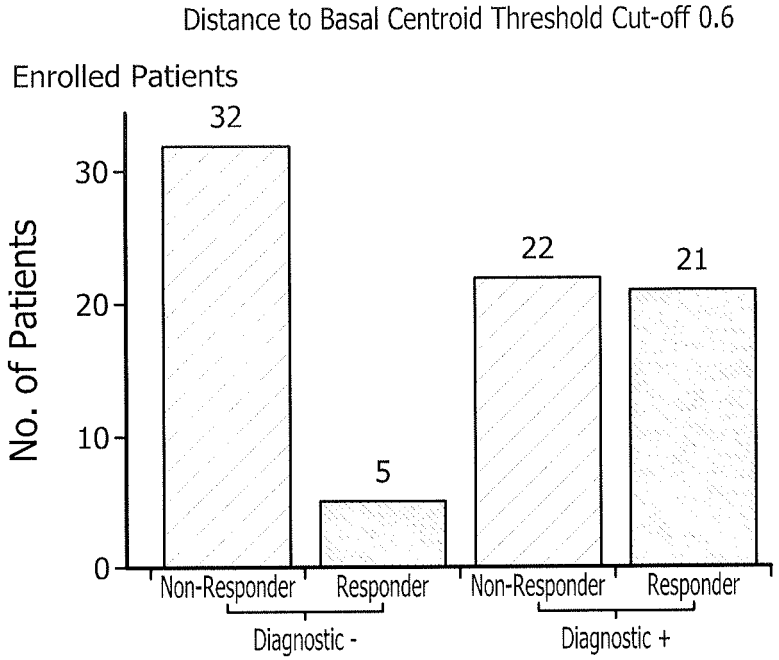

Distance to Basal Centroid Threshold Cut-off 0.6
Enrolled Patients
No. of Patients
0
10
20
30
32
5
22
21
Non-Responder
Responder
Non-Responder
Responder
Diagnostic -
Diagnostic +

FIG. 6A

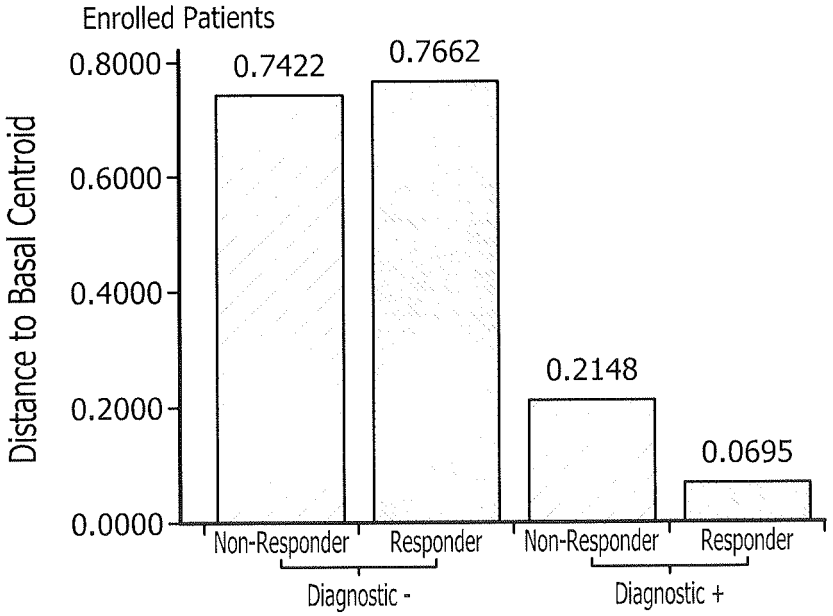

Enrolled Patients
Distance to Basal Centroid
0.0000
0.2000
0.4000
0.6000
0.8000
0.7422
0.7662
0.2148
0.0695
Non-Responder
Responder
Non-Responder
Responder
Diagnostic -
Diagnostic +

FIG. 6B

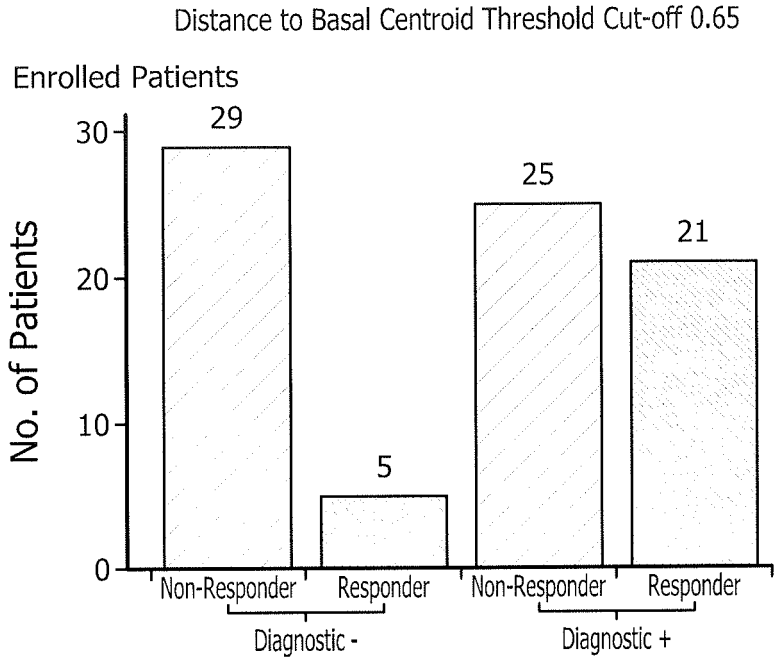

Distance to Basal Centroid Threshold Cut-off 0.65
Enrolled Patients
No. of Patients
30
20
10
0
29
5
25
21
Non-Responder
Responder
Non-Responder
Responder
Diagnostic -
Diagnostic +

FIG. 7A

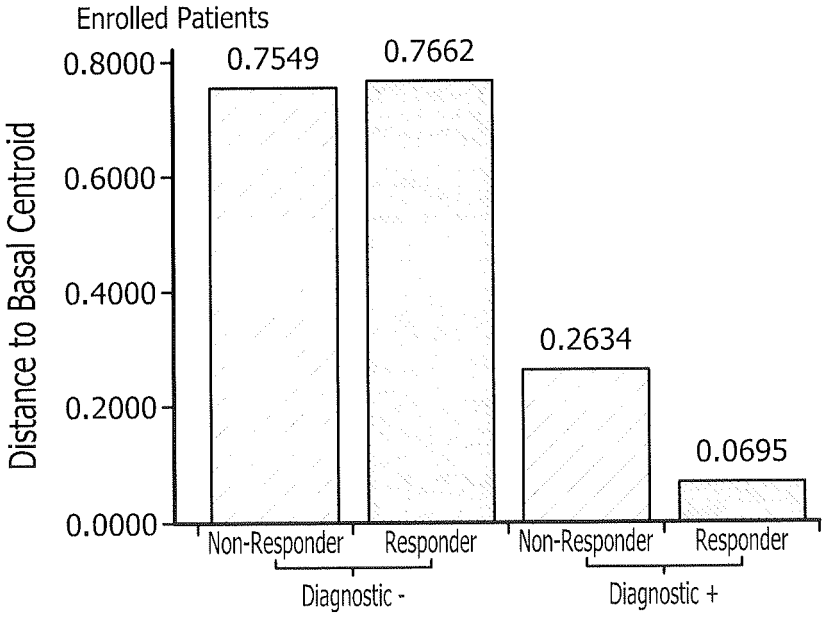

Enrolled Patients
Distance to Basal Centroid
0.8000
0.6000
0.4000
0.2000
0.0000
0.7549
0.7662
0.2634
0.0695
Non-Responder
Responder
Non-Responder
Responder
Diagnostic -
Diagnostic +

FIG. 7B

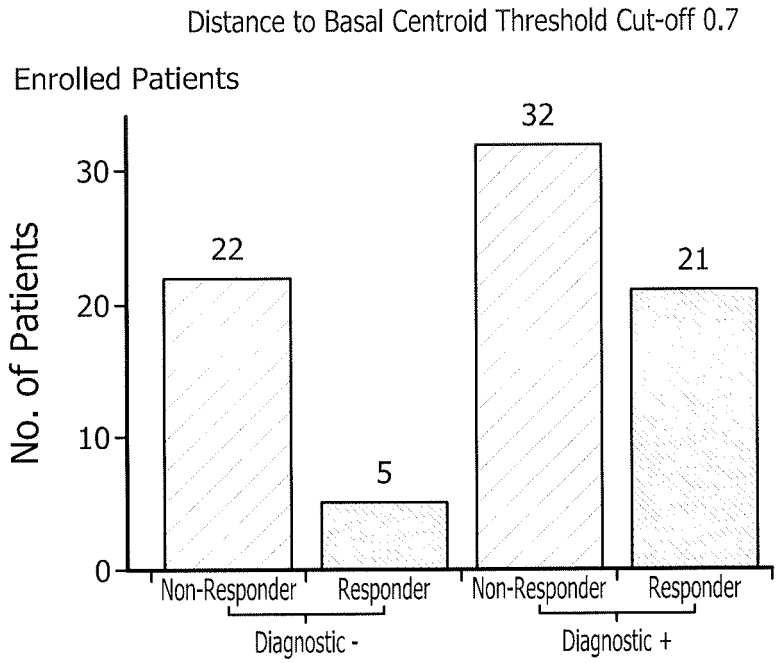

Distance to Basal Centroid Threshold Cut-off 0.7
Enrolled Patients
No. of Patients
0
10
20
30
22
5
32
21
Non-Responder
Responder
Non-Responder
Responder
Diagnostic -
Diagnostic +

FIG. 8A

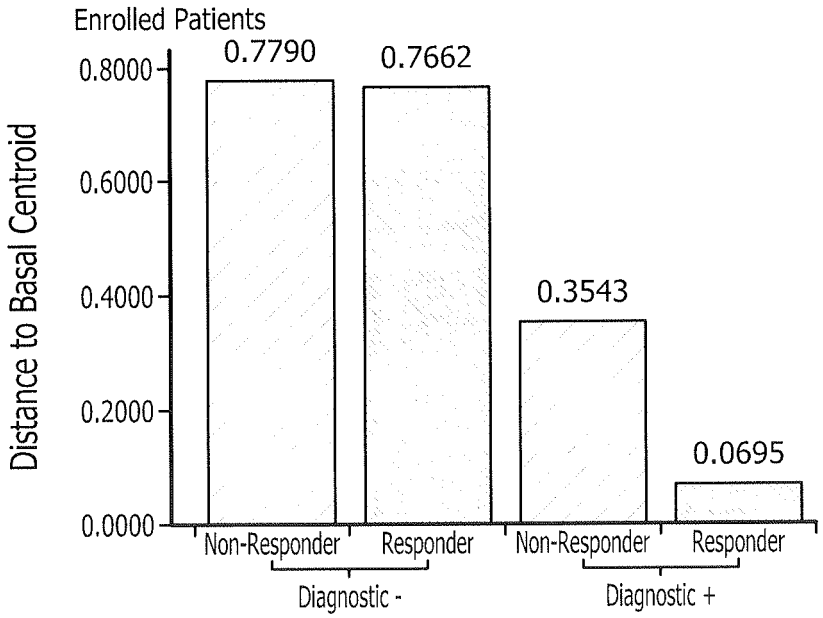

Enrolled Patients
Distance to Basal Centroid
0.0000
0.2000
0.4000
0.6000
0.8000
0.7790
0.7662
0.3543
0.0695
Non-Responder
Responder
Non-Responder
Responder
Diagnostic -
Diagnostic +

