FIG. 1

	AG-013736 5.0 mg (BID)					
	MALE		FEMALE		TOTAL	
Number (%) of Subjects	38		14		52	
Age (years) :						
<65	25	(65.8)	11	(78.6)	36	(69.2)
>=65	13	(34.2)	3	(21.4)	16	(30. 8)
Median	61.5		54.0		61.0	
Mean	59.2		55.6		58.3	
SD	10.0		13.5		11.0	
Range	39-82		22-78		22-82	
Race:						
WHITE	35	(92.1)	12	(85.7)	47	(90.4)
ASIAN	2	(5.3)	2	(14.3)	4	(7. 7)
OTHER	1	(2.6)	0		1	(1.9)
Weight (kg):						
Median	87.5		67.5		84.8	
Mean	90.0		69.8		84.6	
SD	15.4		20.8		19.1	
Range	62.4-121.2		41.0-106.2		41.0-121.2	
N	38	(100. 0)	14	(100.0)	52	(100.0)
Height (cm):						
Median	177.3		159.0		174.6	
Mean	177.9		159.6		173.0	
SD	5.7		5.8		10.0	
Range	169.2-194.0		151.5-174.0		151.5-194.0	
N	38	(100. 0)	14	(100.0)	52	(100.0)
ECOG:						
0	20	(52.6)	7	(50.0)	27	(51.9)
1	18	(47.4)	7	(50.0)	25	(48.1)
Geographic Region:						
NORTH AMERICA	23	(60.5)	7	(50.0)	30	(57.7)
EUROPE	13	(34.2)	4	(28.6)	17	(32.7)
ASIA	1	(2.6)	2	(14.3)	3	(5.8)
OTHER	1	(2.6)	1	(7.1)	2	(3.8)
MSKCC:						
Favorable	8	(21.1)	4	(28.6)	12	(23.1)
Intermediate	14	(36.8)	4	(28.6)	18	(34.6)
Poor	16	(42.1)	6	(42.9)	22	(42.3)

FIG. 2

Biomarkers	AG-013736 5.0 mg (BID) Slides N=26	Blocks N=26	Total N=52
CD3 % Positive			
n	26	26	52
Mean	13.61	17.95	15.78
Std	10.328	13.031	11.846
%CV	75.9	72.6	75.1
25th Percentile	5.00	7.00	7.00
Median	11.37	15.21	12.66
75th Percentile	20.50	29.40	24.00
(Min, Max)	(0.57, 31.1)	(0.08, 44.85)	(0.08, 44.85)
CD3 Cell density			
n	26	26	52
Mean	489.15	590.50	539.83
Std	516.170	513.747	512.448
%CV	105.5	87.0	94.9
25th Percentile	77.00	264.00	168.00
Median	336.50	414.50	399.50
75th Percentile	801.00	775.00	781.50
(Min, Max)	(14,2241)	(1,2056)	(1,2241)
CD68 % Positive			
n	26	26	52
Mean	5.83	8.21	7.02
Std	6.456	6.859	6.704
%CV	110.8	83.5	95.5
25th Percentile	1.00	4.00	2.80
Median	3.94	7.08	5.21
75th Percentile	8.10	10.00	9.70
(Min, Max)	(0.2, 20.92)	(2.48, 36.89)	(0.2, 36.89)
CD68 Cell density			
n	26	26	52
Mean	0.08	0.13	0.11
Std	0.087	0.101	0.096
%CV	103.3	80.5	91.2
25th Percentile	0.00	0.10	0.00
Median	0.05	0.10	0.08
75th Percentile	0.10	0.20	0.20
(Min, Max)	(0, 0.29)	(0.03, 0.53)	(0, 0.53)

