

FIG. 1A: The cDNA (SEQ ID NO:1) and amino acid sequence (SEQ ID NO:2) of 191P4D12. The start methionine is underlined. The open reading frame extends from nucleic acid 264-1796 including the stop codon.

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1  ggccgtcggttggtggccacagcgtgggaagcagctctgggggagctcggagctcccgatc
61  acggcttcttggggtagctacggctgggtgtgtagaacggggccgggctggggctggg
121  tcccctagtgagacccaagtgcgagaggcaagaactctgcagcttcctgccttctgggt
181  cagttccttattcaagtctgcagccggctcccagggagatctcggtggaacttcagaaac
1      M P L S L G A E M W G P E
241  gctgggcagctctgcctttcaaccATGCCCCCTGTCCCTGGGAGCCGAGATGTGGGGCCCTG
14   A W L L L L L L L A S F T G R C P A G E
301  AGGCCTGGCTGCTGCTGCTACTGCTGGCATCATTTACAGGCCGGTGCCCCGCGGGTG
34   L E T S D V V T V V L G Q D A K L P C F
361  AGCTGGAGACCTCAGACGTGGTAACTGTGGTGTGGGCCAGGACGCAAACTGCCCTGCT
54   Y R G D S G E Q V G Q V A W A R V D A G
421  TCTACCGAGGGGACTCCGGCGAGCAAGTGGGGCAAGTGGCATGGGCTCGGGTGGACGCGG
74   E G A Q E L A L L H S K Y G L H V S P A
481  GCGAAGGCGCCCAGGAAGTAGCGCTACTGCACTCCAAATACGGGCTTCATGTGAGCCCGG
94   Y E G R V E Q P P P P R N P L D G S V L
541  CTTACGAGGGCCCGTGGAGCAGCCGCGCCCCACGCAACCCCTGGACGGCTCAGTGC
114  L R N A V Q A D E G E Y E C R V S T F P
601  TCCTGCGCAACGCAGTGCAGGCGGATGAGGGCGAGTACGAGTGCCGGGTGAGCACCTTCC
134  A G S F Q A R L R L R V L V P P L P S L
661  CCGCCGGCAGCTTCCAGGCGCGGTGCGGCTCCGAGTGTGGTGCTCCCTGCCCTCAC
154  N P G P A L E E G Q G L T L A A S C T A
721  TGAATCCTGGTCCAGCACTAGAAGAGGGCCAGGGCCTGACCCTGGCAGCCTCCTGCACAG
174  E G S P A P S V T W D T E V K G T T S S
781  CTGAGGGCAGCCAGCCCCAGCGTGACCTGGGACACGGAGGTCAAAGGCACAACCTCCA
194  R S F K H S R S A A V T S E F H L V P S
841  GCCGTTCCTTCAAGCACTCCCGCTCTGCTGCCGTACCTCAGAGTTCCACTTGGTGCTA
214  R S M N G Q P L T C V V S H P G L L Q D
901  GCCGCAGCATGAATGGGCAGCCACTGACTTGTGTGGTGTCCCATCCTGGCCTGCTCCAGG
234  Q R I T H I L H V S F L A E A S V R G L
961  ACCAAAGGATCACCCACATCCTCCACGTGTCCTTCCTTGCTGAGGCCTCTGTGAGGGGCC
254  E D Q N L W H I G R E G A M L K C L S E
1021 TTGAAGACAAAATCTGTGGCACATTGGCAGAGAAGGAGCTATGCTCAAGTGCTGAGTG
274  G Q P P P S Y N W T R L D G P L P S G V
1081 AAGGGCAGCCCCCTCCCTCATCACTGGACACGGCTGGATGGGCCTCTGCCCAGTGGGG
294  R V D G D T L G F P P L T T E H S G I Y
1141 TACGAGTGGATGGGGACACTTTGGGCTTCCCCCACTGACCACTGAGCACAGCGGCATCT
314  V C H V S N E F S S R D S Q V T V D V L
1201 ACGTCTGCCATGTGCAAGTGTCTCCTCAAGGGATTCTCAGGTCACTGTGGATGTTT
334  D P Q E D S G K Q V D L V S A S V V V V
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1261 TTGACCCCCAGGAAGACTCTGGGAAGCAGGTGGACCTAGTGTGACCTCGGTGGTGGTGG
354 G V I A A L L F C L L V V V V V L M S R
1321 TGGGTGTGATCGCCGCACTCTTGTTCGCCTTCTGGTGGTGGTGGTGGTGCATGTCCC
374 Y H R R K A Q Q M T Q K Y E E E L T L T
1381 GATACCATCGGCGCAAGGCCAGCAGATGACCCAGAAATATGAGGAGGAGCTGACCCCTGA
394 R E N S I R R L H S H H T D P R S Q P E
1441 CCAGGGAGAACTCCATCCGGAGGCTGCATTCCCATCACACGGACCCAGGAGCCAGCCGG
414 E S V G L R A E G H P D S L K D N S S C
1501 AGGAGAGTGTAGGGCTGAGAGCCGAGGGCCACCCTGATAGTCTCAAGGACAACAGTAGCT
434 S V M S E E P E G R S Y S T L T T V R E
1561 GCTCTGTGATGAGTGAAGAGCCGAGGGCCGAGTTACTCCACGCTGACCAGGTGAGGG
454 I E T Q T E L L S P G S G R A E E E E D
1621 AGATAGAAACACAGACTGAACTGCTGTCTCCAGGCTCTGGCGGGCCGAGGAGGAGGAAG
474 Q D E G I K Q A M N H F V Q E N G T L R
1681 ATCAGGATGAAGGCATCAAACAGGCCATGAACCATTTTGTTCAGGAGAATGGGACCTAC
494 A K P T G N G I Y I N G R G H L V *
1741 GGGCCAAGCCCACGGGCAATGGCATCTACATCAATGGGCGGGACACCTGGTCTGAccca
1801 ggccctgcctcccttccttaggcctggctccttctgttgacatgggagatttttagctcatc
1861 ttgggggcctccttaaacacccccatttcttgcggaagatgctccccatcccactgactg
1921 cttgacctttacctccaacccttctgttcacogggagggctccaccaattgagtctctcc
1981 caccatgcatgcaggctcactgtgtgtgtgcatgtgtgcctgtgtgagtgttgactgactg
2041 tgtgtgtgtggaggggtgactgtccgtggaggggtgactgtgtccgtggtgtgtattatg
2101 ctgtcatatcagagtcaagtgaactgtggtgtatgtgccacgggatttgagtgggtgcgt
2161 gggcaacactgtcagggtttggcgtgtgtgtcatgtggctgtgtgtgacctctgcctgaa
2221 aaagcaggatattttctcagaccccagagcagtattaatgatgcagaggttgaggagaga
2281 ggtggagactgtggctcagaccaggtgtgcgggcatagctggagctggaatctgcctcc
2341 ggtgtgagggaaacctgtctcctaccacttcggagccatgggggcaagtgtgaagcagcca
2401 gtccctgggtcagccagaggcttgaactgttacagaagccctctgccctctggtggcctc
2461 tgggctgtgtcatgtacatatattttctgtaaatatacatgcgcggggagcttcttgacg
2521 aatactgctccgaatcacttttaatttttttctttttttttcttgccctttccattagt
2581 tgtattttttattttattttttatttttttttagagatggagtctcactatgttgc
2641 tcaggctggccttgaactcctgggtcaagcaatcctcctgcctcagcctccctagtagc
2701 tgggactttaagtgtacaccactgtgcctgctttgaatcctttacgaagagaaaaaaaaa
2761 attaaagaaagccttttagatttatccaatgtttactactgggattgcttaaagtgagggc
2821 cctccaacaccaggggttaattcctgtgattgtgaaaggggctacttccaaggcatcct
2881 catgcaggcagccccttgggagggcacctgagagctggttagagtctgaaattagggatgt
2941 gagcctcgtggttactgagtaaggtaaaattgcatccaccattgtttgtgataccttagg
3001 gaattgcttgacctggtgacaagggtcctgttcaatagtggtgttggggagagagaga
3061 gcagtgattatagaccgagagagtaggagtgagggtgagggtgaaggaggtgctgggggtg
3121 agaatgtcgccctttccccctgggttttgatcactaattcaaggctcttctggtgtttc
3181 tctgggttggggctggagttcaatgaggtttatttttagctggccaccagatacactc
3241 agccagaatacctagatttagtaccctccttcttagtctgaaatctgctggatttct
3301 ggccctaaggagagggctcccaccttcgttccccagccagcctaggacttcgaatgtgga
3361 gcctgaagatctaagatcctaacatgtacattttatgtaaatatgtgcatattttgtacat
3421 aaaatgatattctgtttttaataaacagacaaaacttgaaaaa

FIG. 1A
(Continued)

FIG. 1B: The cDNA (SEQ ID NO:3) and amino acid sequence (SEQ ID NO:4) of Ha22-2(2,4)6.1 heavy chain. Double-underlined is the leader sequence, underlined is the heavy chain variable region, and underlined with a dashed line is the human IgG1 constant region.