FIG. 8B

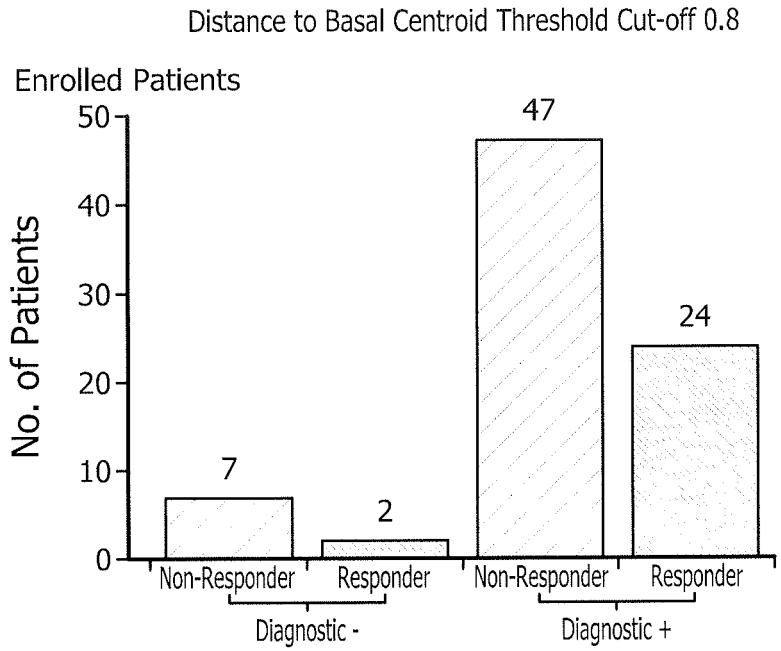

Distance to Basal Centroid Threshold Cut-off 0.8
Enrolled Patients
No. of Patients
50
40
30
20
10
0
7
2
47
24
Non-Responder
Responder
Non-Responder
Responder
Diagnostic -
Diagnostic +

FIG. 9A

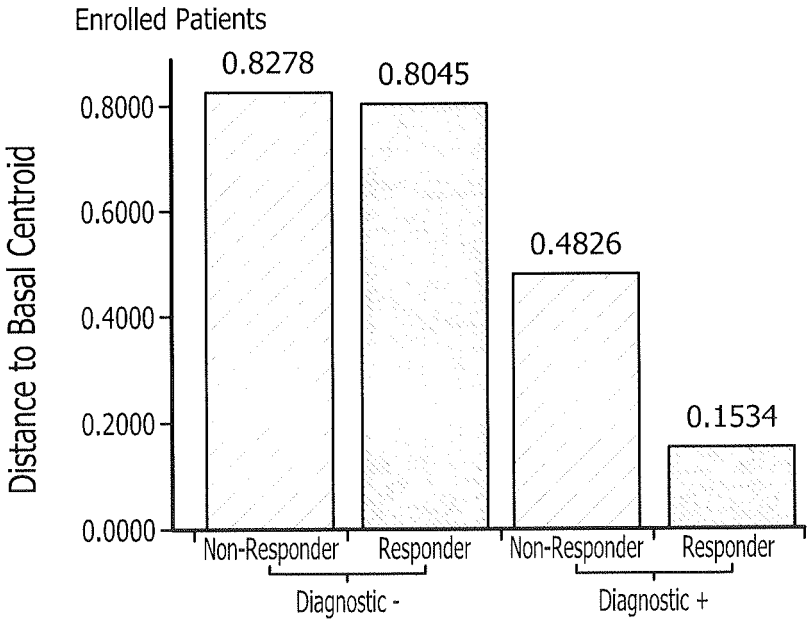

Enrolled Patients
Distance to Basal Centroid
0.8000
0.6000
0.4000
0.2000
0.0000
0.8278
0.8045
0.4826
0.1534
Non-Responder
Responder
Non-Responder
Responder
Diagnostic -
Diagnostic +

FIG. 9B

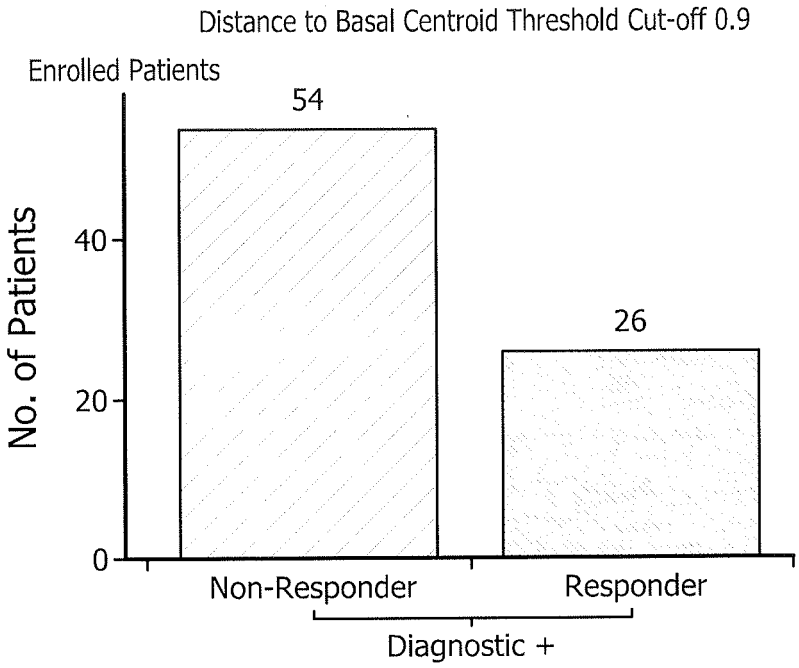


FIG. 10A

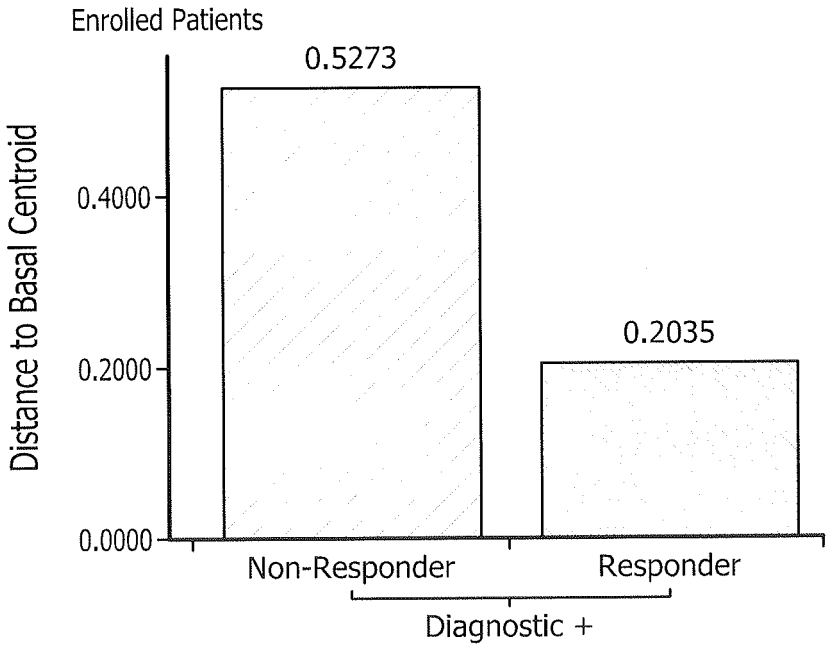


FIG. 10B

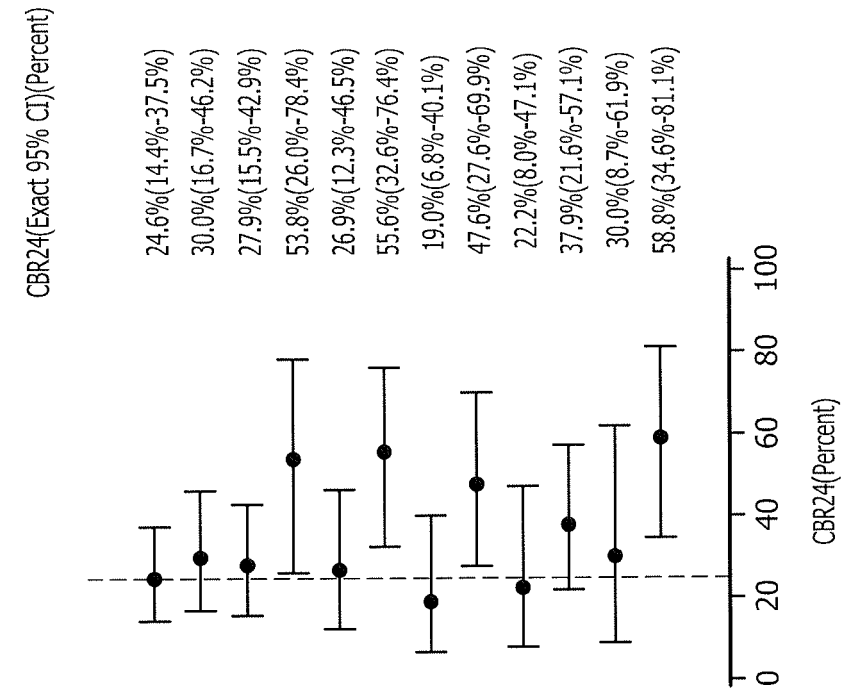

Subgroups
Number of Patients
Number of Patients with Clinical Benefit
CBR24(Exact 95% CI)(Percent)
All ITT Patients 57 14 24.6%(14.4%-37.5%)
Evaluable Patients 40 12 30.0%(16.7%-46.2%)
IHC AR >= 10% 43 12 27.9%(15.5%-42.9%)
PAM50 Non-basal 13 7 53.8%(26.0%-78.4%)
PAM50 Basal 26 7 26.9%(12.3%-46.5%)
DX+ < 0.6 18 10 55.6%(32.6%-76.4%)
DX- >= 0.6 21 4 19.0%(6.8%-40.1%)
DX+ < 0.7 21 10 47.6%(27.6%-69.9%)
DX- >= 0.7 18 4 22.2%(8.0%-47.1%)
DX+ < 0.75 29 11 37.9%(21.6%-57.1%)
DX- >= 0.75 10 3 30.0%(8.7%-61.9%)
IHC AR>= 10% and DX+ < 0.6 17 10 58.8%(34.6%-81.1%)
0
20
40
60
80
100
CBR24(Percent)

FIG. 11

Stage 1 Patient Subgroups	No. of Patients	No. of Patients with Clinical Benefit	CBR24, % (Exact 95%CI)
All ITT Patients	42	10	23.8% (12.3%-39.1%)
Evaluable Patients	26	9	34.6% (18.3%-54.2%)
IHC AR ≥10%	32	9	28.1% (14.8%-46.2%)
Novel DX+*	19	8	42.1% (22.2%-65.5%)
1st or 2nd Line of Therapy	23	8	34.8% (17.8%-56.8%)
1st or 2nd Line of Therapy and Novel DX+*	10	6	60.0% (28.3%-85.0%)