FIG. 3

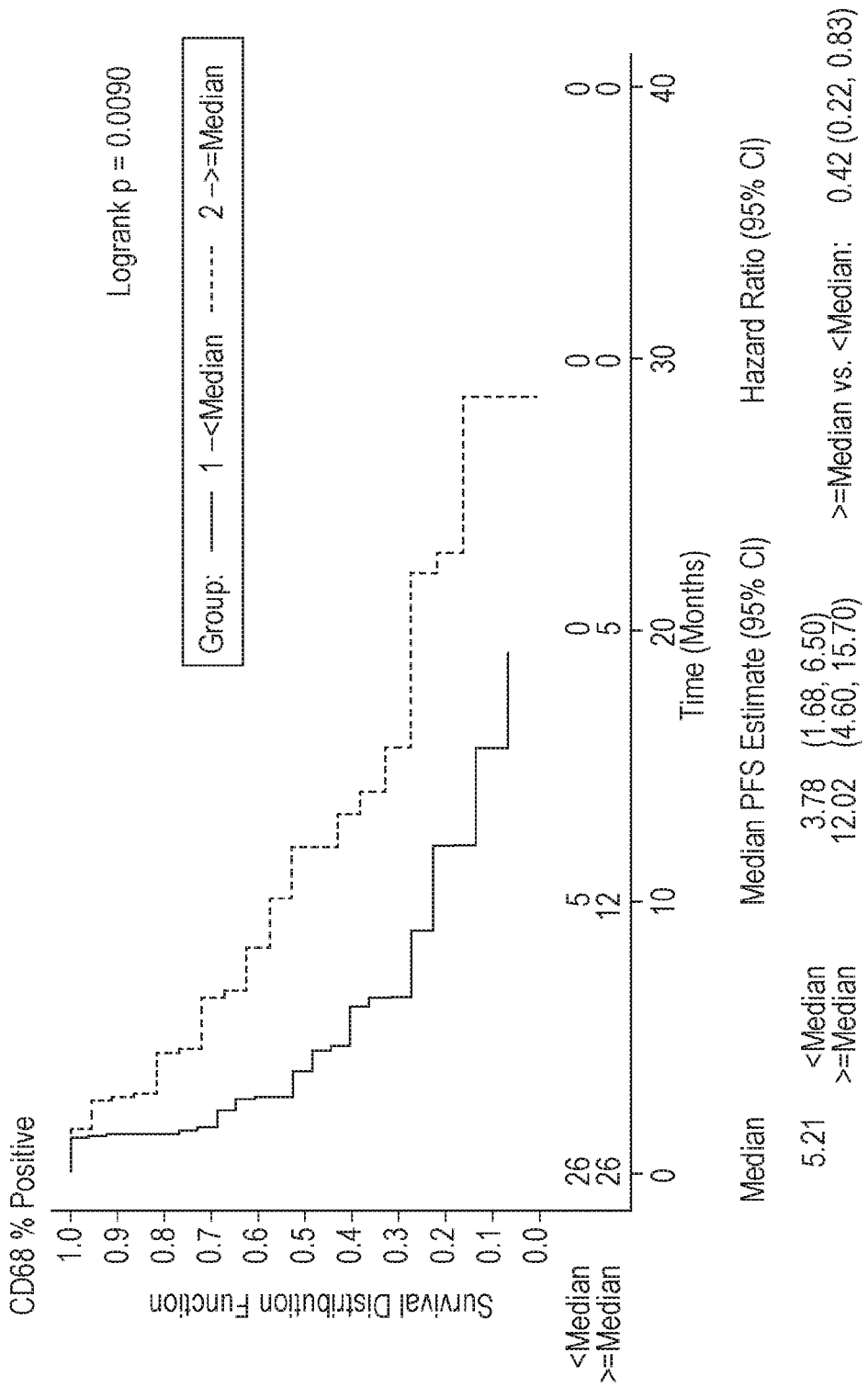

CD68 % Positive
Logrank p = 0.0090
Group: —— 1 -<Median ------ 2 ->=Median
Survival Distribution Function
1.0
0.9
0.8
0.7
0.6
0.5
0.4
0.3
0.2
0.1
0.0
<Median
>=Median
26 5 0 0 0
26 12 5 0 0
0 10 20 30 40
Time (Months)
Median
5.21
Median PFS Estimate (95% CI)
<Median 3.78 (1.68, 6.50)
>=Median 12.02 (4.60, 15.70)
Hazard Ratio (95% CI)
>=Median vs. <Median: 0.42 (0.22, 0.83)