M E L G L C W V F L V A I L E

1 GGTGATCAGCACTGAACACAGAGGACTCACCATGGAGTTGGGGCTGTGCTGGGTTTTCCTTGTGTGCTATTTAGA
· G V Q C E V Q L V E S G G G L V Q P G G S L R L S
76 AGGTGTCAGTGTGAGGTGCAGCTGGTGGAGTCTGGGGGAGGCTTGGTACAGCCTGGGGGGTCCCTGAGACTCTC
· C A A S G F T F S S Y N M N W V R Q A P G K G L E
151 CTGTGCAGCCTCTGGATTCACCTTCAGTAGCTATAACATGAACCTGGGTCCGCCAGGCTCCAGGGAAGGGCTGGA
· W V S Y I S S S S S T I Y Y A D S V K G R F T I S
226 GTGGGTTCATACATTAGTAGTAGTAGTAGTACCATATACTACGAGACTCTGTGAAGGGCCGATTACCATCTC
· R D N A K N S L S L Q M N S L R D E D T A V Y Y C
301 CAGAGACAATGCCAAGAACTCACTGTCTCTGCAAAATGAACAGCCTGAGAGACGAGGACACGGCTGTGTATTACTG
· A R A Y Y Y G M D V W G Q G T T V T V S S A S T K
376 TGGCAGAGCATACTACTACGGTATGGAGCTCTGGGGCAAGGACCAAGGTCACCGTCTCTCAGCCTCCACCAA
· G P S V F P L A P S S K S T S G G T A A L G C L V
451 GGGCCCCATCGGTCTTCCTCCCTGGGACCTCTCCAGAGCACTCTGGGGGCAAGCGGCTGGGCTGGCTGGT
· K D Y F P E P V T V S W N S G A L T S G V H T F P
526 CAAGGACTACTTCCCCGAACCGGTGACGGTGTCTGGAACTCAGGCGCCCTGACAGCGGCGTGCACACCTTCCC
· A V L Q S S G L Y S L S S V V T V P S S S L T Q
601 GGCTGTCTACAGTCTCTCAGGACTCTACTCCCTCAGCAGCGTGGTGACCGTGCCCTCCAGCAGCTTGGGCACCA
· T Y I C N V N H K P S N T K V D K R V E P K S C D
676 GACCTACATCTGCAACGTGAATCACAAGCCAGCAACCAAGGTGGACAAGAGAGTTGAGCCCAATCTTGTGA
· K T H T C P P C P A P E L L G G P S V F L F P P K
751 CAAACTCACACATGCCACCGTGCCAGCACTGAACTCTGGGGGACCGTCAGTCTTCTCTTCCCCCAAA
· P K D T L M I S R T P E V T C V V V D V S H E D P
826 ACCCAAGGACACCCCTCATGATCTCCCGGACCCCTGAGGTGACATGCGTGGTGGTGGACGTGAGCCACGAAGACCC
· E V K F N W Y V D G V E V H N A K T K P R E E Q Y
901 TGAGGTCAAGTTCAACTGGTACGTGGAGCGGTGGAGGTGCATAATGCCAAGACAAAGCCCGGGAGAGCAGTA
· N S T Y R V V S V L T V L H Q D W L N G K E Y K C
976 CAACGACAGTACCGTGTGGTTCAGCGTCTCCAGCTCTGACACAGGACTGGCTGAATGGCAAGGAGTACAAAG
· K V S N K A L P A P I E K T I S K A K G Q P R E P
1051 CAAGGTCTCCAAAGCCCTCCAGGCCCCATCGAGAAACCATCTCCAAAGCCAAAGGCGAGCCCCGAGAACC
· Q V Y T L P P S R E E M T K N Q V S L T C L V S K G
1126 ACAGGTGTACACCTGCCCCATCCCGGAGGAGATGACCAAGAACAGGTGAGCCTGACCTGCTGTGCAAGG
· F Y P S D I A V E W E S N G Q P E N N Y K T T P P
1201 CTTCTCCAGCAGATCGCCCTGGAGTGGGAGCAATGGGCGCCGAGAACCACTACAGACCAAGCCTCC
· V L D S D G S F F L Y S K L T V D K S R W Q Q G N
1276 CGTCTGAGTCCGACGCTCTTCTCTCTCTATAGCAAGCTCACCCTGACCAAGAGCAGGTGGCAGCAGGGAA
· V F S C S V M H E A L H N H Y T Q K S L S L S P G
1351 CGTCTCTCATGCTCCGTCATGATGATGAGGCTCTGCAACCACTACACGACAGAGCCTCTCCTGTCCCCGGG
· K *
1426 TAAATGA

FIG. 1C: The cDNA (SEQ ID NO:5) and amino acid sequence (SEQ ID NO:6) of Ha22-2(2,4)6.1 light chain. Double-underlined is the leader sequence, underlined is the light chain variable region, and underlined with a dashed line is the human kappa constant region.

M D M R V P A Q L L G L L L L W F

1 AGTCAGACCCAGTCAGGACACAGCATGGACATGAGGGTCCCGCTCAGCTCCTGGGGCTCCTGCTGCTCTGGTTC
P G S R C D I Q M T Q S P S S V S A S V G D R V T
76 CCAGGTTCAGATGCGACATCCAGATGACCCAGTCTCCATCTTCCGTGTCTGCATCTGTGGAGACAGAGTCACC
I T C R A S Q G I S G W L A W Y Q Q K P G K A P K
151 ATCACTTGTTCGGGCGAGTCAGGGTATTAGCGGCTGGTTAGCCTGGTATCAGCAGAAACAGGGAAGCCCTAAG
F L I Y A A S T L Q S G V P S R F S G S G S G T D
226 TTCTGATCTATGCTGCATCCACTTTGCAAAGTGGGTCCCATCAAGTTTCAAGGTCAGCGGCTGGATCTGGGACAGAT
T T C T I S S L Q P E D F A T Y Y C Q Q A N S F P
301 TTCACTCTCACCATCAGCAGCCTGCAGCCTGAAGATTITGCAACTTACTATGTCAACAGGCTAACAGTTTCCCT
P T F G G G T K V E I K R T V A A P S V F I F P P
376 CCCAGTTTCGGCGGAGGACCAAGCTGGAGATCAAAACCAACTGTGGCTGCAACCATCTGTCTTCACTCTCCCGCCA
S D E Q L K S G T A S V V C L L N N F Y P R E A K
451 TCTGATGAGCAGTTGAAATCTGGAACCTGCTCTGTGTGTGCTGCTGAATAACTTCTATCCAGAGAGGCCAAV
V Q W K V D N A L Q S G N S Q E S V T E Q D S K D
526 GTACAGTGAAGGTGGATAACGCCCTCCAATCGGGTAACTCCAGGAGAGTGTACAGAGCAGGACAGCAAGGAC
S T Y S L S S T L T L S K A D Y E K H K V Y A C E
601 AGCAGCTACAGCCTCAGCAGCACCCTGACGCTGACCAAGCAGACTACGAGAAACACAAAGTCTACGCTGCGAA
V T H Q G L S S P V T K S F N R G E C *
676 GTCACCCATCAGGGCTGAGCTCGCCCGTCACAAAGAGCTTCAACAGGGGAGTGTAG

FIG. 1D: The amino acid sequence (SEQ ID NO:7) of Ha22-2(2,4)6.1 heavy chain. Double-underlined is the leader sequence, underlined is the heavy chain variable region, (SEQ ID NO:22, which is the sequence ranging from the 20th to the 136th amino acid of SEQ ID NO:7) and underlined with a dashed line is the human IgG1 constant region.

1 MELGLCWVFLVAILEGVQCEVQLVESGGGLVQPGGSLRLSCAASGFTFSS
51 YNMNWVRQAPGKGLEWVSYISSSSSTIYYADSVKGRFTISRDNAKNSLSL
101 QMSLRDEDTAVYYCARAYYYGMDVWGQGTITVTVSSASTKGPSVFPLAPS
151 SKSTSGGTAAAGCLVKDYFPEPVTVSWNSGALTSGVHTFPAVLQSSGLYS
201 LSSVTVPPSSSLGTQTYICNVNHKPSNTKVDKRVEPKSCDKTHTCPPCPA
251 PELLGGPSVFLFPPKPKDTLMISRTPEVTCVVDVSHEDPEVKFNWYVDG
301 VEVHNAKTKPREEQYNSTYRVVSVLTVLHQDWLNGKEYKCKVSNKALPAP
351 IEKTIISKAKGQPREPQVYTLPPSREEMTKNQVSLTCLVKGFYPSDIAVEW
401 ESNGQPENNYKTPPVLDSDGSFFLYSKLTVDKSRWQQGNVFCSCVMHEA
451 LHNHYTQKSLSLSPGK

FIG. 1E: The amino acid sequence (SEQ ID NO:8) of Ha22-2(2,4)6.1 light chain. Double-underlined is the leader sequence, underlined is the light chain variable region (SEQ ID NO:23, which is the sequence ranging from the 23rd to the 130th amino acid of SEQ ID NO:8), and underlined with a dashed line is the human kappa constant region.

1 MDMRVPAQLLGLLLLWFPGSRCDIQMTQSPSSVSASVGDRVTITCRASQG
51 ISGWLAWYQQKPGKAPKFLIYAASLTQSGVPSRFSGSGSGTDFTLTISL
101 QPEDFATYYCQQANSFPPTFGGGTKVEIKRTVAAPSVFIFPPSDEQLKSG
151 TASVVCLLNNFYPREAKVQWKVDNALQSGNSQESVTEQDSKDSYSTLSST
201 LTLSKADYEKHKVYACEVTHQGLSPVTKSFNRGEC