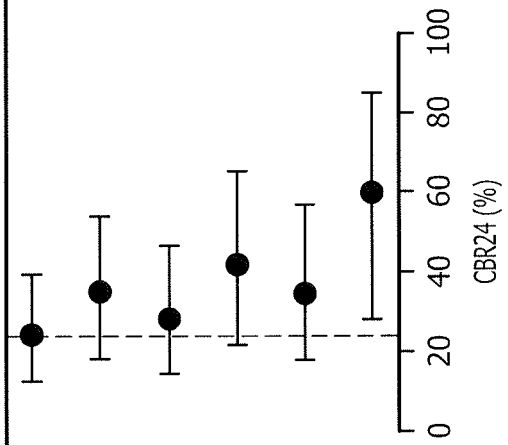


FIG. 12

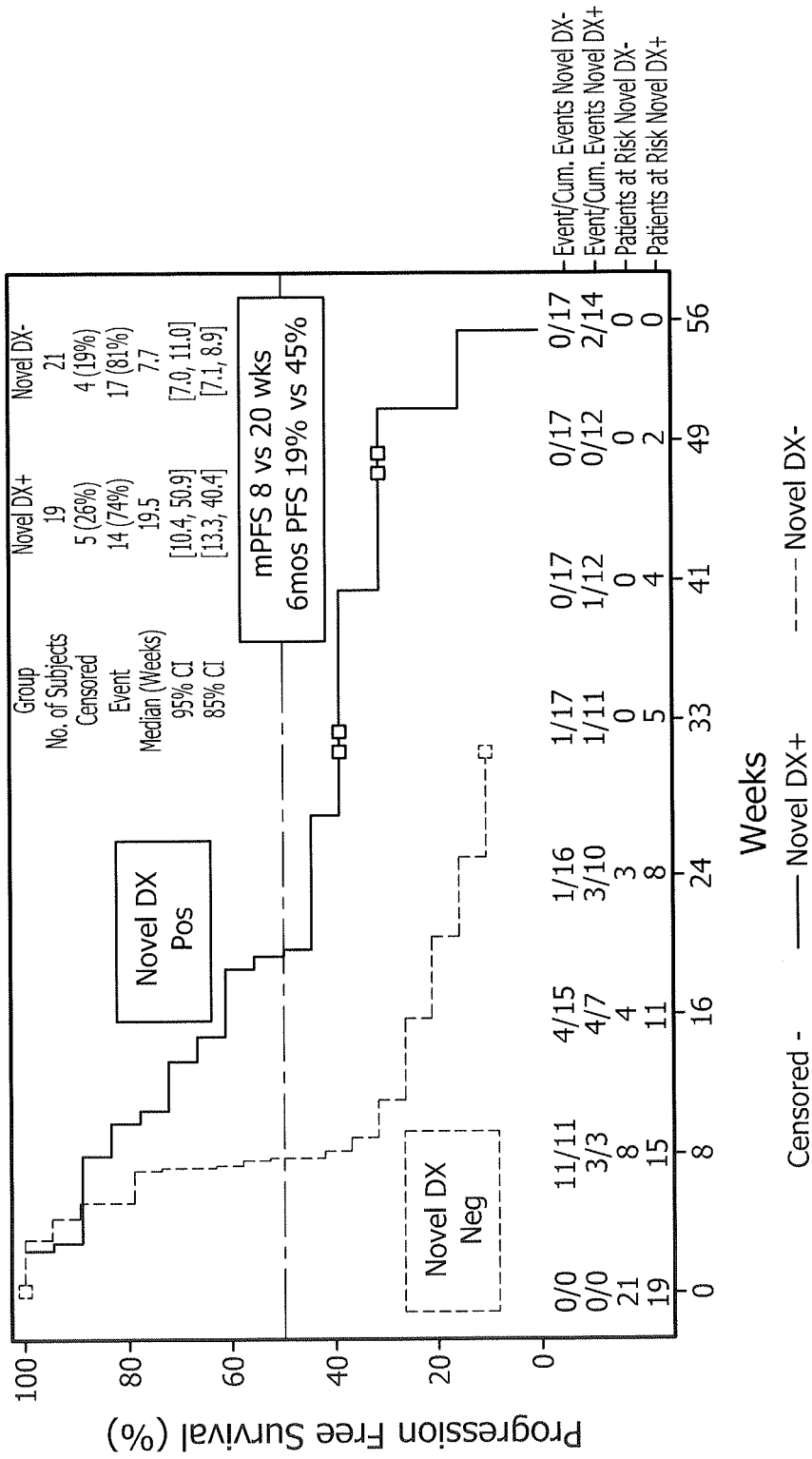

Progression Free Survival (%)
100
80
60
40
20
0
Novel DX Pos
Novel DX Neg
mPFS 8 vs 20 wks
6mos PFS 19% vs 45%
Group
No. of Subjects
Censored
Event
Median (Weeks)
95% CI
85% CI
Novel DX+
19
5 (26%)
14 (74%)
19.5
[10.4, 50.9]
[13.3, 40.4]
Novel DX-
21
4 (19%)
17 (81%)
7.7
[7.0, 11.0]
[7.1, 8.9]
Event/Cum. Events Novel DX-
Event/Cum. Events Novel DX+
Patients at Risk Novel DX-
Patients at Risk Novel DX+
0/0 11/11 4/15 1/16 1/17 0/17 0/17 0/17
0/0 3/3 4/7 3/10 1/11 1/12 0/12 2/14
21 8 4 3 0 0 0 0
19 15 11 8 5 4 2 0
0 8 16 24 33 41 49 56
Weeks
Censored -
Novel DX+
Novel DX-