FIG. 4

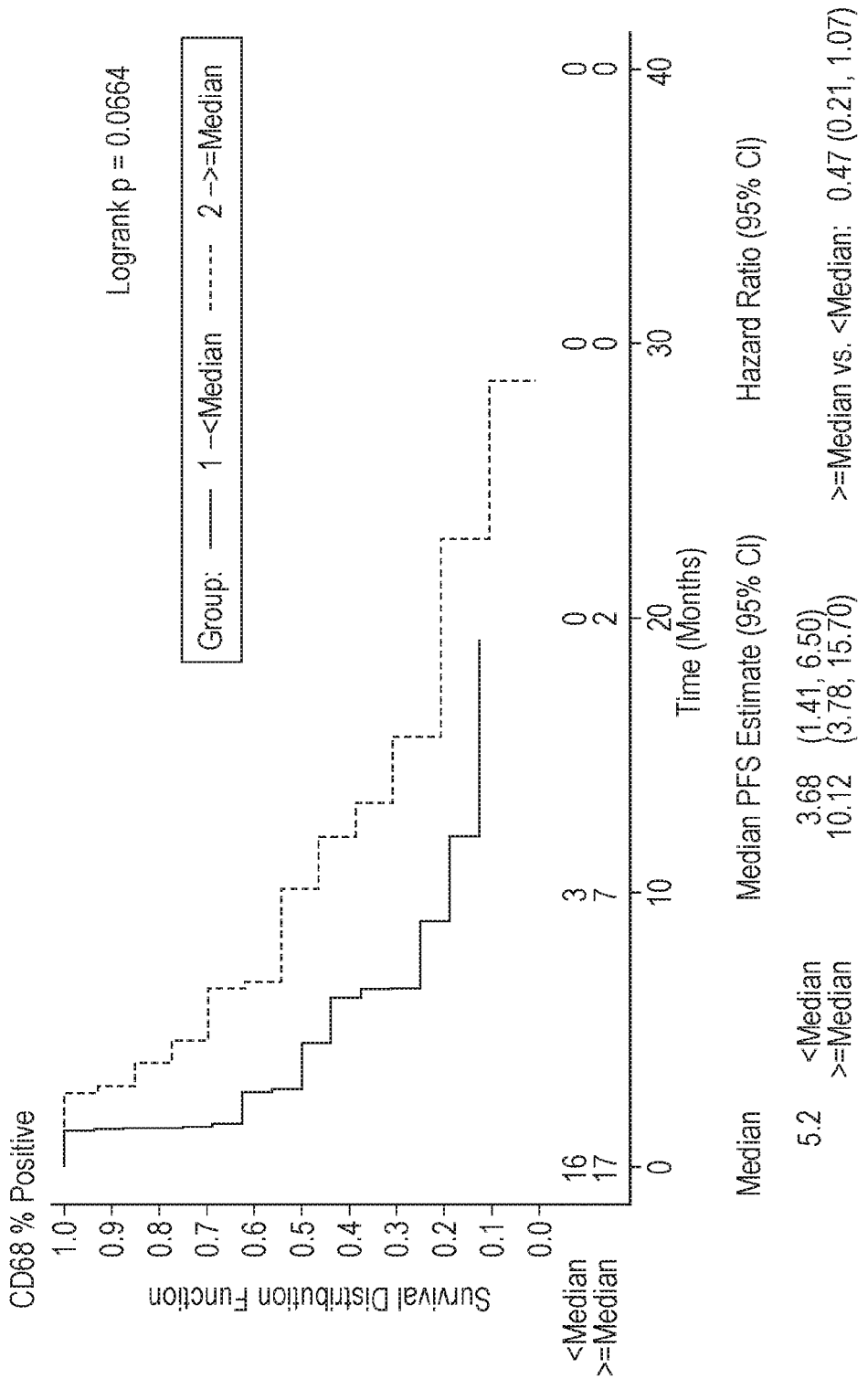

CD68 % Positive
Survival Distribution Function
1.0
0.9
0.8
0.7
0.6
0.5
0.4
0.3
0.2
0.1
0.0
Logrank p = 0.0664
Group: —— 1 –<Median ------ 2 –>=Median
<Median
>=Median
16
17
0
3
7
10
0
2
20
0
0
30
0
0
40
Time (Months)
Median
5.2
Median PFS Estimate (95% CI)
<Median 3.68 (1.41, 6.50)
>=Median 10.12 (3.78, 15.70)
Hazard Ratio (95% CI)
>=Median vs. <Median: 0.47 (0.21, 1.07)