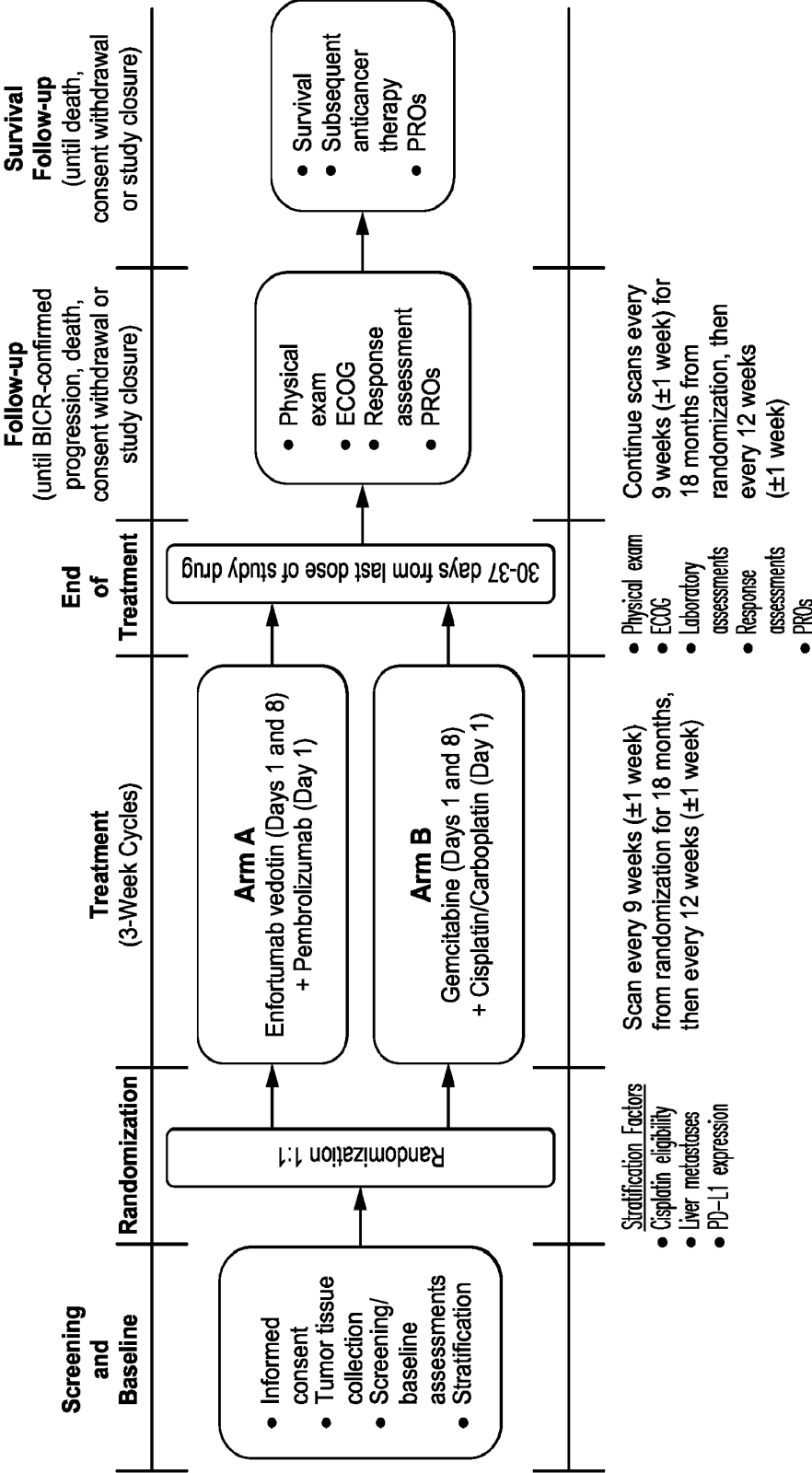


FIG. 2

RECIST CRITERIA VERSION 1.1

Table 1 - Time point response: patients with target (+/- non-target) disease.			
Target lesions	Non-target lesions	New lesions	Overall response
CR	CR	No	CR
CR	Non-CR/non-PD	No	PR
CR	Not evaluated	No	PR
PR	Non-PD or not all evaluated	No	PR
SD	Non-PD or not all evaluated	No	SD
Not all evaluated	Non-PD	No	NE
PD	Any	Yes or No	PD
Any	PD	Yes or No	PD
Any	Any	Yes	PD
CR = complete response, PR = partial response, SD = stable disease, PD = progressive disease, and NE = inevaluable.			

FIG. 3A

Table 2 - Time point response: patients with non-target disease only.		
Non-target lesions	New lesions	Overall response
CR	No	CR
Non-CR/non-PD	No	Non-CR/non-PD ^a
Not all evaluated	No	NE
Unequivocal PD	Yes or No	PD
Any	Yes	PD
CR = complete response, PD = progressive disease, and NE = inevaluable.		
a 'Non-CR/non-PD' is preferred over 'stable disease' for non-target disease since SD is increasingly used as endpoint for assessment of efficacy in some trials so to assign this category when no lesions can be measured is not advised.		

FIG. 3B

Table 3 - Best overall response when confirmation of CR and PR required.		
Overall response First time point	Overall response Subsequent time point	BEST overall response
CR	CR	CR
CR	PR	SD, PD or PR ^a
CR	SD	SD provided minimum criteria for SD duration met, otherwise, PD
CR	PD	SD provided minimum criteria for SD duration met, otherwise, PD
CR	NE	SD provided minimum criteria for SD duration met, otherwise NE
PR	CR	PR
PR	PR	PR
PR	SD	SD
PR	PD	SD provided minimum criteria for SD duration met, otherwise, PD
PR	NE	SD provided minimum criteria for SD duration met, otherwise NE
NE	NE	NE
CR = complete response, PR = partial response, SD = stable disease, PD = progressive disease, and NE = inevaluable. a if a CR is <i>truly</i> met at first time point, then any disease seen at a subsequent time point, even disease meeting PR criteria relative to baseline, makes the disease PD at that point (since disease must have reappeared after CR). Best response would depend on whether minimum duration for SD was met. However, sometimes 'CR' may be claimed when subsequent scans suggest small lesions were likely still present and in fact the patient had PR, not CR at the first time point. Under these circumstances, the original CR should be changed to PR and the best response is PR.		

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FIG. 3C



EORTC QLQ-C30 (version 3)

We are interested in some things about you and your health. Please answer all of the questions yourself by circling the number that best applies to you. There are no "right" or "wrong" answers. The information that you provide will remain strictly confidential.

Please fill in your initials:

--	--	--	--

Your birthdate (Day, Month, Year):

--	--	--	--	--	--	--	--	--	--

Today's date (Day, Month, Year): 31

--	--	--	--	--	--	--	--	--	--

	Not at All	A Little	Quite a Bit	Very Much
1. Do you have any trouble doing strenuous activities, like carrying a heavy shopping bag or a suitcase?	1	2	3	4
2. Do you have any trouble taking a <u>long</u> walk?	1	2	3	4
3. Do you have any trouble taking a <u>short</u> walk outside of the house?	1	2	3	4
4. Do you need to stay in bed or a chair during the day?	1	2	3	4
5. Do you need help with eating, dressing, washing yourself or using the toilet?	1	2	3	4
During the past week:				
6. Were you limited in doing either your work or other daily activities?	1	2	3	4
7. Were you limited in pursuing your hobbies or other leisure time activities?	1	2	3	4
8. Were you short of breath?	1	2	3	4
9. Have you had pain?	1	2	3	4
10. Did you need to rest?	1	2	3	4
11. Have you had trouble sleeping?	1	2	3	4
12. Have you felt weak?	1	2	3	4
13. Have you lacked appetite?	1	2	3	4
14. Have you felt nauseated?	1	2	3	4
15. Have you vomited?	1	2	3	4
16. Have you been constipated?	1	2	3	4

Please go on to the next page

FIG. 4
SUBSTITUTE SHEET (RULE 26)

During the past week:	Not at All	A Little	Quite a Bit	Very Much
17. Have you had diarrhea?	1	2	3	4
18. Were you tired?	1	2	3	4
19. Did pain interfere with your daily activities?	1	2	3	4
20. Have you had difficulty in concentrating on things, like reading a newspaper or watching television?	1	2	3	4
21. Did you feel tense?	1	2	3	4
22. Did you worry?	1	2	3	4
23. Did you feel irritable?	1	2	3	4
24. Did you feel depressed?	1	2	3	4
25. Have you had difficulty remembering things?	1	2	3	4
26. Has your physical condition or medical treatment interfered with your <u>family</u> life?	1	2	3	4
27. Has your physical condition or medical treatment interfered with your <u>social</u> activities?	1	2	3	4
28. Has your physical condition or medical treatment caused you financial difficulties?	1	2	3	4

For the following questions please circle the number between 1 and 7 that best applies to you

29. How would you rate your overall health during the past week?

1 2 3 4 5 6 7

Very poor

Excellent

30. How would you rate your overall quality of life during the past week?

1 2 3 4 5 6 7

Very poor

Excellent

Under each heading, please tick the ONE box that best describes your health TODAY.

MOBILITY

- I have no problems in walking about ☐
- I have slight problems in walking about ☐
- I have moderate problems in walking about ☐
- I have severe problems in walking about ☐
- I am unable to walk about ☐

SELF-CARE

- I have no problems washing or dressing myself ☐
- I have slight problems washing or dressing myself ☐
- I have moderate problems washing or dressing myself ☐
- I have severe problems washing or dressing myself ☐
- I am unable to wash or dress myself ☐

USUAL ACTIVITIES (e.g. work, study, housework, family or leisure activities)

- I have no problems doing my usual activities ☐
- I have slight problems doing my usual activities ☐
- I have moderate problems doing my usual activities ☐
- I have severe problems doing my usual activities ☐
- I am unable to do my usual activities ☐

PAIN / DISCOMFORT

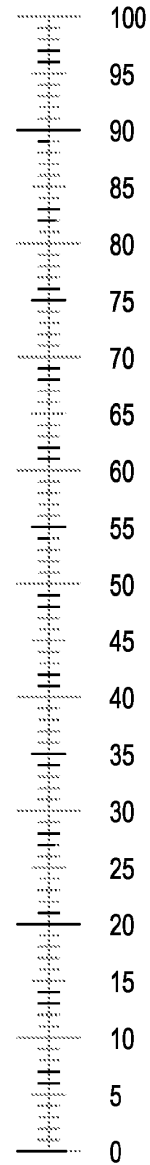
- I have no pain or discomfort ☐
- I have slight pain or discomfort ☐
- I have moderate pain or discomfort ☐
- I have severe pain or discomfort ☐
- I have extreme pain or discomfort ☐