FIG. 13

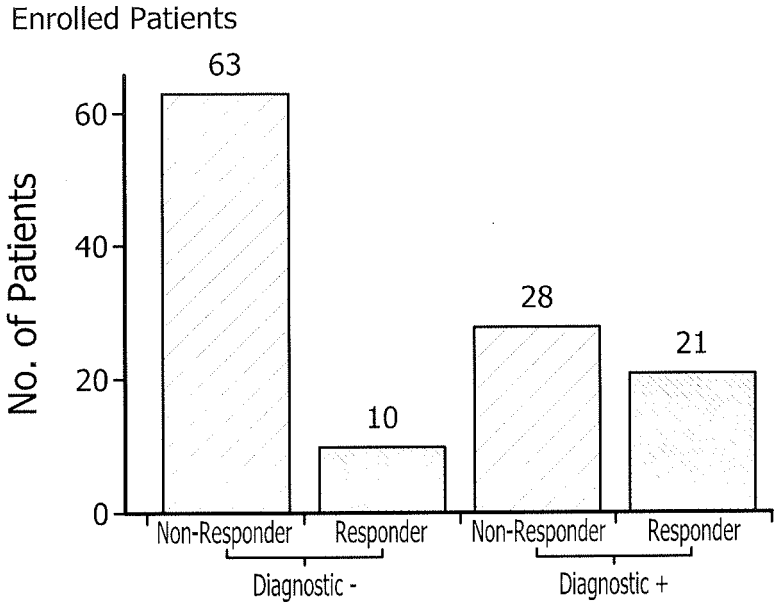


FIG. 14A

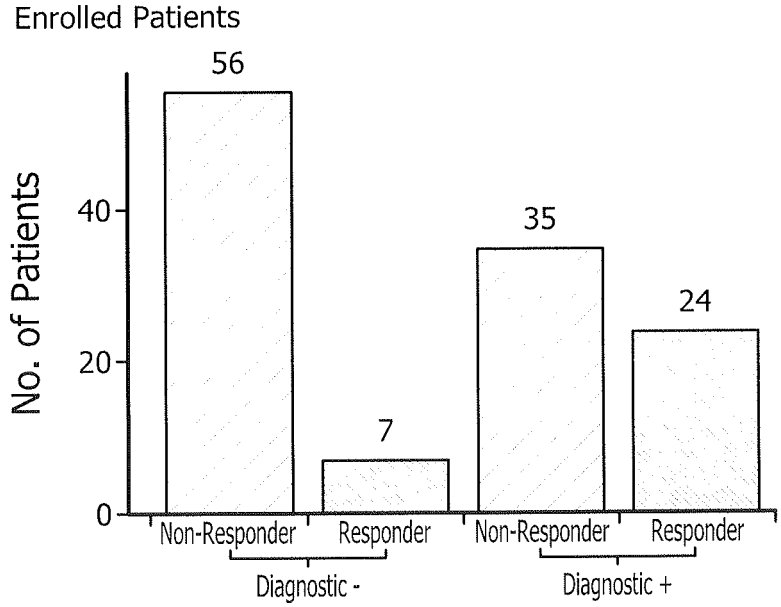


FIG. 14B

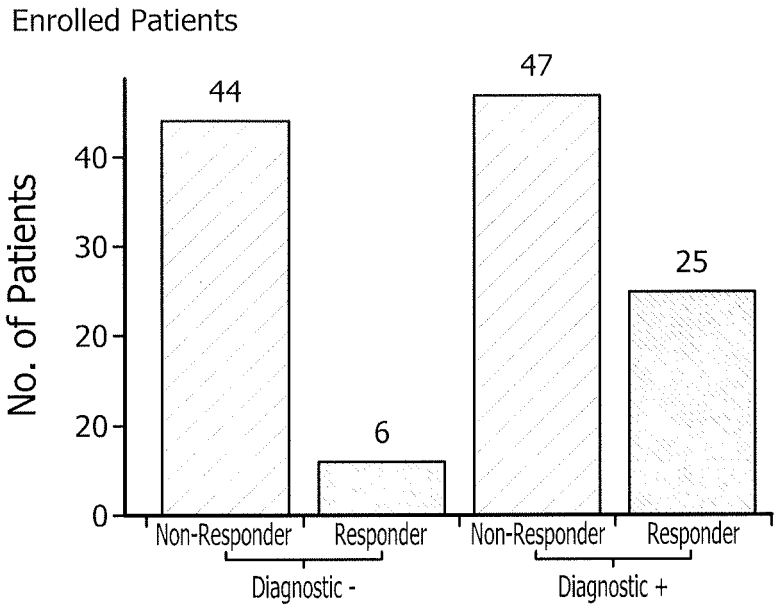


FIG. 14C

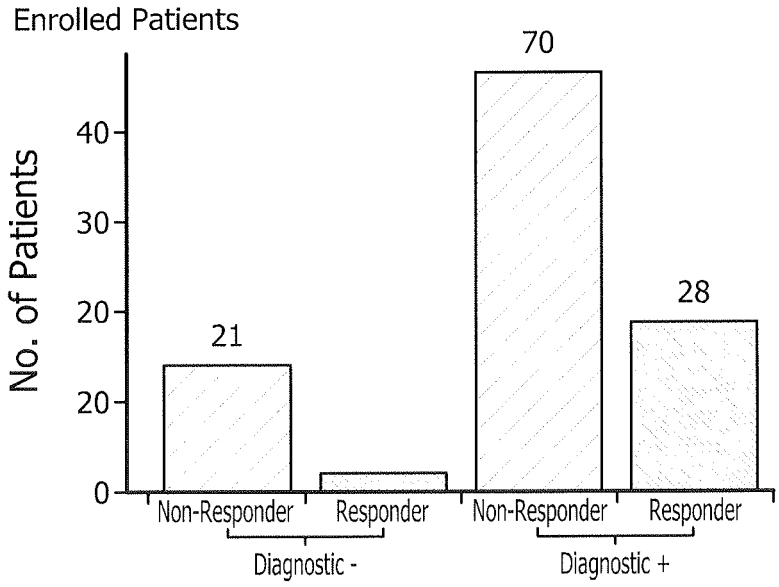


FIG. 14D

Subgroups	Number of Patients	Number of Patients with Clinical Benefit	CBR24(Exact 95% CI)(Percent)
All ITT Patients	118	24	20.3%(13.7%-28.6%)
Evaluable	75	22	29.3%(19.6%-40.6%)
PR-AR DX+:> -0.2	46	17	37.0%(23.4%-52.2%)
PR-AR DX-:<= -0.2	72	7	9.7%(4.4%-18.6%)
PR-AR DX+:> -0.25	56	20	35.7%(23.7%-49.1%)
PR-AR DX-:<= -0.25	62	4	6.5%(2.2%-15.6%)
PR-AR DX+:> -0.3	69	21	30.4%(20.3%-42.7%)
PR-AR DX-:<= -0.3	49	3	6.1%(1.7%-16.7%)
PR-AR DX+:> -0.35	95	22	23.2%(15.5%-32.5%)
PR-AR DX-:<= -0.35	23	2	8.7%(1.6%-27.4%)
0 - 1 Prior Therapy	62	18	29.0%(18.8%-41.8%)
>= 2 Prior Therapies	56	6	10.7%(4.8%-21.8%)
PR-AR DX+:> -0.25 and 0-1 Prior Therapy	25	14	56.0%(35.5%-74.8%)
PR-AR DX+:> -0.25 and >= 2 Prior Therapies	31	6	19.4%(8.8%-36.7%)
PR-AR DX-:<= -0.25 and 0-1 Prior Therapy	37	4	10.8%(3.8%-25.1%)
PR-AR DX-:<= -0.25 and >= 2 Prior Therapies	25	0	

FIG. 15

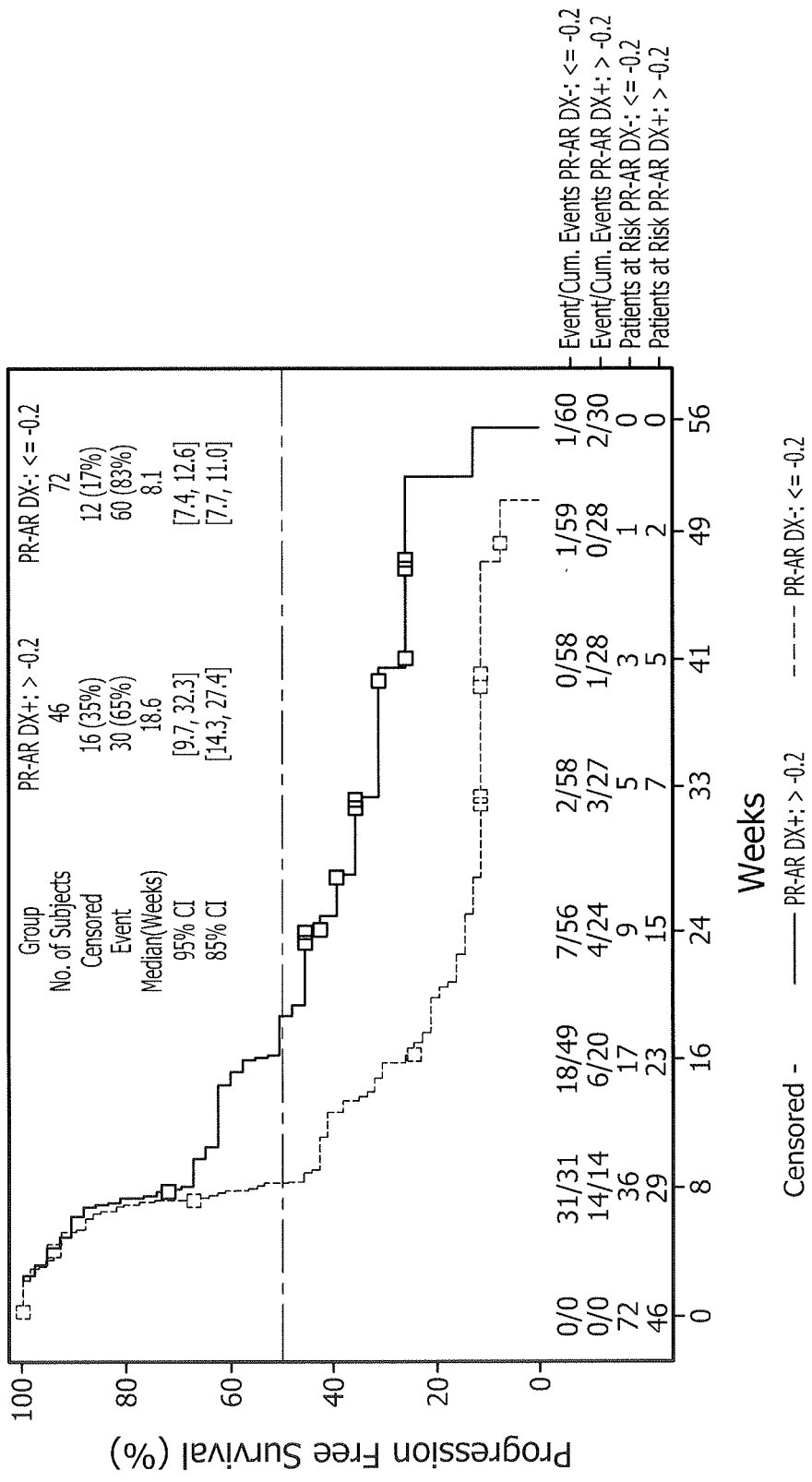

Progression Free Survival (%)
100
80
60
40
20
0
Group
No. of Subjects
Censored
Event
Median(Weeks)
95% CI
85% CI
PR-AR DX+: > -0.2
46
16 (35%)
30 (65%)
18.6
[9.7, 32.3]
[14.3, 27.4]
PR-AR DX-: <= -0.2
72
12 (17%)
60 (83%)
8.1
[7.4, 12.6]
[7.7, 11.0]
0/0 31/31 18/49 7/56 2/58 0/58 1/59 1/60
0/0 14/14 6/20 4/24 3/27 1/28 0/28 2/30
72 36 17 9 5 3 1 0
46 29 23 15 7 5 2 0
0 8 16 24 33 41 49 56
Weeks
Censored -
PR-AR DX+: > -0.2
PR-AR DX-: <= -0.2
Event/Cum. Events PR-AR DX-: <= -0.2
Event/Cum. Events PR-AR DX+: > -0.2
Patients at Risk PR-AR DX-: <= -0.2
Patients at Risk PR-AR DX+: > -0.2

FIG. 16

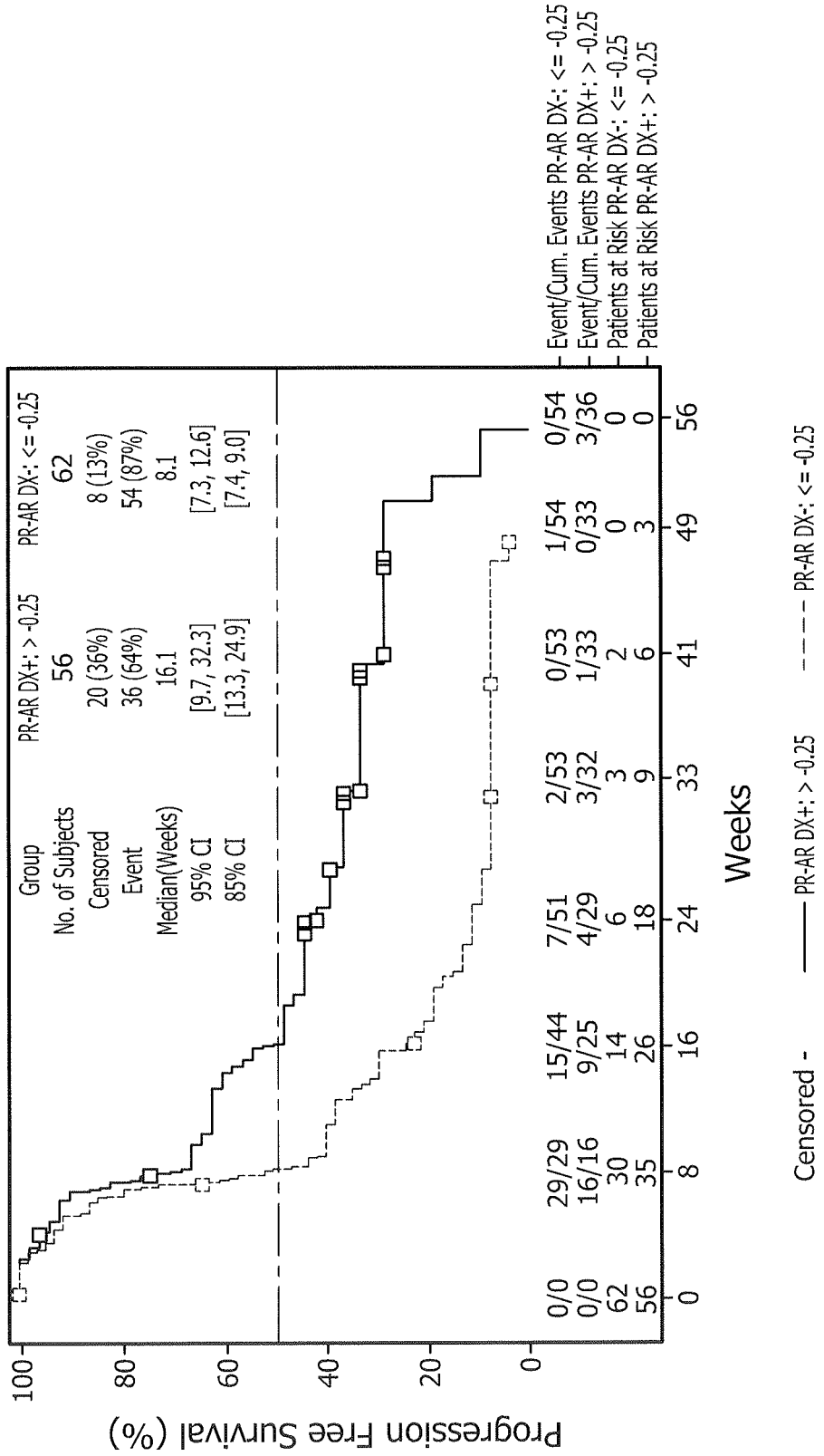

Progression Free Survival (%)
100
80
60
40
20
0
Weeks
0
8
16
24
33
41
49
56
Group
No. of Subjects
Censored
Event
Median(Weeks)
95% CI
85% CI
PR-AR DX+: > -0.25
56
20 (36%)
36 (64%)
16.1
[9.7, 32.3]
[13.3, 24.9]
PR-AR DX-: <= -0.25
62
8 (13%)
54 (87%)
8.1
[7.3, 12.6]
[7.4, 9.0]
Censored -
PR-AR DX+: > -0.25
PR-AR DX-: <= -0.25
Event/Cum. Events PR-AR DX-: <= -0.25
Event/Cum. Events PR-AR DX+: > -0.25
Patients at Risk PR-AR DX-: <= -0.25
Patients at Risk PR-AR DX+: > -0.25
0/0 29/29 15/44 7/51 2/53 0/53 1/54 0/54
0/0 16/16 9/25 4/29 3/32 1/33 0/33 3/36
62 30 14 6 3 2 0 0
56 35 26 18 9 6 3 0