FIG. 5

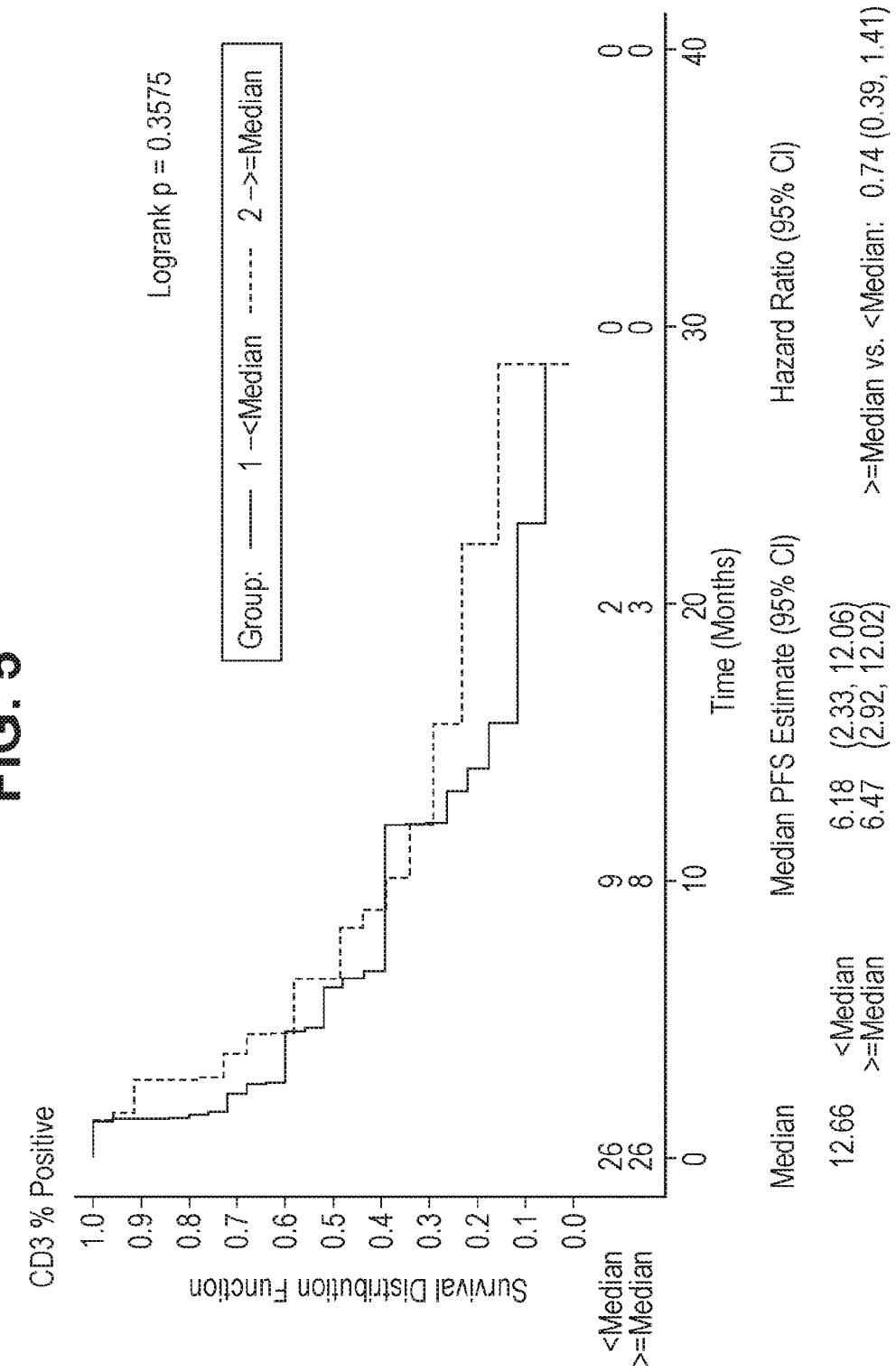

CD3 % Positive
Survival Distribution Function
1.0
0.9
0.8
0.7
0.6
0.5
0.4
0.3
0.2
0.1
0.0
Logrank p = 0.3575
Group: —— 1 –<Median ------ 2 –>=Median
<Median
>=Median
26 9 2 0
26 8 3 0
0 10 20 30 40
Time (Months)
Median
12.66
Median PFS Estimate (95% CI)
<Median 6.18 (2.33, 12.06)
>=Median 6.47 (2.92, 12.02)
Hazard Ratio (95% CI)
>=Median vs. <Median: 0.74 (0.39, 1.41)