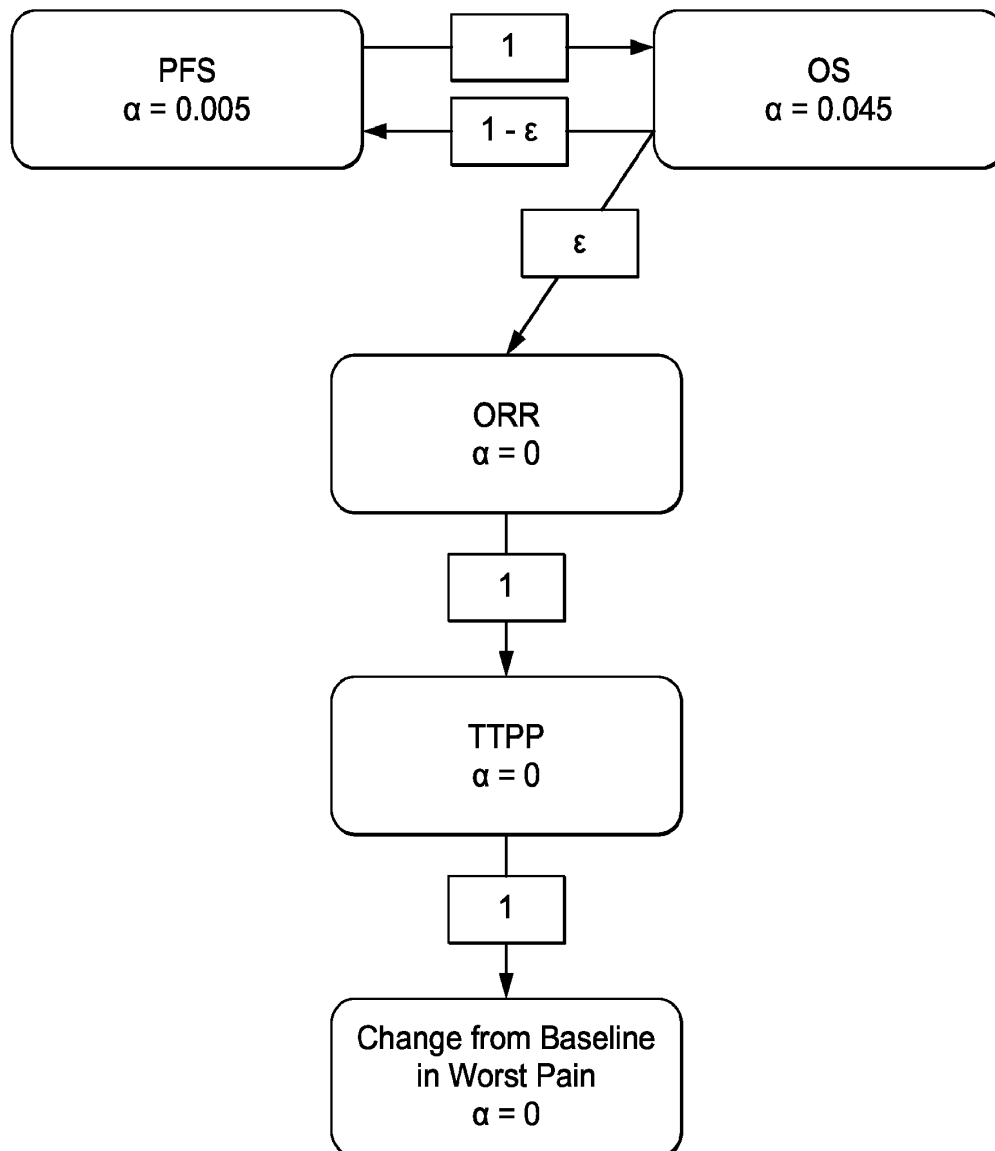
ANXIETY / DEPRESSION

- I am not anxious or depressed ☐
- I am slightly anxious or depressed ☐
- I am moderately anxious or depressed ☐
- I am severely anxious or depressed ☐
- I am extremely anxious or depressed ☐

- We would like to know how good or bad your health is TODAY.
- This scale is numbered from 0 to 100.
- 100 means the best health you can imagine.
0 means the worst health you can imagine.
- Mark an X on the scale to indicate how your health is TODAY.
- Now, please write the number you marked on the scale in the box below.

YOUR HEALTH TODAY =

The best health
you can imagineThe worst health
you can imagine

**FIG. 6**

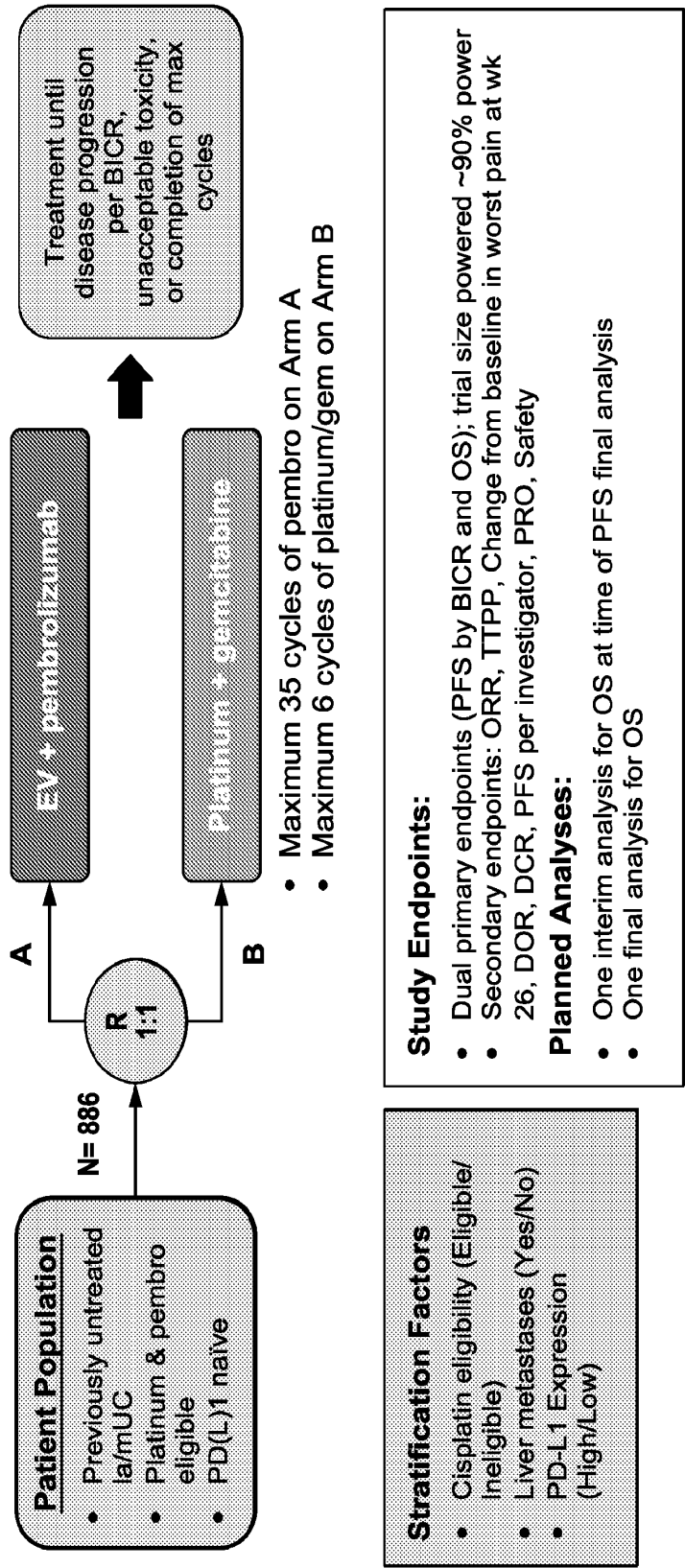


FIG. 7

Efficacy boundaries for PFS Analysis

Analysis	alpha=0.005		alpha=0.05 ^a	
	p-value	HR	p-value	HR
PFS FA	0.005	0.783	0.05	0.843

a. If OS is statistically significant, PFS will be tested at alpha = 0.05.

FIG. 8A

Efficacy boundaries for OS Analysis

Analysis	alpha=0.045		alpha=0.05 ^b	
	p-value	HR	p-value	HR
OS IA (356 OS events) ^c	0.015	0.773	0.017	0.777
OS FA ^c	0.040	0.831	0.045	0.834

- b. If PFS is statistically significant, OS will be tested at alpha = 0.05.
- c. The alpha level at the OS IA and FA will be calculated based on the actual number of OS events observed.

FIG. 8B

Summary of Disposition

	EV + Pembro (N=442) n (%)	Plat + Gem (N=444) n (%)	Total (N=886) n (%)
Subjects who received any amount of study drug	440 (99.5)	433 (97.5)	873 (98.5)
Subjects on treatment	144 (32.6)	0	144 (16.3)
Subjects off treatment	296 (67.0)	433 (97.5)	729 (82.3)
Primary reason for treatment discontinuation			
Completed treatment	8 (1.8)	244 (55.0)	252 (28.4)
Progressive disease	153 (34.6)	73 (16.4)	226 (25.5)
Adverse event	97 (21.9)	62 (14.0)	159 (17.9)
Physician decision	9 (2.0)	28 (6.3)	37 (4.2)
Subject decision	22 (5.0)	24 (5.4)	46 (5.2)
Other	7 (1.6)	2 (0.5)	9 (1.0)
Subjects on study	296 (67.0)	203 (45.7)	499 (56.3)
Subjects off study	146 (33.0)	241 (54.3)	387 (43.7)

FIG. 9

Stratification Factors at Randomization

	EV + Pembro (N=442) n (%)	Plat + Gem (N=444) n (%)	Total (N=886) n (%)
Cisplatin eligibility			
Eligible	240 (54.3)	242 (54.5)	482 (54.4)
Ineligible	202 (45.7)	202 (45.5)	404 (45.6)
Liver metastases			
Present	98 (22.2)	98 (22.1)	196 (22.1)
Absent	344 (77.8)	346 (77.9)	690 (77.9)
PD-L1 expression			
Low (CPS <10)	186 (42.1)	189 (42.6)	375 (42.3)
High (CPS ≥10)	256 (57.9)	255 (57.4)	511 (57.7)

FIG. 10

Summary of Demographics

	EV + Pembro (N=442)	Plat + Gem (N=444)	Total (N=886)
Age (yr)			
Median	69.0	69.0	69.0
Min, Max	37, 87	22, 91	22, 91
≥75 years, n (%)	102 (23.1)	108 (24.3)	210 (23.7)
Sex, n (%)			
Male	344 (77.8)	336 (75.7)	680 (76.7)
Female	98 (22.2)	108 (24.3)	206 (23.3)
Race, n (%)			
Asian	99 (22.4)	92 (20.7)	191 (21.6)
Black or African American	3 (0.7)	7 (1.6)	10 (1.1)
White	308 (69.7)	290 (65.3)	598 (67.5)
Other*	5 (1.1)	8 (1.8)	13 (1.5)
Unknown or not reportable	27 (6.1)	47 (10.6)	74 (8.4)
Geographic region, n (%)			
North America	103 (23.3)	85 (19.1)	188 (21.2)
Europe	172 (38.9)	197 (44.4)	369 (41.6)
Rest of World	167 (37.8)	162 (36.5)	329 (37.1)