FIG. 17

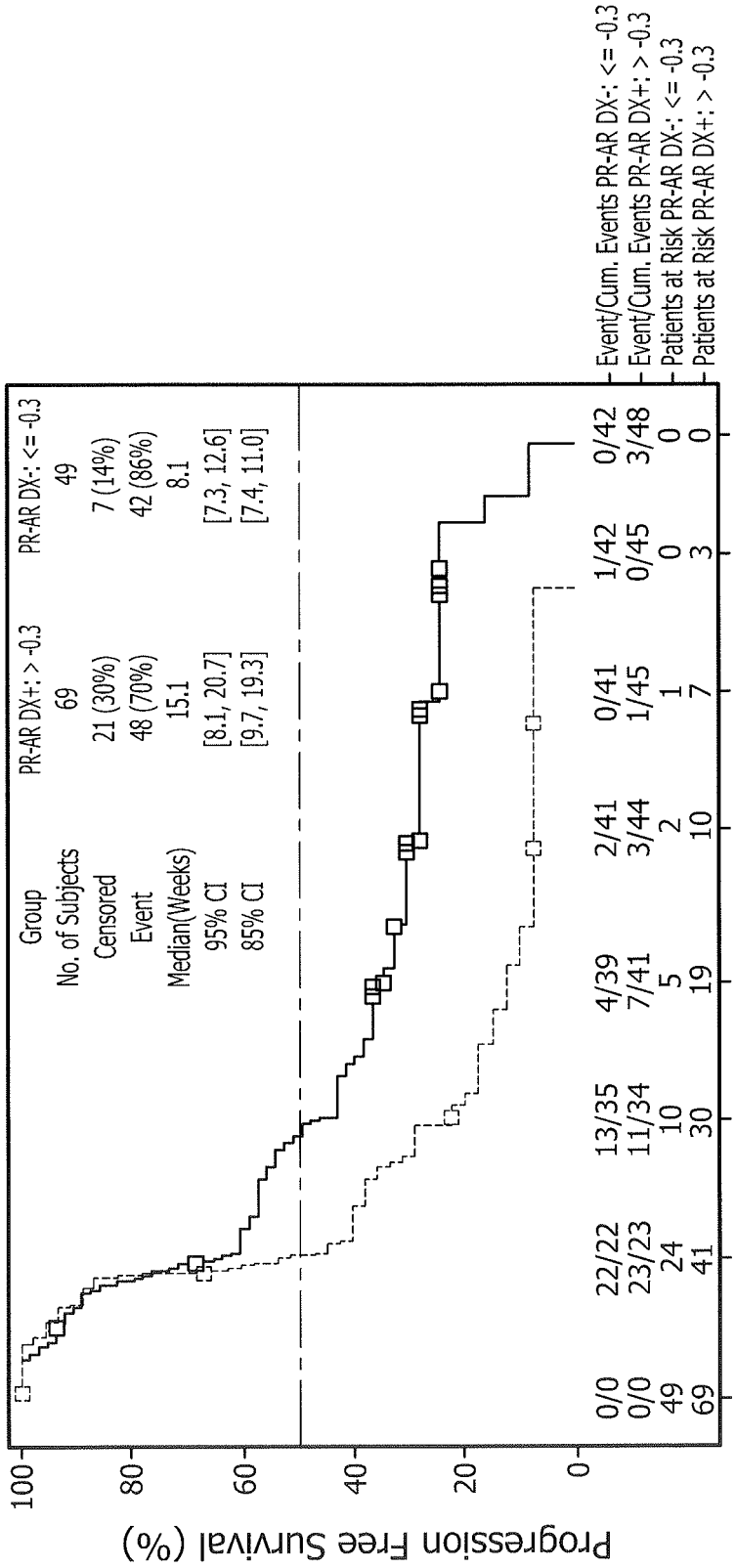

Progression Free Survival (%)
100
80
60
40
20
0
Group
No. of Subjects
Censored
Event
Median(Weeks)
95% CI
85% CI
PR-AR DX+: > -0.3
69
21 (30%)
48 (70%)
15.1
[8.1, 20.7]
[9.7, 19.3]
PR-AR DX-: <= -0.3
49
7 (14%)
42 (86%)
8.1
[7.3, 12.6]
[7.4, 11.0]
0/0 22/22 13/35 4/39 2/41 0/41 1/42 0/42
0/0 23/23 11/34 7/41 3/44 1/45 0/45 3/48
49 24 10 5 2 1 0 0
69 41 30 19 10 7 3 0
0 8 16 24 33 41 49 56
Weeks
Censored -
PR-AR DX+: > -0.3
PR-AR DX-: <= -0.3
Event/Cum. Events PR-AR DX-: <= -0.3
Event/Cum. Events PR-AR DX+: > -0.3
Patients at Risk PR-AR DX-: <= -0.3
Patients at Risk PR-AR DX+: > -0.3

FIG. 18

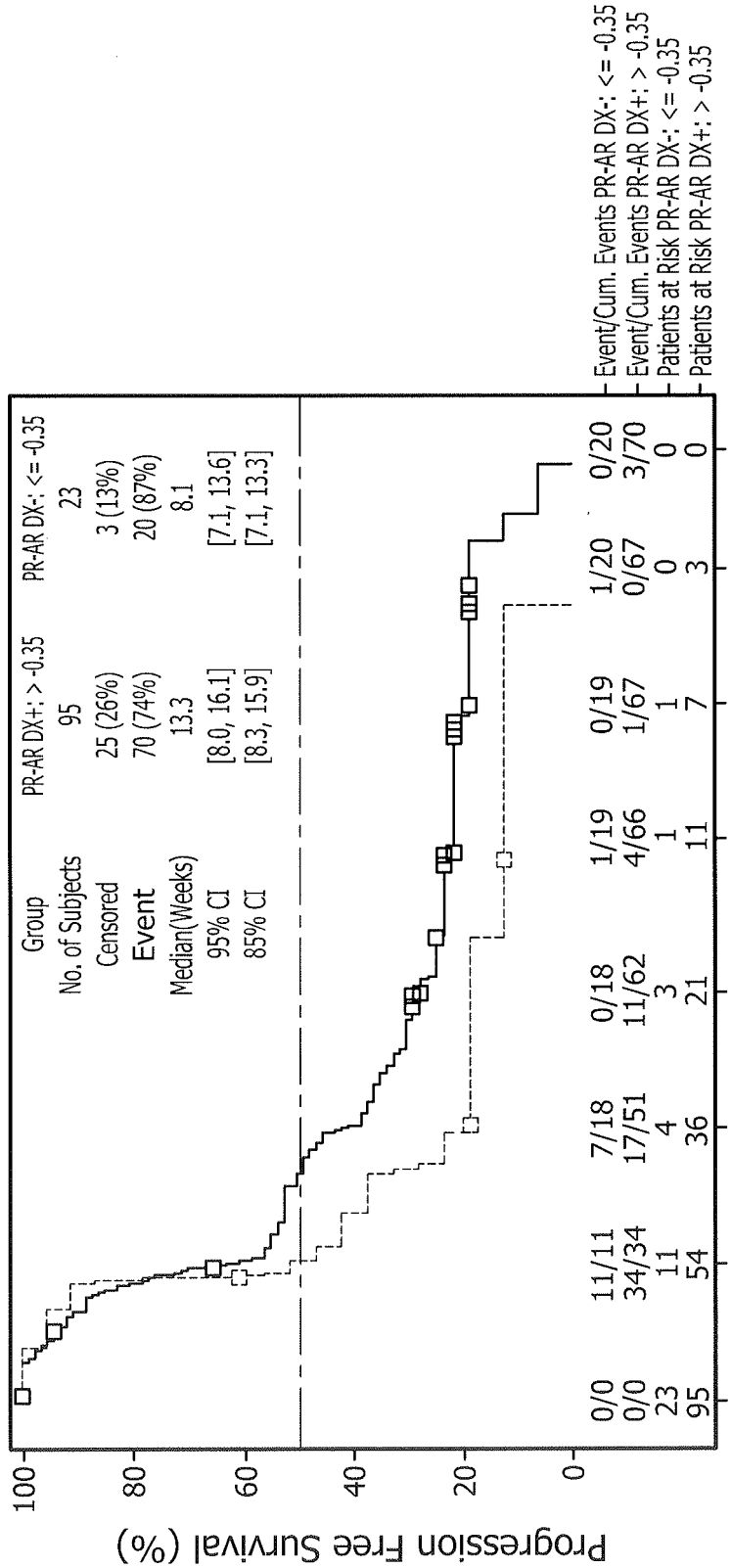

Progression Free Survival (%)
100
80
60
40
20
0
Weeks
0
8
16
24
33
41
49
56
Group
No. of Subjects
Censored
Event
Median(Weeks)
95% CI
85% CI
PR-AR DX+: > -0.35
95
25 (26%)
70 (74%)
13.3
[8.0, 16.1]
[8.3, 15.9]
PR-AR DX-: <= -0.35
23
3 (13%)
20 (87%)
8.1
[7.1, 13.6]
[7.1, 13.3]
Event/Cum. Events PR-AR DX-: <= -0.35
0/0 11/11 7/18 0/18 1/19 0/19 1/20 0/20
Event/Cum. Events PR-AR DX+: > -0.35
0/0 34/34 17/51 11/62 4/66 1/67 0/67 3/70
Patients at Risk PR-AR DX-: <= -0.35
23 11 4 3 1 1 0 0
Patients at Risk PR-AR DX+: > -0.35
95 54 36 21 11 7 3 0
Censored -
PR-AR DX+: > -0.35
PR-AR DX-: <= -0.35