FIG. 6

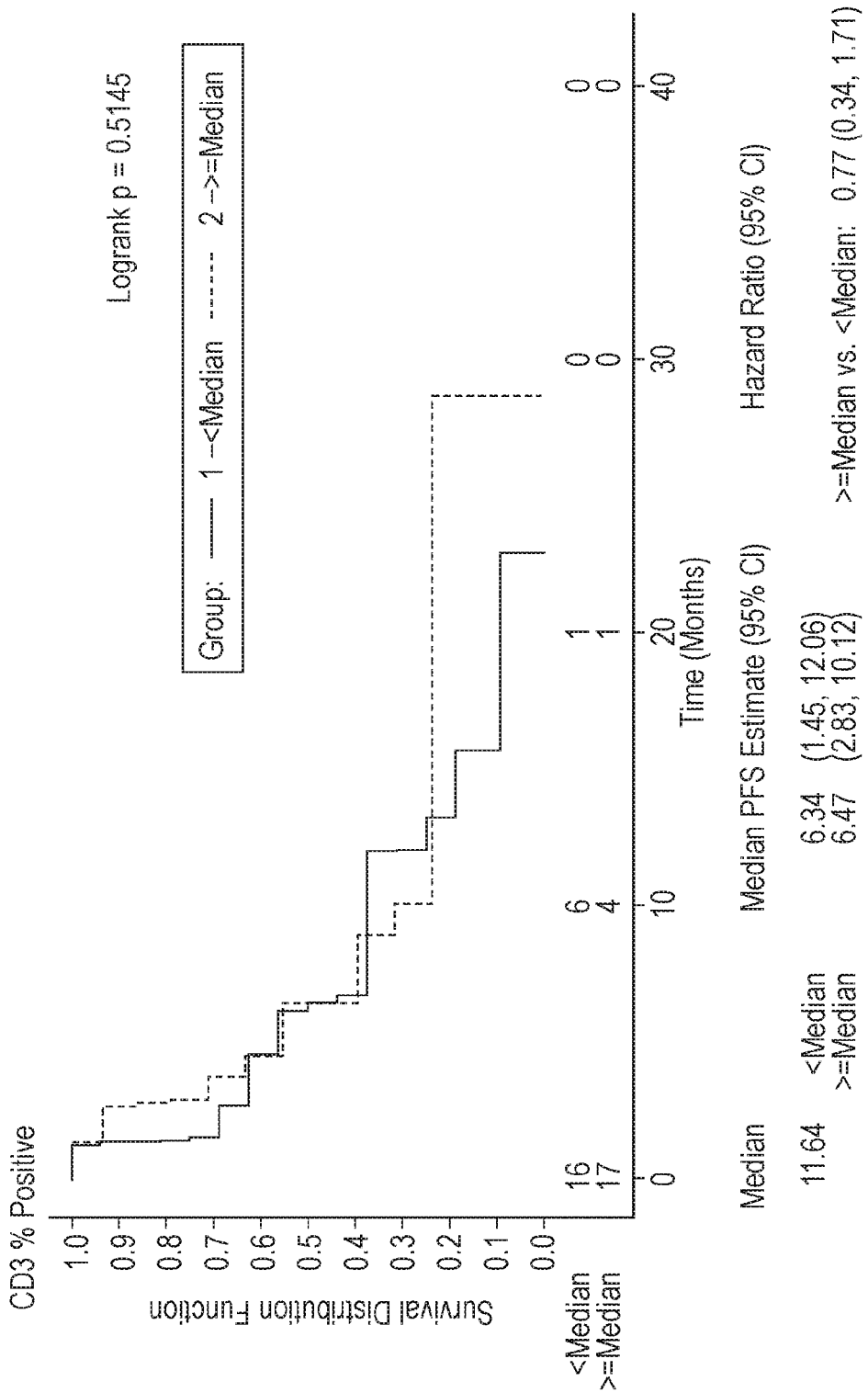

CD3 % Positive
Survival Distribution Function
1.0
0.9
0.8
0.7
0.6
0.5
0.4
0.3
0.2
0.1
0.0
Logrank p = 0.5145
Group: —— 1 -<Median ------ 2 ->=Median
<Median
>=Median
16
17
6
4
1
1
0
0
0
0
0
10
20
30
40
Time (Months)
Median
11.64
Median PFS Estimate (95% CI)
<Median 6.34 (1.45, 12.06)
>=Median 6.47 (2.83, 10.12)
Hazard Ratio (95% CI)
>=Median vs. <Median: 0.77 (0.34, 1.71)

FIG. 7

			Median OS (Months)				
Variable	Median BM value	N	< Median BM Value (95% CI)	N	>= Median BM Value (95% CI)	Logrank p-value	Hazard Ratio (95 % CI)
CD3 % Positive	12.66	26	20.0 (11.53, 32.36)	26	21.8 (9.33, 23.82)	0.5668	1.222 (0.615, 2.426)
CD3 Cell density	399.50	26	19.2 (10.61, 32.36)	26	22.6 (13.08, 24.41)	0.8153	0.922 (0.465, 1.826)
CD68 % Positive	5.21	26	21.8 (11.53, .)	26	20.0 (10.61, 32.36)	0.9901	0.996 (0.497, 1.994)
CD68 Cell density	0.08	23	17.8 (7.03, 24.41)	29	22.6 (13.47, .)	0.1733	0.619 (0.308, 1.243)

FIG. 8

		Median OS (Months)					
Variable	Median BM value	N	< Median BM Value (95% CI)	N	>= Median BM Value (95% CI)	Logrank p-value	Hazard Ratio (95 % CI)
CD3 % Positive	11.64	16	21.4 (6.87, 32.36)	17	20.0 (5.65, 23.82)	0.6444	1.225 (0.517, 2.900)
CD3 Cell density	334.00	16	19.2 (10.61, 32.36)	17	21.8 (4.73, 24.41)	0.6802	1.198 (0.508, 2.824)
CD68 % Positive	5.20	16	18.2 (7.00, .)	17	23.8 (5.65, 32.36)	0.6576	0.818 (0.337, 1.989)
CD68 Cell density	0.06	15	16.7 (4.27, 21.82)	18	24.1 (10.61, .)	0.0777	0.451 (0.182, 1.116)