FIG. 11

Summary of Baseline Characteristics

	EV + Pembro (N=442)	Plat + Gem (N=444)	Total (N=886)
ECOG performance status, n (%)			
0	223 (50.5)	215 (48.4)	438 (49.4)
1	204 (46.2)	216 (48.6)	420 (47.4)
2	15 (3.4)	11 (2.5)	26 (2.9)
BMI ≥ 30 kg/m ² , n (%)	89 (20.1)	101 (22.7)	190 (21.4)
Renal function based on CrCL, n (%)			
Normal: ≥ 90 mL/min	84 (19.0)	95 (21.4)	179 (20.2)
Mild decrease: ≥ 60 and < 90 mL/min	165 (37.3)	162 (36.5)	327 (36.9)
Moderate decrease: ≥ 30 and < 60 mL/min	186 (42.1)	179 (40.3)	365 (41.2)
Severe decrease : ≥ 15 and < 30 mL/min	7 (1.6)	8 (1.8)	15 (1.7)
Bajorin risk factors, n (%)			
0	179 (40.5)	183 (41.2)	362 (40.9)
1	263 (59.5)	259 (58.3)	522 (58.9)
Nectin-4 expression			
n	394	406	800
Median	280	270	275
Q1, Q3	230, 298	215, 297	225, 297
Min, Max	0, 300	0, 300	0, 300

FIG. 12

Summary of Disease Characteristics

	EV + Pembro (N=442)	Plat + Gem (N=444)	Total (N=886)
Current extent of disease, n (%)			
Locally advanced	21 (4.8)	24 (5.4)	45 (5.1)
Metastatic	421 (95.2)	420 (94.6)	841 (94.9)
Time from diagnosis of la/mUC to enrollment (months)			
Median	1.58	1.56	1.58
Min, Max	0.0, 125.2	0.0, 59.9	0.0, 125.2
Primary tumor location, n (%)			
Upper tract	135 (30.5)	104 (23.4)	239 (27.0)
Lower tract	305 (69.0)	339 (76.4)	644 (72.7)
Metastasis Category, n (%)			
Lymph node only	103 (23.3)	104 (23.4)	207 (23.4)
Visceral metastases	318 (71.9)	318 (71.6)	636 (71.8)
Bone	81 (18.3)	102 (23.0)	183 (20.7)
Liver	100 (22.6)	99 (22.3)	199 (22.5)
Lung	170 (38.5)	157 (35.4)	327 (36.9)

FIG. 13

Summary of Prior Anticancer Therapies

	EV + Pembro (N=442) n (%)	Plat + Gem (N=444) n (%)	Total (N=886) n (%)
Prior systemic therapy in neoadjuvant/adjuvant setting	40 (9.0)	39 (8.8)	79 (8.9)
Platinum-based therapy	40 (9.0)	36 (8.1)	76 (8.6)
Non-platinum-based therapy	1 (0.2)	4 (0.9)	5 (0.6)
Prior surgery	165 (37.3)	163 (36.7)	328 (37.0)
Cystectomy	92 (20.8)	106 (23.9)	198 (22.3)
Nephrectomy/ureterectomy	85 (19.2)	68 (15.3)	153 (17.3)
Metastasectomy	8 (1.8)	14 (3.2)	22 (2.5)
Prior radiation therapy	33 (7.5)	39 (8.8)	72 (8.1)

FIG. 14

Duration of Treatment

	EV + Pembro (N=440)			Plat + Gem (N=433)
	EV	Pembro	EV or Pembro	
Duration of treatment (months)				
Median	7.01	8.46	9.43	4.14
Min, Max	0.3, 31.9	0.3, 28.5	0.3, 31.9	0.0, 7.7
Number of cycles				
Median	9	11	12	6
Min, Max	1, 46	1, 35	1, 46	1, 6

FIG. 15

Summary of Subsequent Anticancer Therapies

	EV + Pembro (N=442) n (%)	Plat + Gem (N=444) n (%)
Subjects received subsequent anticancer therapies	140 (31.7)	313 (70.5)
Number of lines of subsequent systemic therapies		
1	94 (21.3)	196 (44.1)
2	22 (5.0)	75 (16.9)
≥3	12 (2.7)	23 (5.2)
First subsequent systemic therapy		
Platinum-based therapy	110 (24.9)	17 (3.8)
Maintenance PD-1/L1 inhibitor-containing therapy	1 (0.2)	143 (32.2)
Avelumab	1 (0.2)	135 (30.4)
Other PD-1/L1 inhibitor-containing therapy	8 (1.8)	118 (26.6)
Other	11 (2.5)	18 (4.1)

FIG. 16

Progression-Free Survival (PFS) per RECIST by BICR – ITT

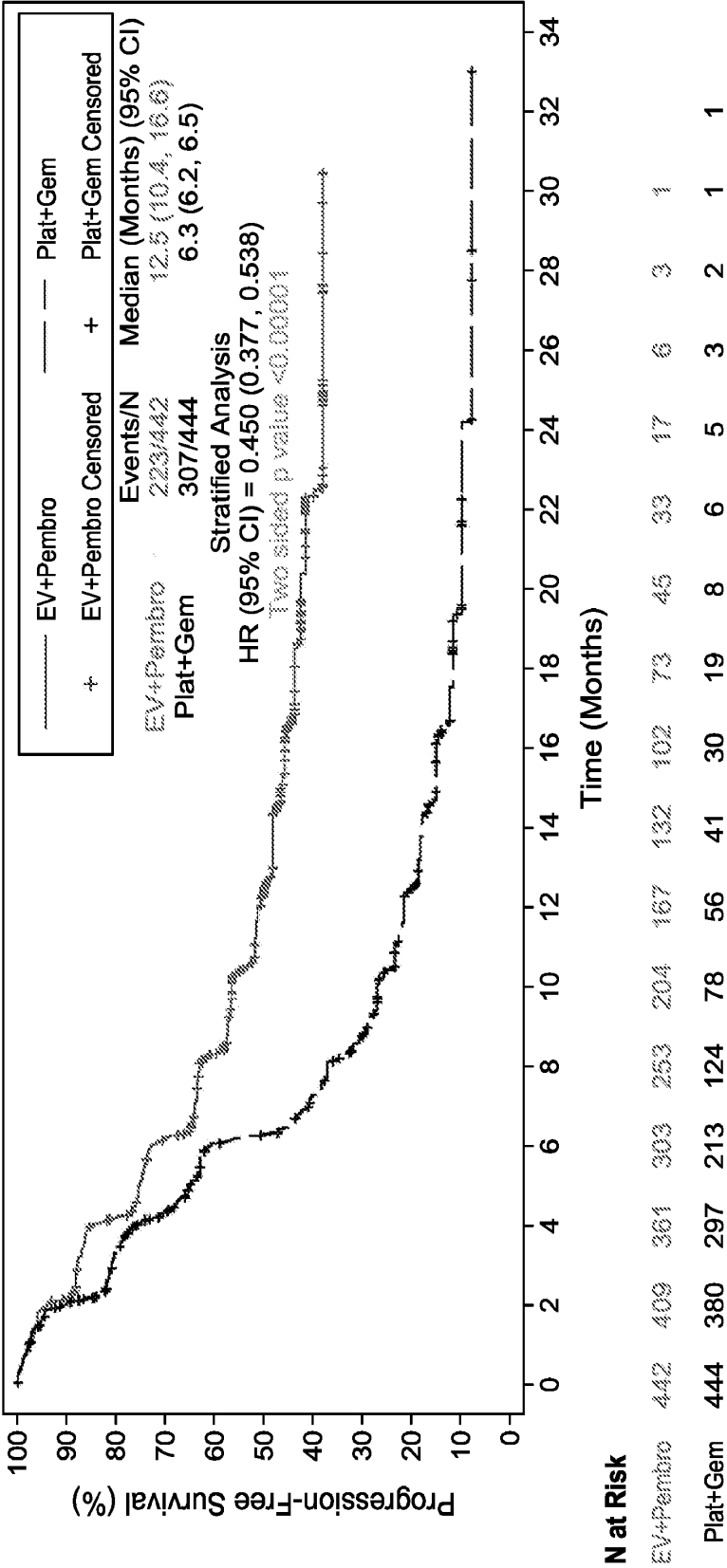


FIG. 17A

Progression-Free Survival (PFS) per RECIST by BICR – ITT

	EV + Pembro (N=442)	Plat + Gem (N=444)
No. of events (%)	223 (50.5)	307 (69.1)
HR (95% CI)	0.450 (0.377, 0.538)	
2-sided p-value	<0.00001	
mPFS (95% CI), months	12.5 (10.4, 16.6)	6.3 (6.2, 6.5)
PFS at 6 months	72.8 %	60.7%
PFS at 12 months	50.7%	21.6%
PFS at 18 months	43.9%	11.7%