FIG. 19

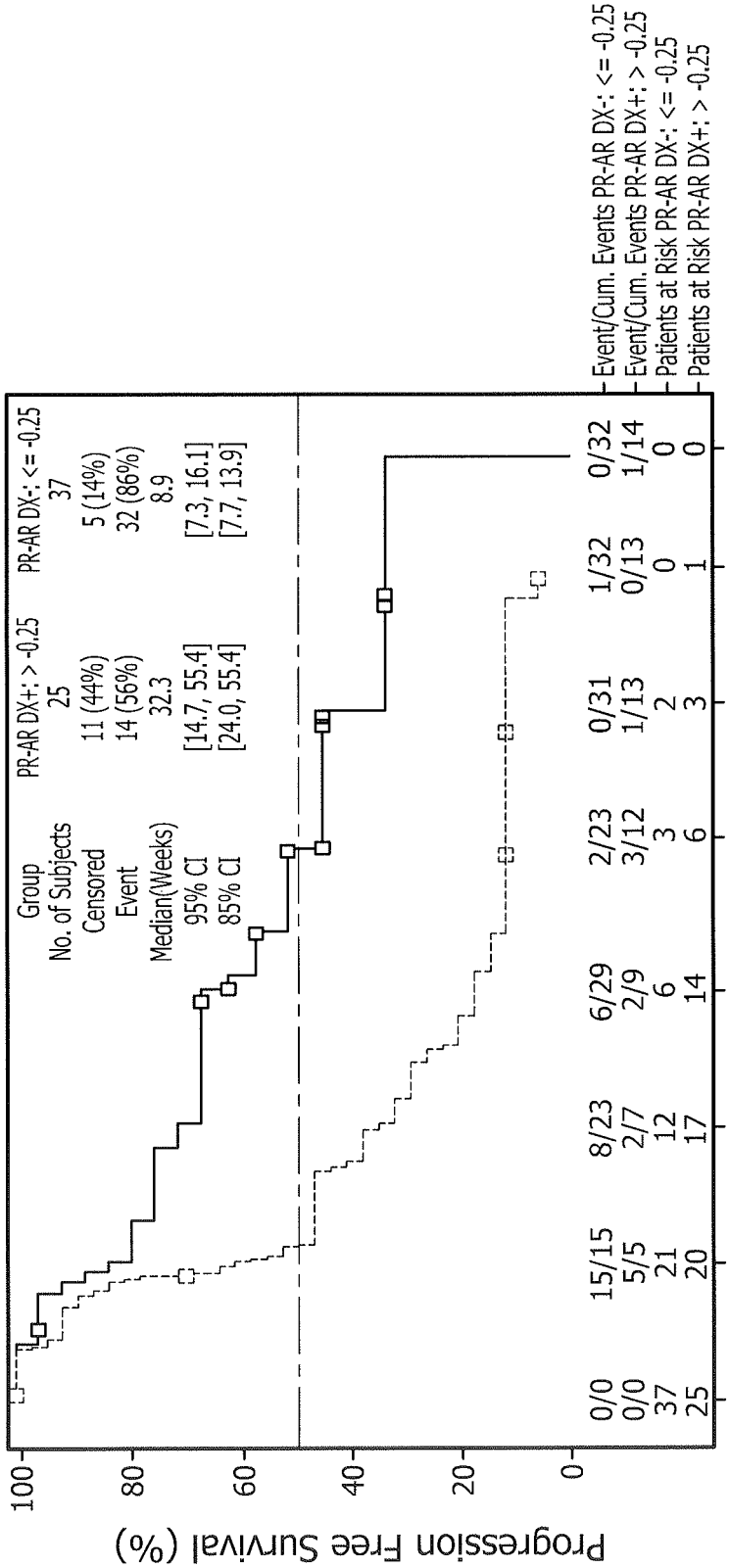

Progression Free Survival (%)
100
80
60
40
20
0
Weeks
0
8
16
24
33
41
49
56
Group
No. of Subjects
Censored
Event
Median(Weeks)
95% CI
85% CI
PR-AR DX+; > -0.25
25
11 (44%)
14 (56%)
32.3
[14.7, 55.4]
[24.0, 55.4]
PR-AR DX-; <= -0.25
37
5 (14%)
32 (86%)
8.9
[7.3, 16.1]
[7.7, 13.9]
0/0 15/15 8/23 6/29 2/23 0/31 1/32 0/32
0/0 5/5 2/7 2/9 3/12 1/13 0/13 1/14
37 21 12 6 3 2 0 0
25 20 17 14 6 3 1 0
Event/Cum. Events PR-AR DX-; <= -0.25
Event/Cum. Events PR-AR DX+; > -0.25
Patients at Risk PR-AR DX-; <= -0.25
Patients at Risk PR-AR DX+; > -0.25
Censored -
PR-AR DX+; > -0.25
PR-AR DX-; <= -0.25

FIG. 20

PR-AR-DX-

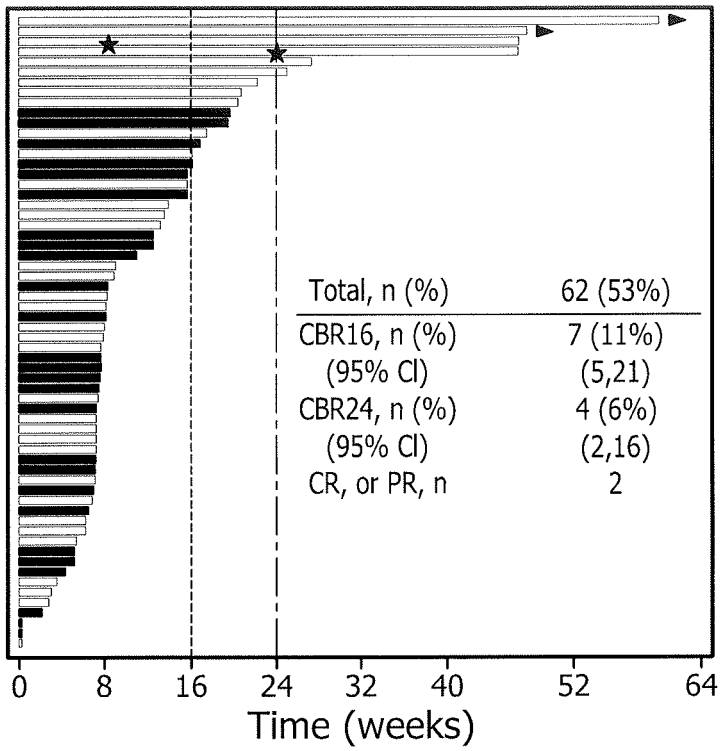


FIG. 21A

PR-AR-DX+

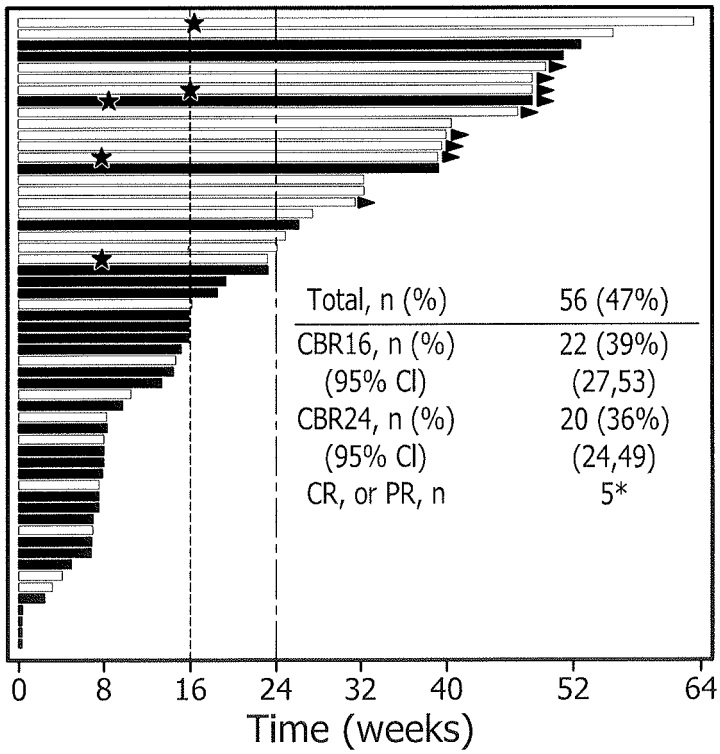
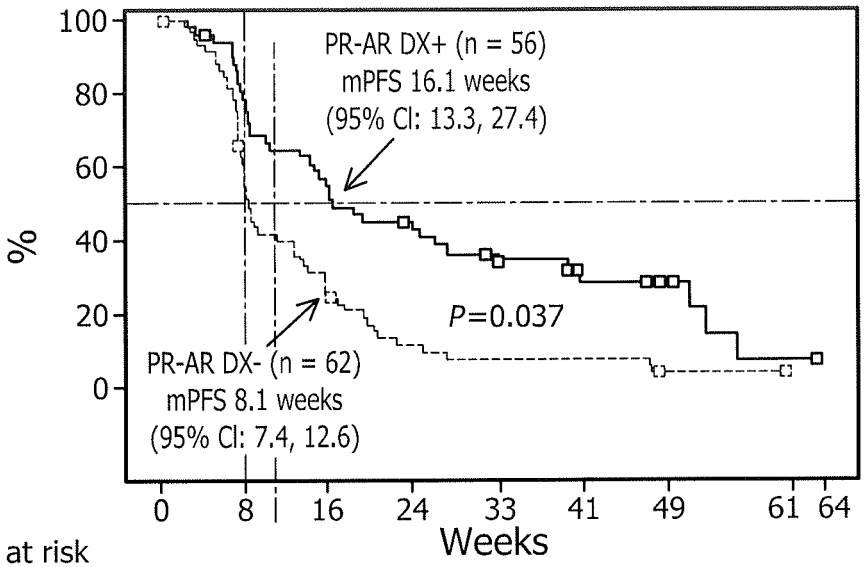