FIG. 9

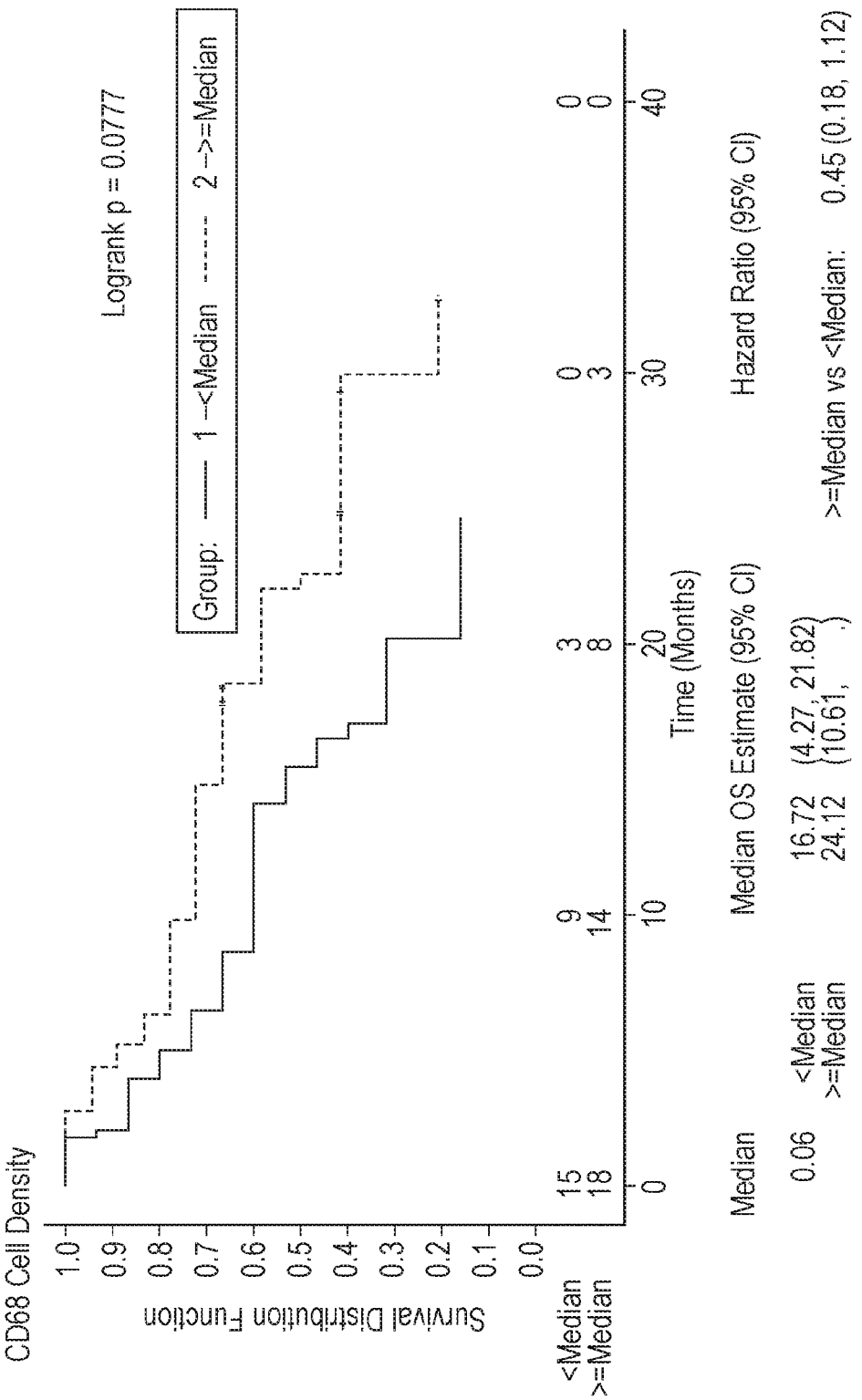

CD68 Cell Density
Logrank p = 0.0777
Group: —— 1 –<Median ------ 2 –>=Median
Survival Distribution Function
1.0
0.9
0.8
0.7
0.6
0.5
0.4
0.3
0.2
0.1
0.0
<Median
>=Median
15
18
9
14
3
8
0
3
0
0
0
10
20
30
40
Time (Months)
Median
Median OS Estimate (95% CI)
Hazard Ratio (95% CI)
0.06
<Median 16.72 (4.27, 21.82)
>=Median 24.12 (10.61, .)
>=Median vs <Median: 0.45 (0.18, 1.12)