FIG. 17B

Subgroup Analysis of PFS per Recist by BICR

Subgroup	Median PFS, months (Events/N)		Hazard Ratio (95% CI)
	EV+Pembro	Plat+Gem	
Overall	12.5 (223/442)	6.3 (307/444)	0.450 (0.377,0.538)
Age			
<65 years	12.7 (75/144)	6.4 (88/135)	0.446 (0.321,0.621)
≥65 years	12.0 (148/298)	6.2 (219/309)	0.451 (0.364,0.558)
Race			
White	10.4 (168/308)	6.2 (207/290)	0.482 (0.390,0.596)
Other	22.3 (55/134)	6.5 (100/154)	0.387 (0.274,0.547)
Region			
North America	12.0 (58/103)	6.3 (55/85)	0.555 (0.376,0.818)
Europe	10.4 (94/172)	6.3 (144/197)	0.502 (0.383,0.657)
Rest of World	-(71/167)	6.2 (108/162)	0.350 (0.255,0.481)
Sex			
Female	10.4 (55/98)	6.1 (74/108)	0.490 (0.336,0.714)
Male	14.6 (168/344)	6.3 (233/336)	0.442 (0.360,0.544)
ECOG PS			
0	22.3 (93/223)	6.7 (146/215)	0.362 (0.277,0.475)
1-2	9.3 (130/219)	6.1 (161/227)	0.534 (0.420,0.678)
Primary disease site of origin			
Upper tract	12.7 (69/135)	6.2 (70/104)	0.497 (0.350,0.706)
Lower tract	12.5 (152/305)	6.3 (236/339)	0.437 (0.354,0.539)
Liver metastases			
Present	8.2 (66/100)	6.0 (78/99)	0.534 (0.378,0.755)
Absent	16.4 (157/342)	6.4 (229/345)	0.425 (0.346,0.524)
PD-L1 expression			
Low (CPS < 10)	10.5 (105/184)	6.3 (127/185)	0.501 (0.384,0.653)
High (CPS ≥ 10)	18.5 (116/254)	6.2 (176/254)	0.415 (0.326,0.529)
Cisplatin eligibility			
Eligible	14.6 (117/244)	6.5 (149/234)	0.483 (0.377,0.619)
Ineligible	10.6 (106/198)	6.1 (158/210)	0.429 (0.333,0.553)
Metastatic disease site			
Visceral metastases	10.4 (176/318)	6.2 (238/318)	0.452 (0.369,0.552)
Lymph node only	-(38/103)	8.3 (55/104)	0.400 (0.258,0.621)
Renal function			
Normal	18.7 (38/84)	6.7 (61/95)	0.461 (0.299,0.709)
Mild	12.7 (79/165)	6.3 (114/162)	0.463 (0.344,0.623)
Moderate/Severe	10.5 (106/193)	6.2 (132/187)	0.469 (0.359,0.613)

FIG. 18A

SUBSTITUTE SHEET (RULE 26)