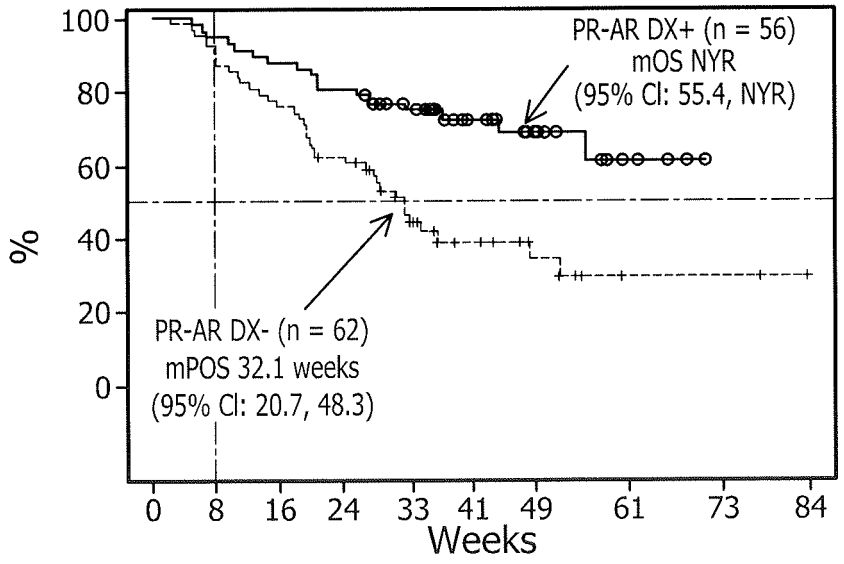
FIG. 21B



Patients at risk

PR-AR DX-	62	31	15	6	4	4	1	0	0
PR-AR DX+	56	38	27	21	14	9	5	1	0

FIG. 22A



Patients at risk

PR-AR DX-	62	56	46	35	20	12	7	2	2	0
PR-AR DX+	56	53	49	45	36	23	13	5	0	0

FIG. 22B

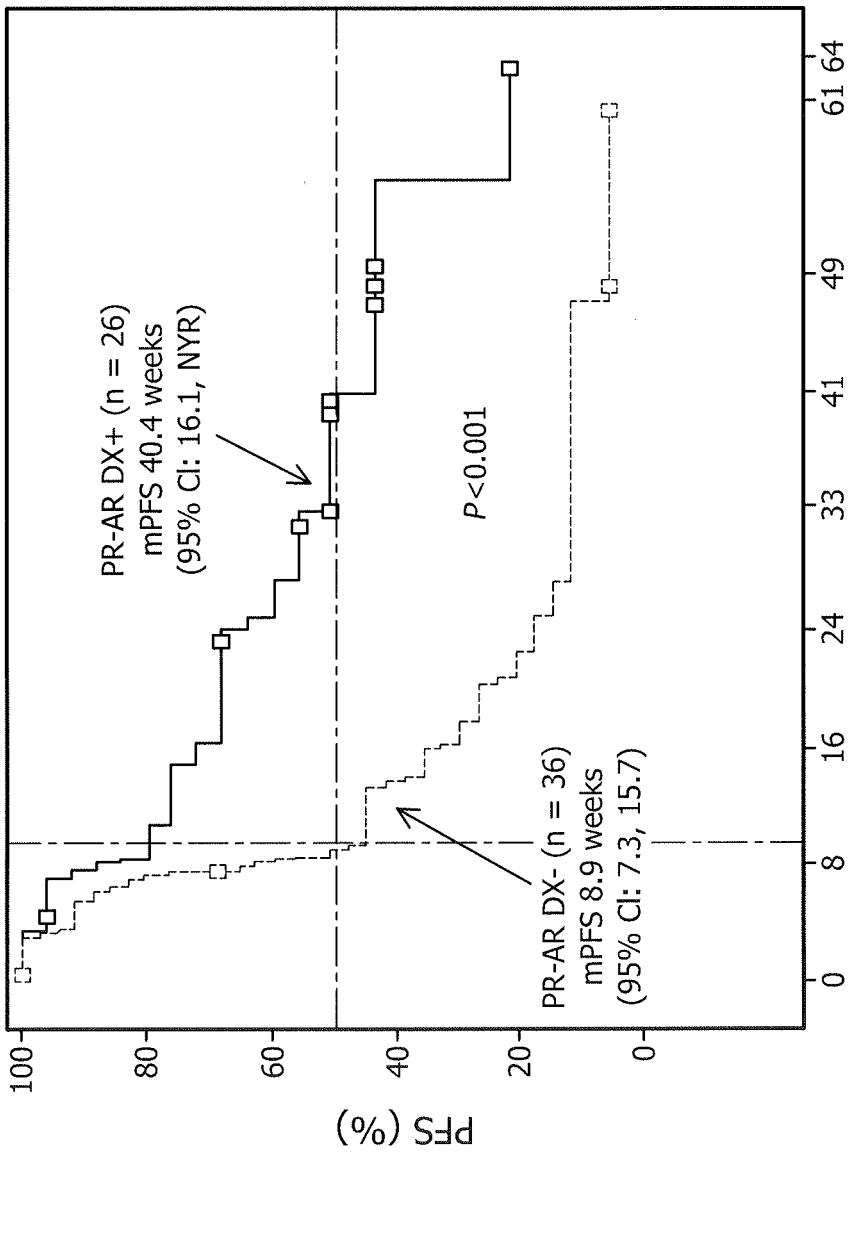

PFS (%)
100
80
60
40
20
0
PR-AR DX+ (n = 26)
mPFS 40.4 weeks
(95% CI: 16.1, NYR)
P<0.001
PR-AR DX- (n = 36)
mPFS 8.9 weeks
(95% CI: 7.3, 15.7)
0 8 16 24 33 41 49 61 64
Weeks
PR-AR DX- 36 20 11 6 4 4 1 0 0
PR-AR DX+ 26 22 18 16 10 6 3 1 0

FIG. 23

FIG. 24A

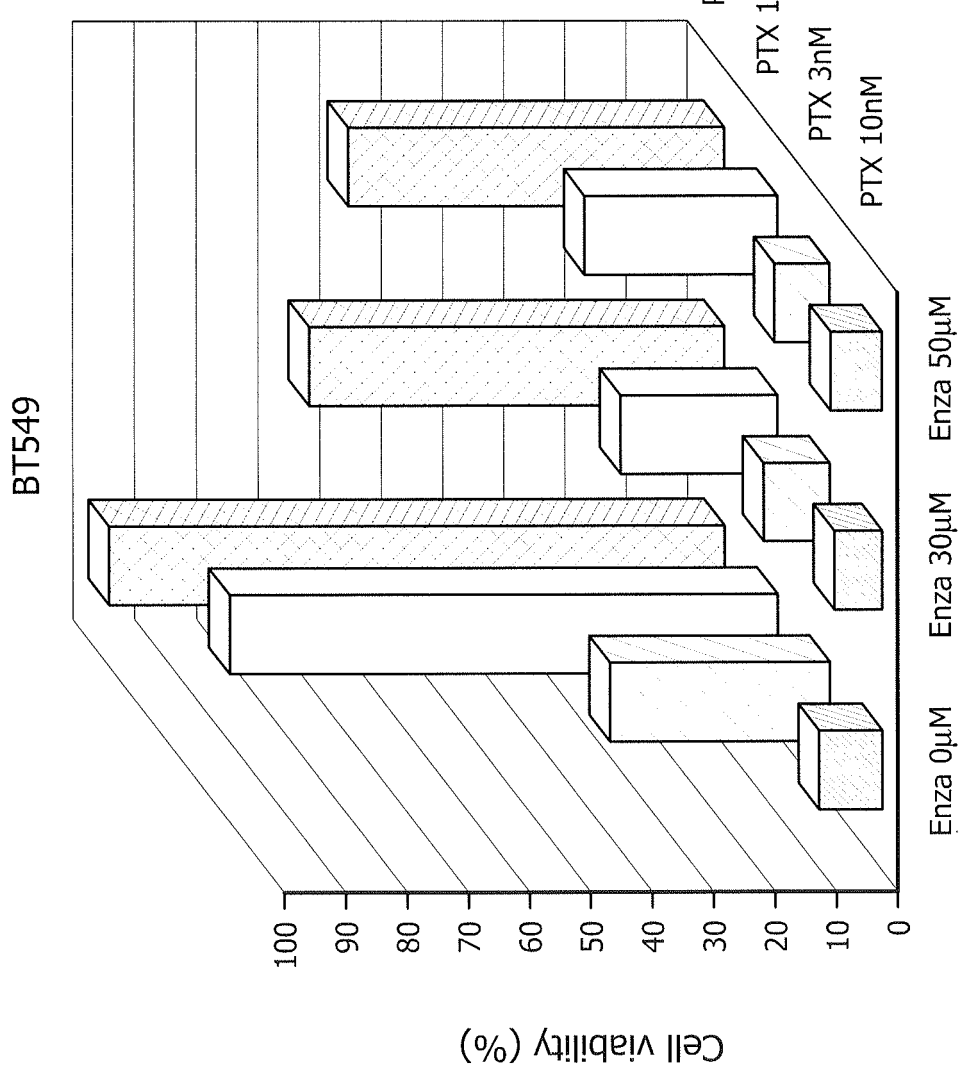

BT549
Cell viability (%)
0
10
20
30
40
50
60
70
80
90
100
Enza 0μM
Enza 30μM
Enza 50μM
PTX 0nM
PTX 1nM
PTX 3nM
PTX 10nM

FIG. 24B

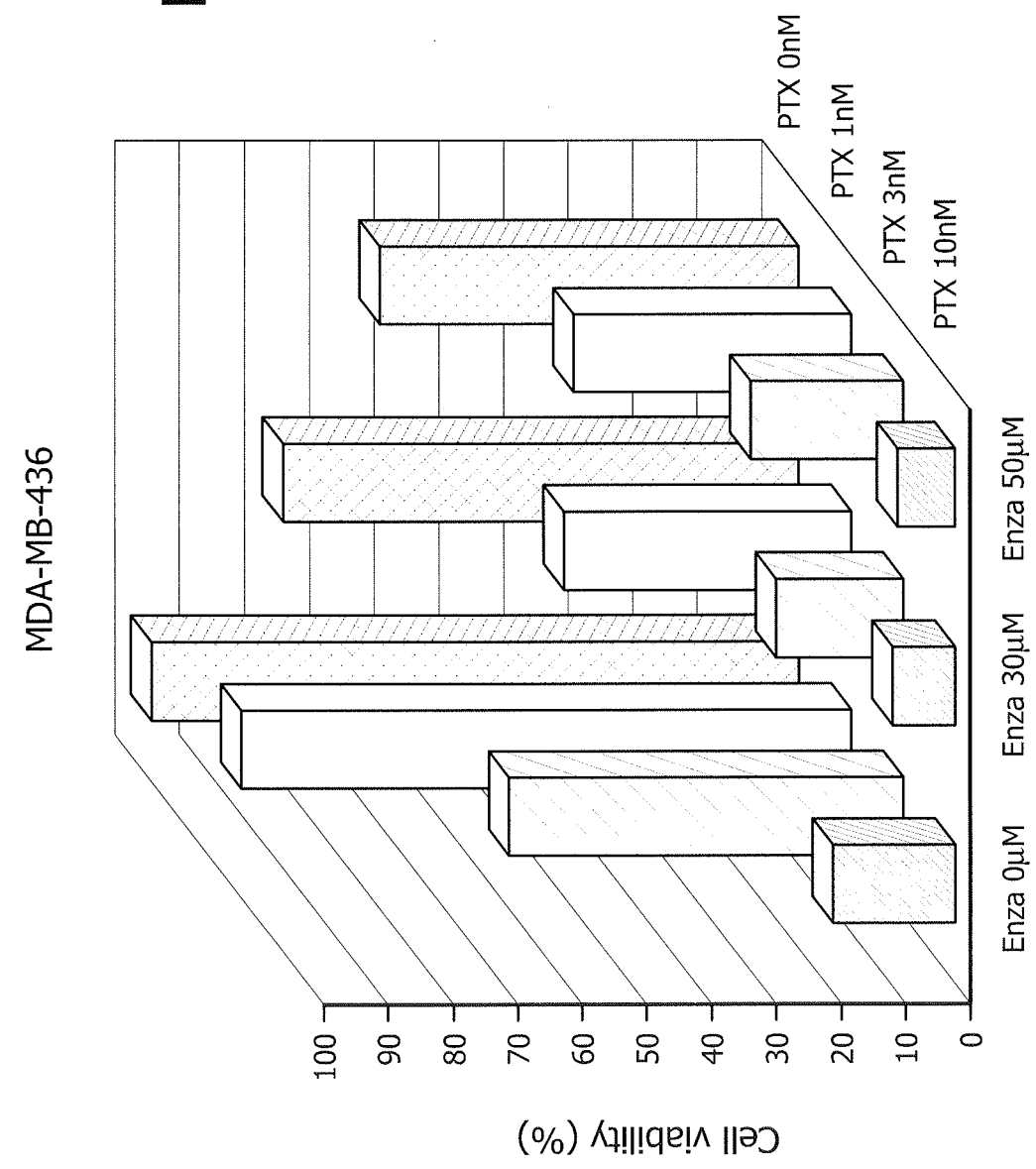
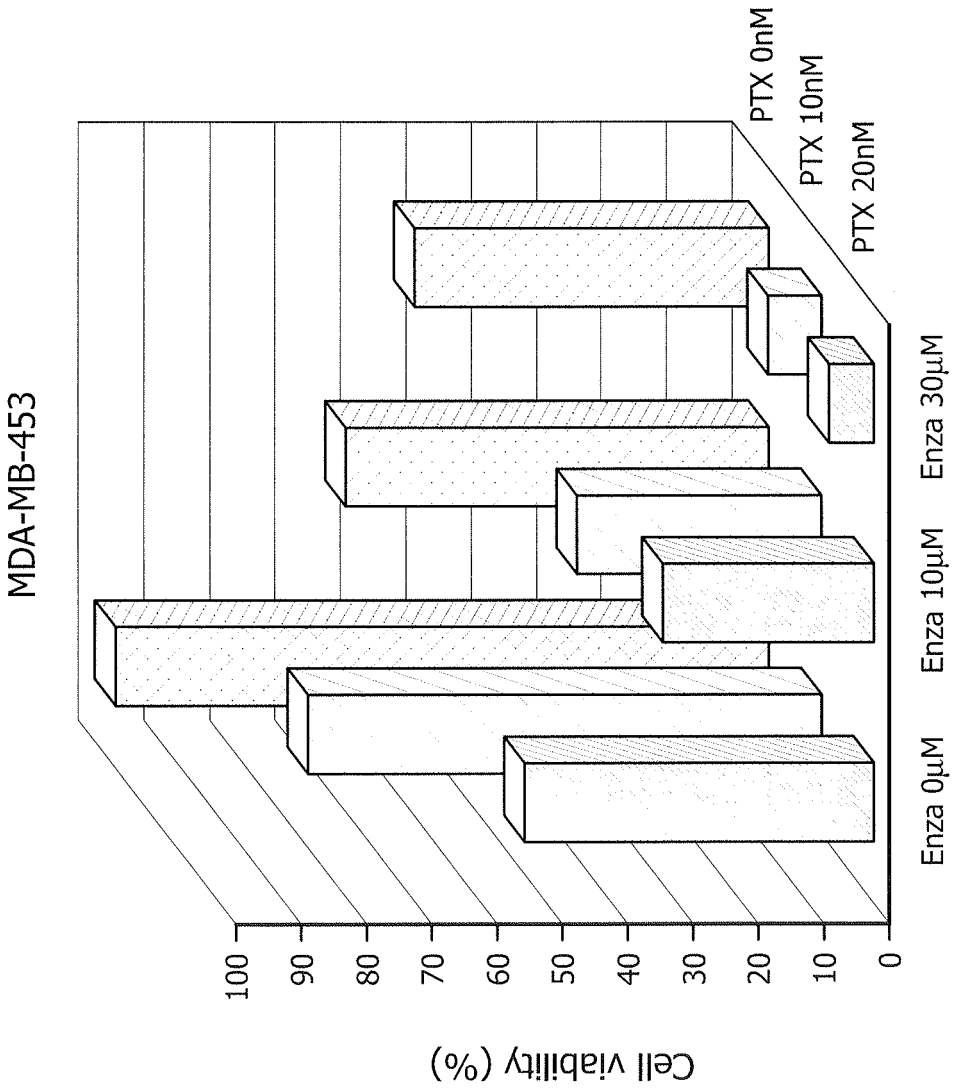