FIG. 10

Biomarkers	AG-013736 5.0 mg (BID) CR+PR N=11	SD+PD N=33	*P-Value	Total N=44
CD3 % Positive				
n	11	33	0.1364	44
Mean	19.54	12.93		14.58
Std	13.168	10.265		11.274
%CV	67.4	79.4		77.3
25th Percentile	9.20	5.00		6.00
Median	11.20	11.60		11.40
75th Percentile	30.20	19.20		19.90
(Min, Max)	(5.01,44.85)	(0.57,39.15)		(0.57, 44.85)
CD3 Cell density				
n	11	33	0.174	44
Mean	683.18	455.39		512.34
Std	635.836	479.921		524.766
%CV	93.1	105.4		102.4
25th Percentile	223.00	93.00		162.00
Median	415.00	295.00		356.00
75th Percentile	936.00	643.00		715.50
(Min, Max)	(159,2241)	(14,2056)		(14,2241)
CD68 % Positive				
n	11	33	0.0059	44
Mean	10.21	4.58		5.98
Std	6.206	4.235		5.328
%CV	60.8	92.6		89.0
25th Percentile	4.40	1. 30		2.10
Median	10.02	3.73		4.34
75th Percentile	15.50	6.50		8.30
(Min, Max)	(1.18, 20.66)	(0.2, 20.92)		(0.2, 20.92)
CD68 Cell density				
n	11	33	0.0071	44
Mean	0.15	0.07		0.09
Std	0.085	0.055		0.072
%CV	58.3	82.0		82.4
25th Percentile	0.10	0.00		0.00
Median	0.16	0.05		0.08
75th Percentile	0.20	0.10		0.10
(Min, Max)	(0.02, 0.29)	(0, 0.22)		(0, 0.29)

*Wilcoxon Rank Sum Test P-value is two-sided t-approximation.

FIG. 11

Biomarkers	AG-013736 5.0 mg (BID) CR+PR N=05	SD+PD N=22	*P-Value	Total N=27
CD3 % Positive				
n	5	22	0.1912	27
Mean	17.83	11.88		12.98
Std	10.975	9.995		10.235
%CV	61.6	84.1		78.8
25th Percentile	9.20	4.50		5.00
Median	11.20	8.25		9.16
75th Percentile	29.40	18.60		19.40
(Min, Max)	(9.15, 30.21)	(0.57, 39.15)		(0.57, 39.15)
CD3 Cell density				
n	5	22	0.4071	27
Mean	744.20	410.23		472.07
Std	862.342	422.772		525.592
%CV	115.9	103.1		111.3
25th Percentile	223.00	93.00		111.00
Median	401.00	267.50		271.00
75th Percentile	697.00	643.00		697.00
(Min, Max)	(159,2241)	(14,1744)		(14,2241)
CD68 % Positive				
n	5	22	0.0407	27
Mean	10.15	3.52		4.74
Std	7.429	2.611		4.570
%CV	73.2	74.3		96.4
25th Percentile	5.40	0.90		1.00
Median	10.81	3.47		3.92
75th Percentile	12.70	5.20		6.50
(Min, Max)	(1.18, 20.66)	(0.2, 8.71)		(0.2, 20.66)
CD68 Cell density				
n	5	22	0.0762	27
Mean	0.14	0.06		0.07
Std	0.102	0.045		0.066
%CV	74.0	80.8		92.6
25th Percentile	0.10	0.00		0.00
Median	0.16	0.05		0.05
75th Percentile	0.20	0.10		0.10
(Min, Max)	(0.02, 0.28)	(0, 0.16)		(0, 0.28)

*Wilcoxon Rank Sum Test P-value is two-sided t-approximation.