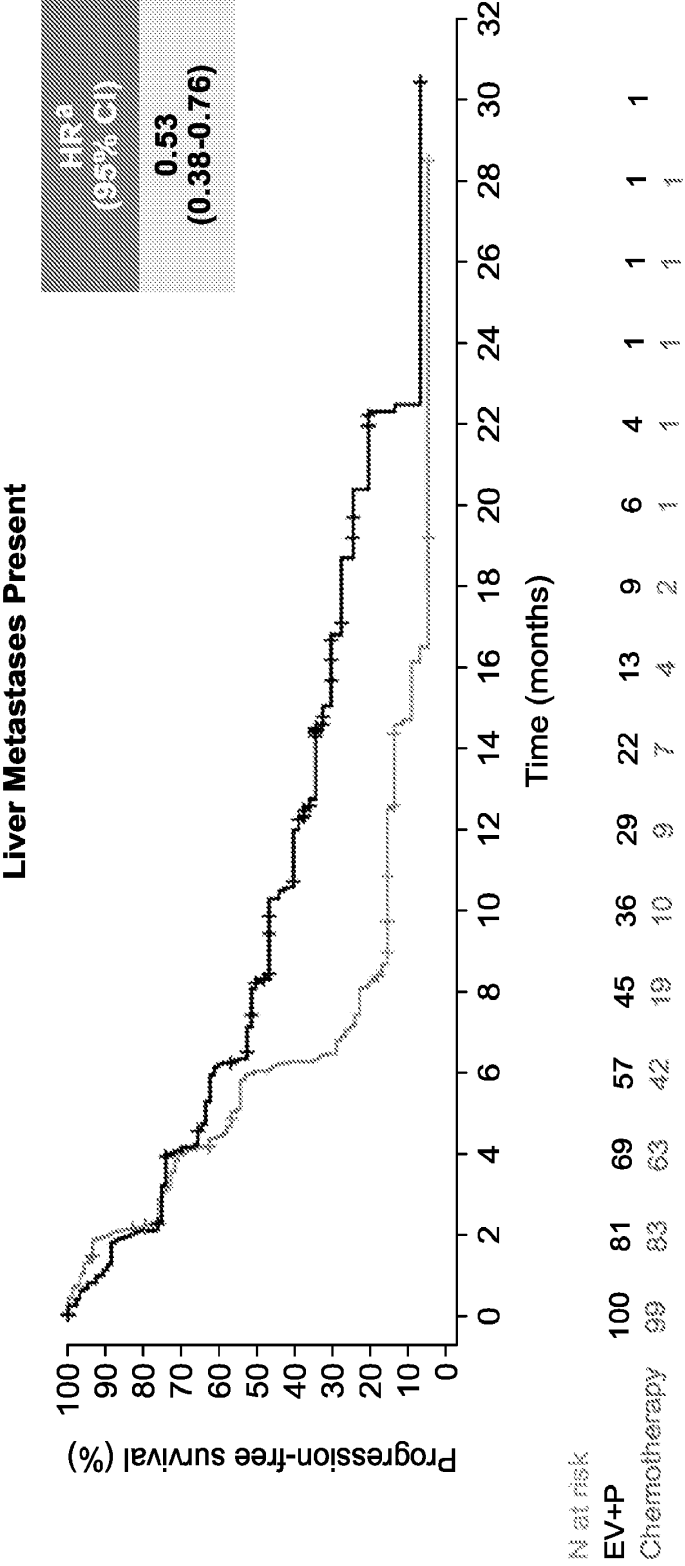


FIG. 18B

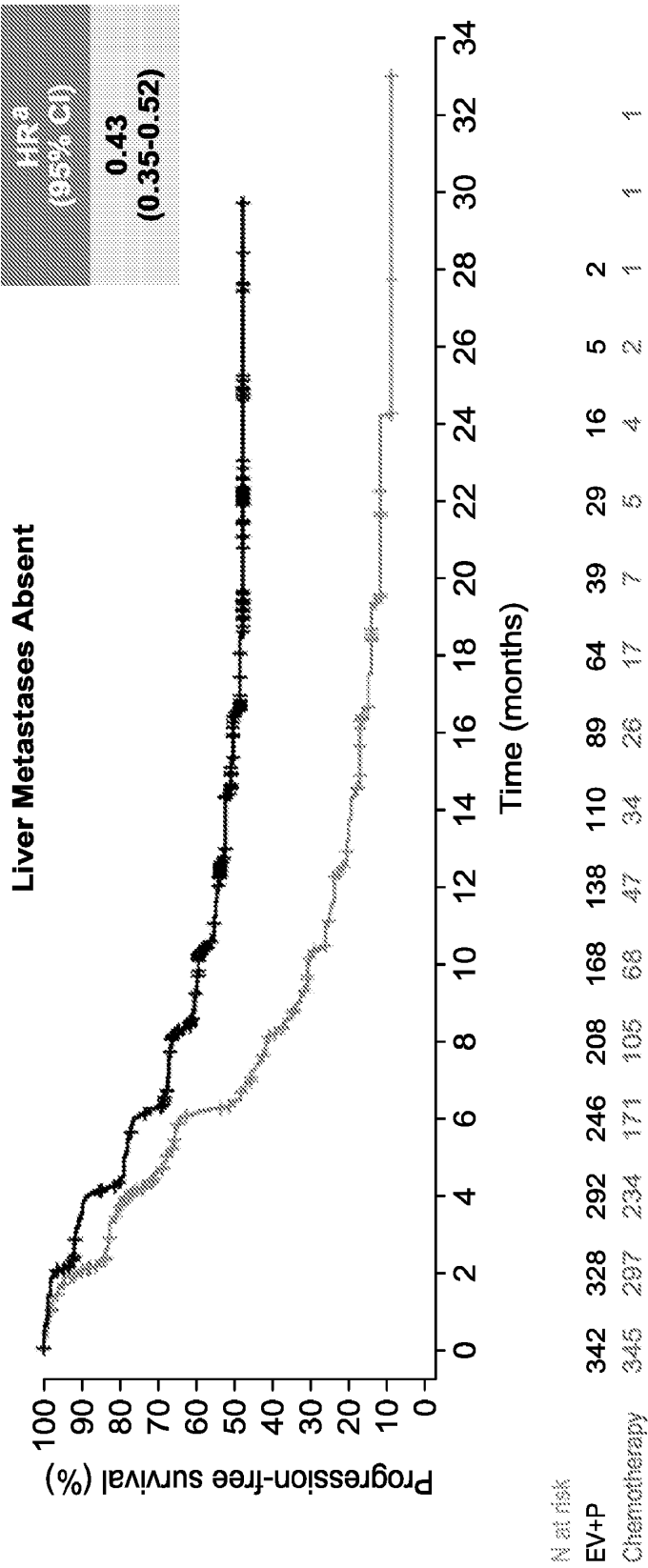


FIG. 18C

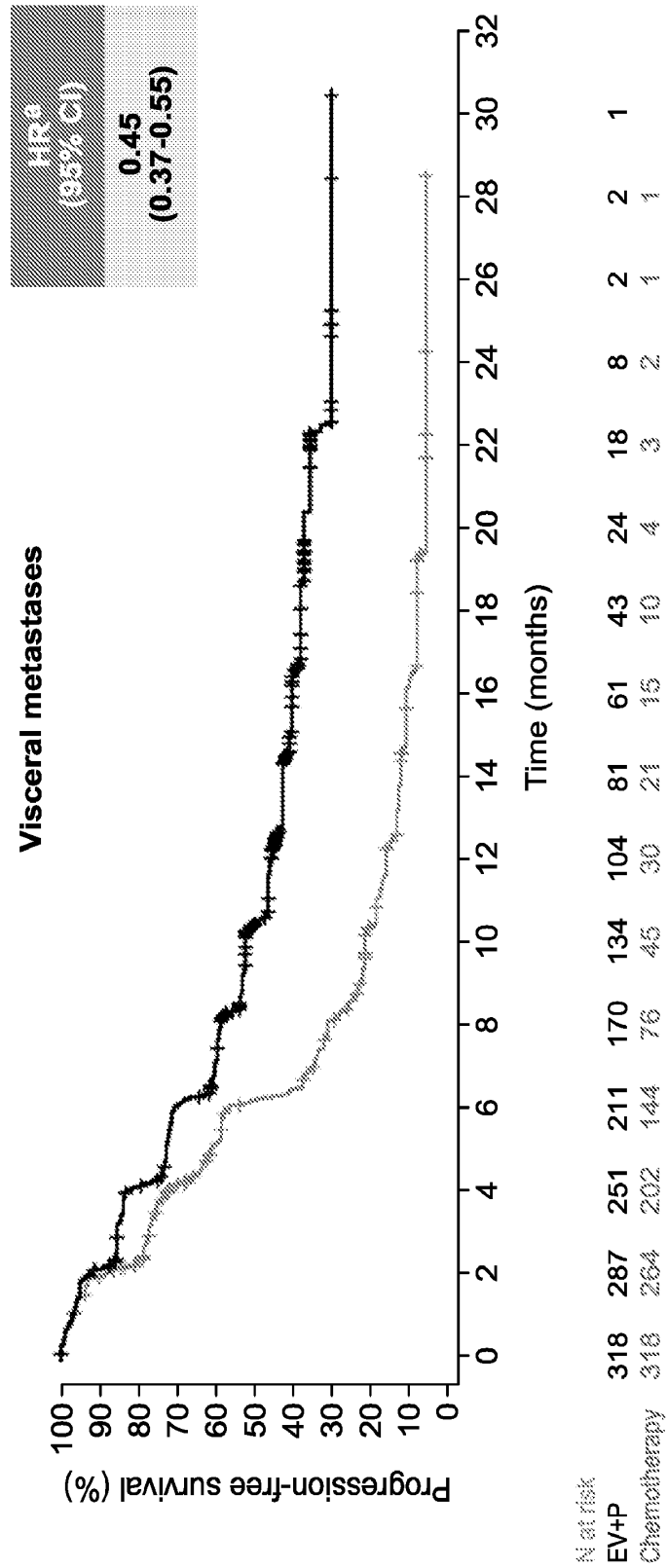


FIG. 18D

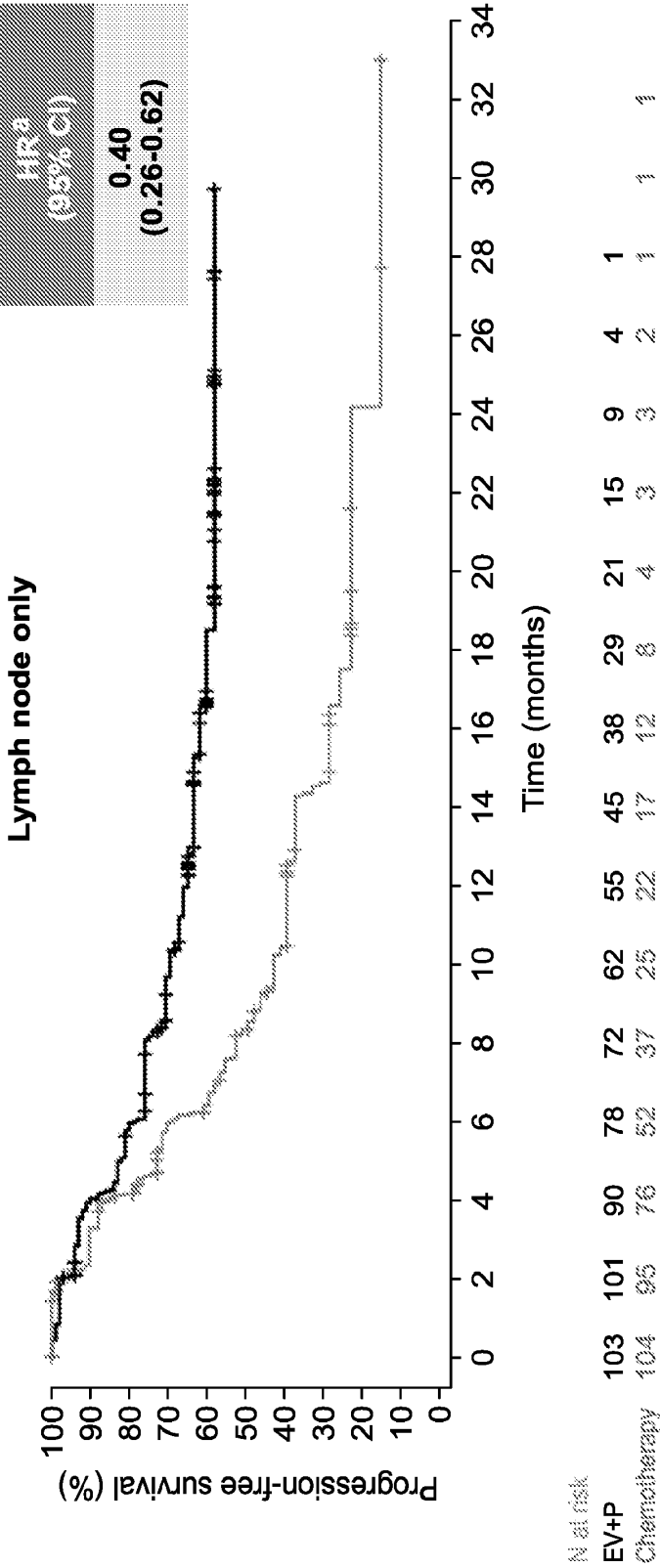


FIG. 18E