MDA-MB-436
Cell viability (%)
0
10
20
30
40
50
60
70
80
90
100
Enza 0μM
Enza 30μM
Enza 50μM
PTX 0nM
PTX 1nM
PTX 3nM
PTX 10nM

FIG. 24C


MDA-MB-453
Cell viability (%)
0
10
20
30
40
50
60
70
80
90
100
Enza 0μM
Enza 10μM
Enza 30μM
PTX 0nM
PTX 10nM
PTX 20nM

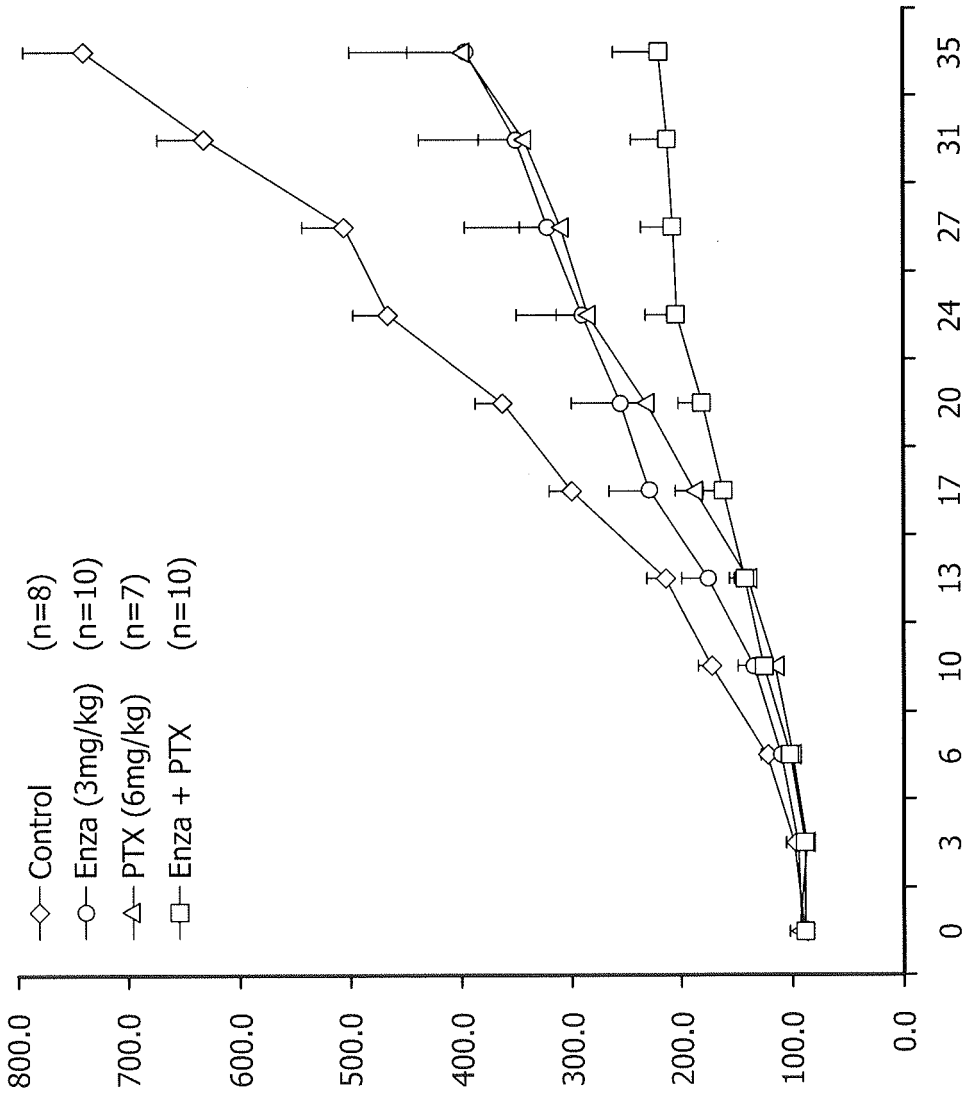

Control (n=8)
Enza (3mg/kg) (n=10)
PTX (6mg/kg) (n=7)
Enza + PTX (n=10)
800.0
700.0
600.0
500.0
400.0
300.0
200.0
100.0
0.0
0
3
6
10
13
17
20
24
27
31
35

FIG. 25A

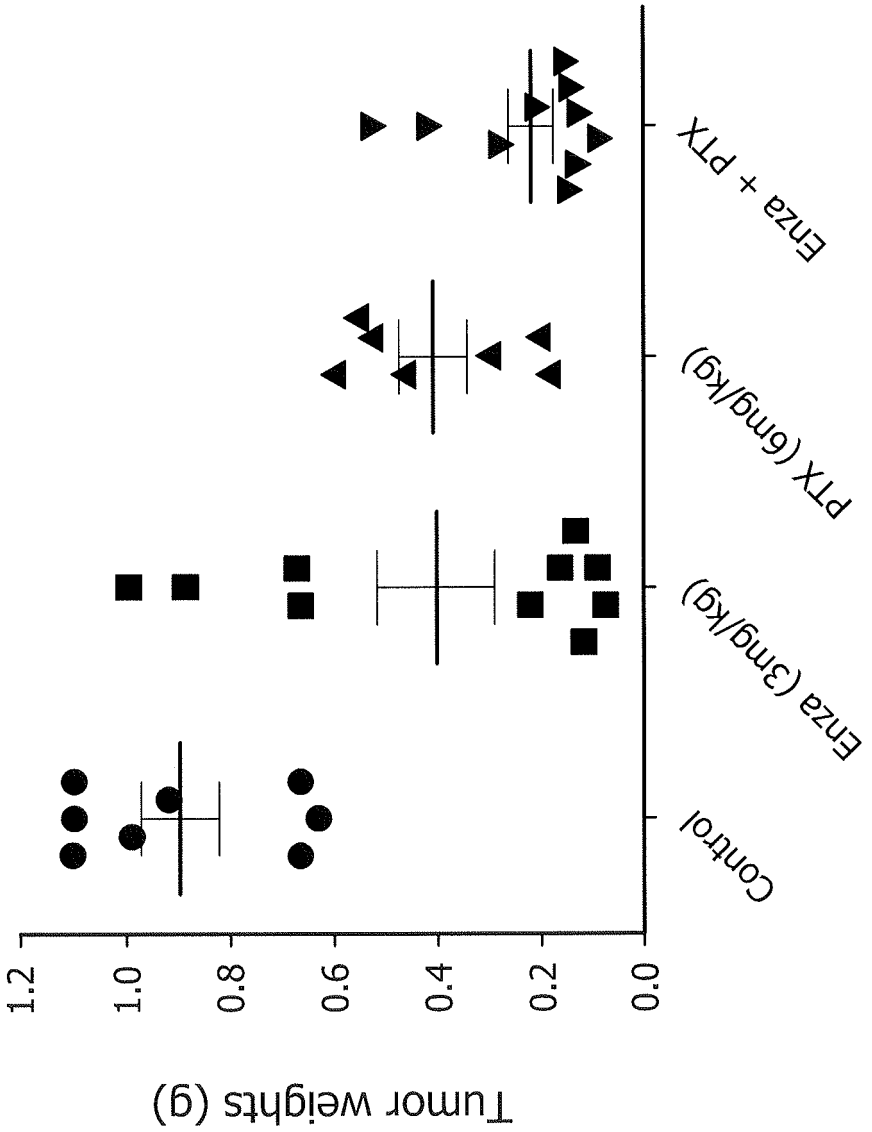

Tumor weights (g)
1.2
1.0
0.8
0.6
0.4
0.2
0.0
Control
Enza (3mg/kg)
PTX (6mg/kg)
Enza + PTX

FIG. 25B