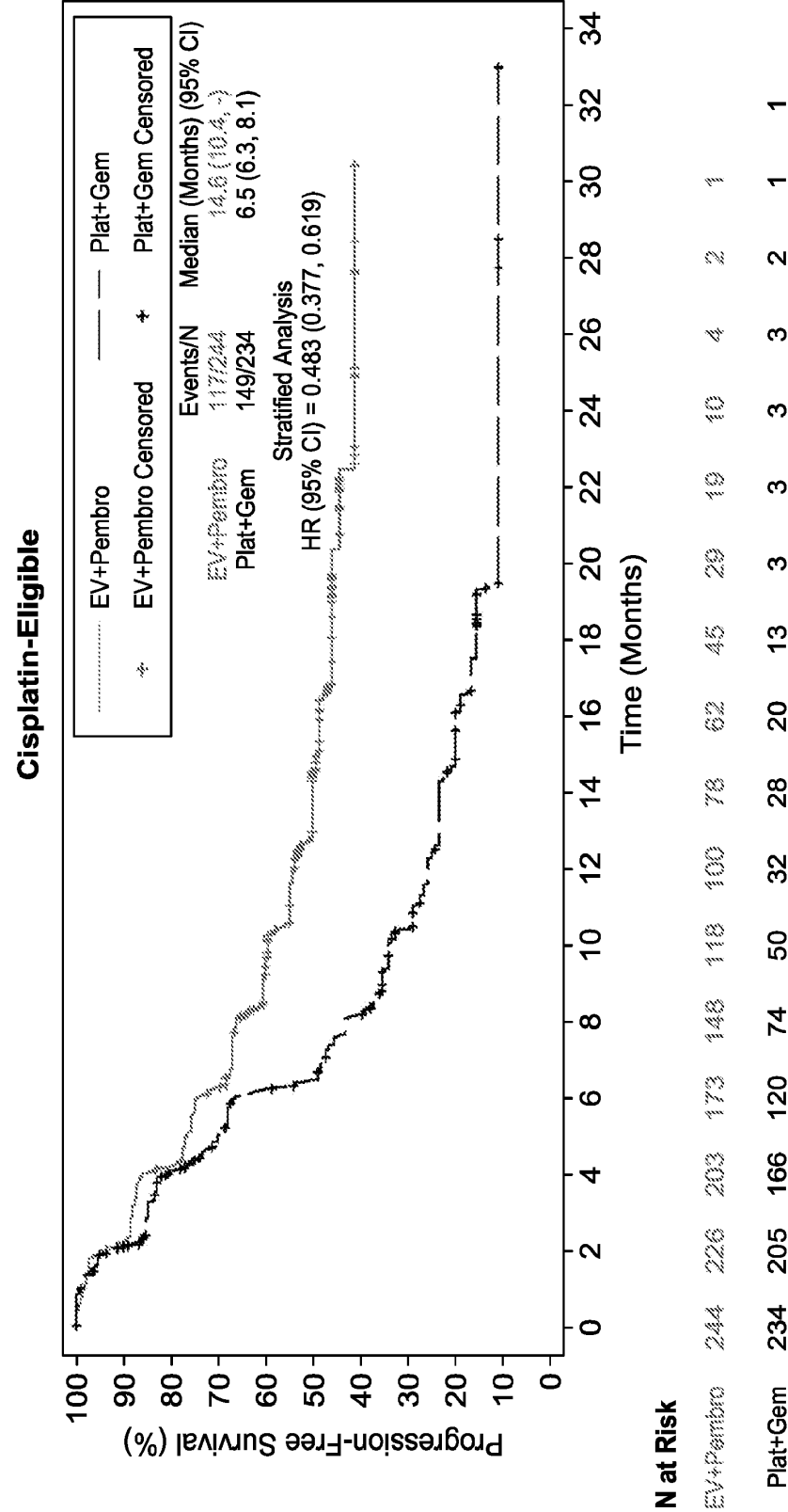


FIG. 19A

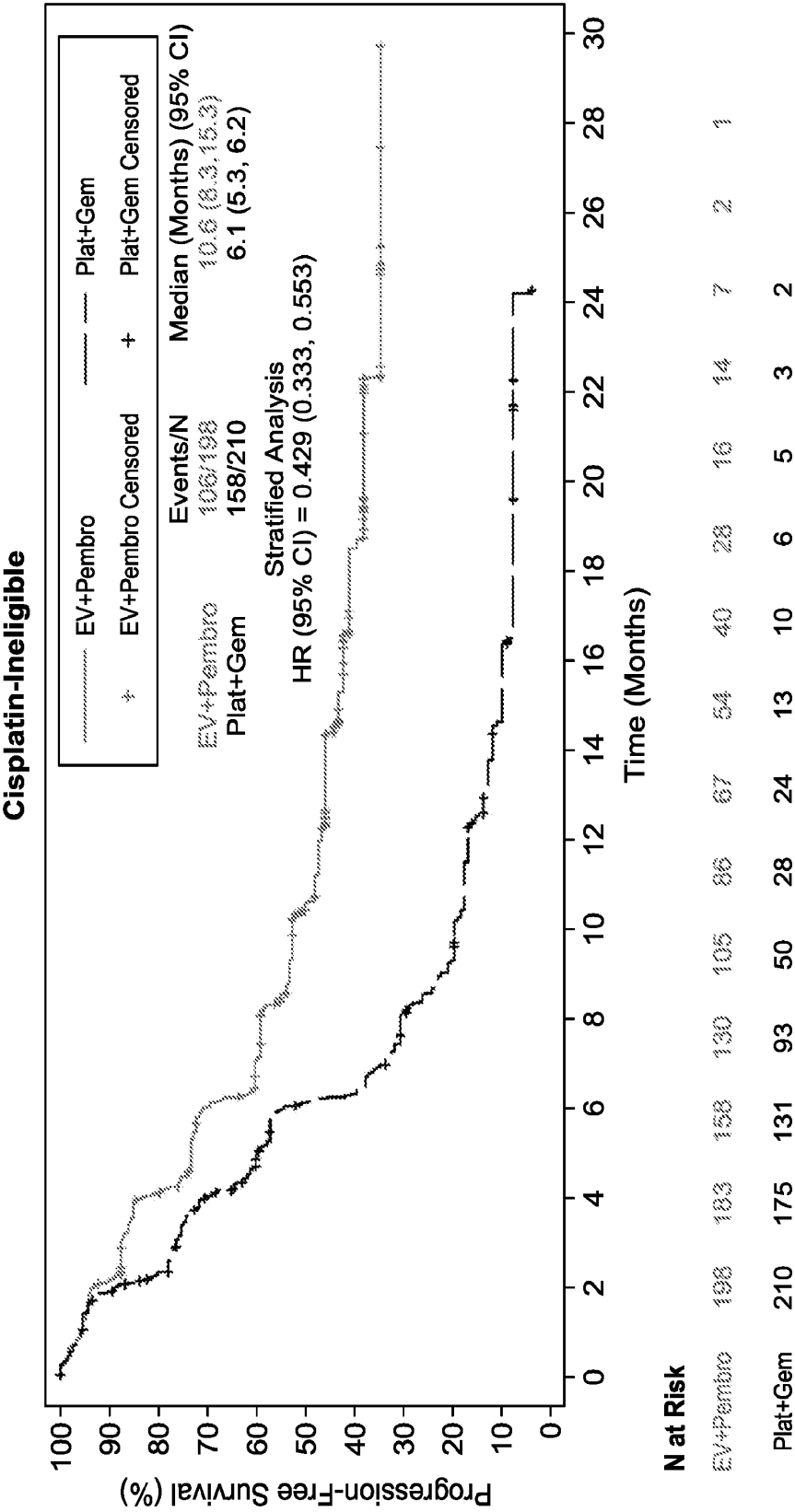


FIG. 19B

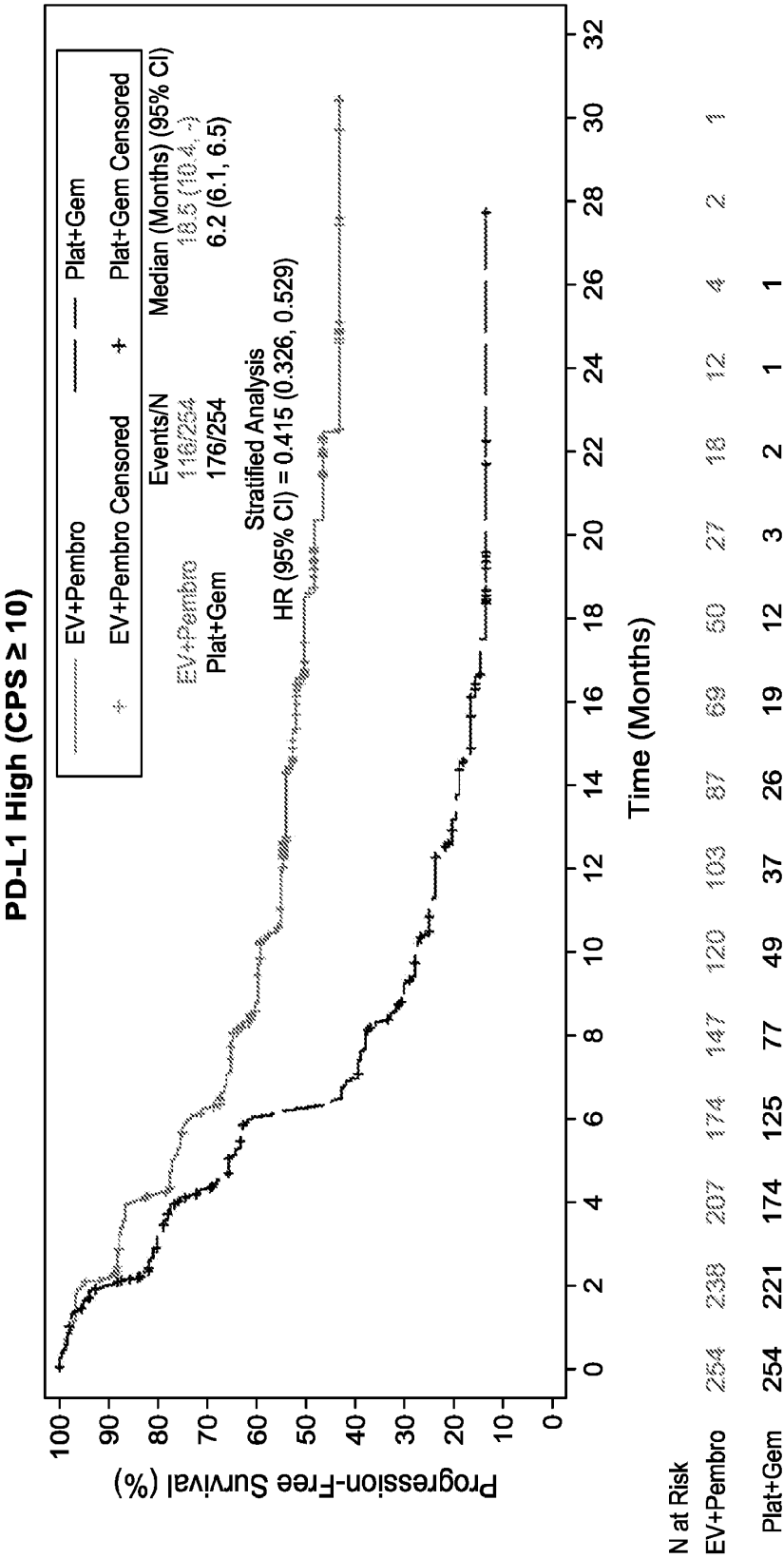


FIG. 20A

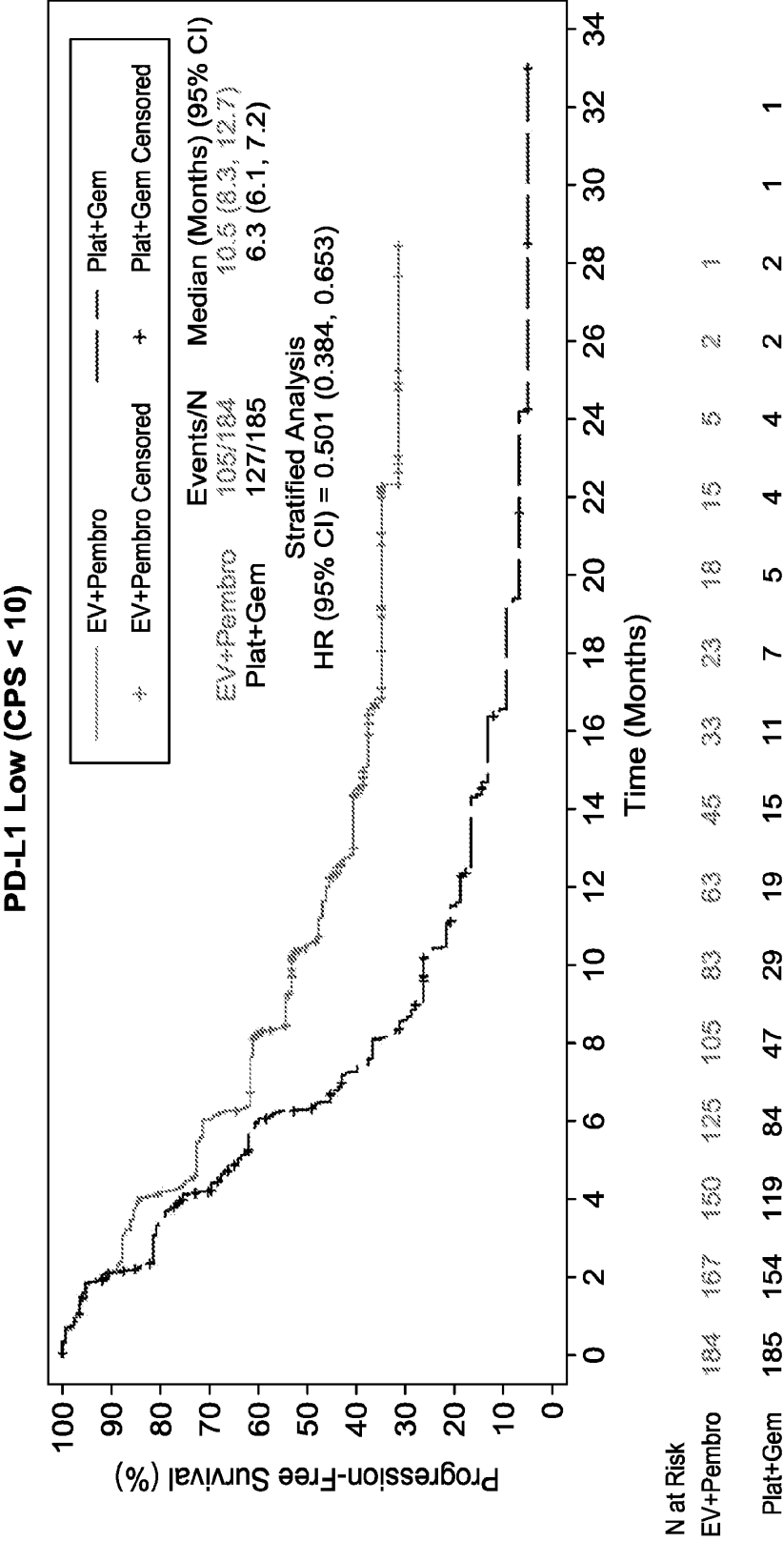


FIG. 20B

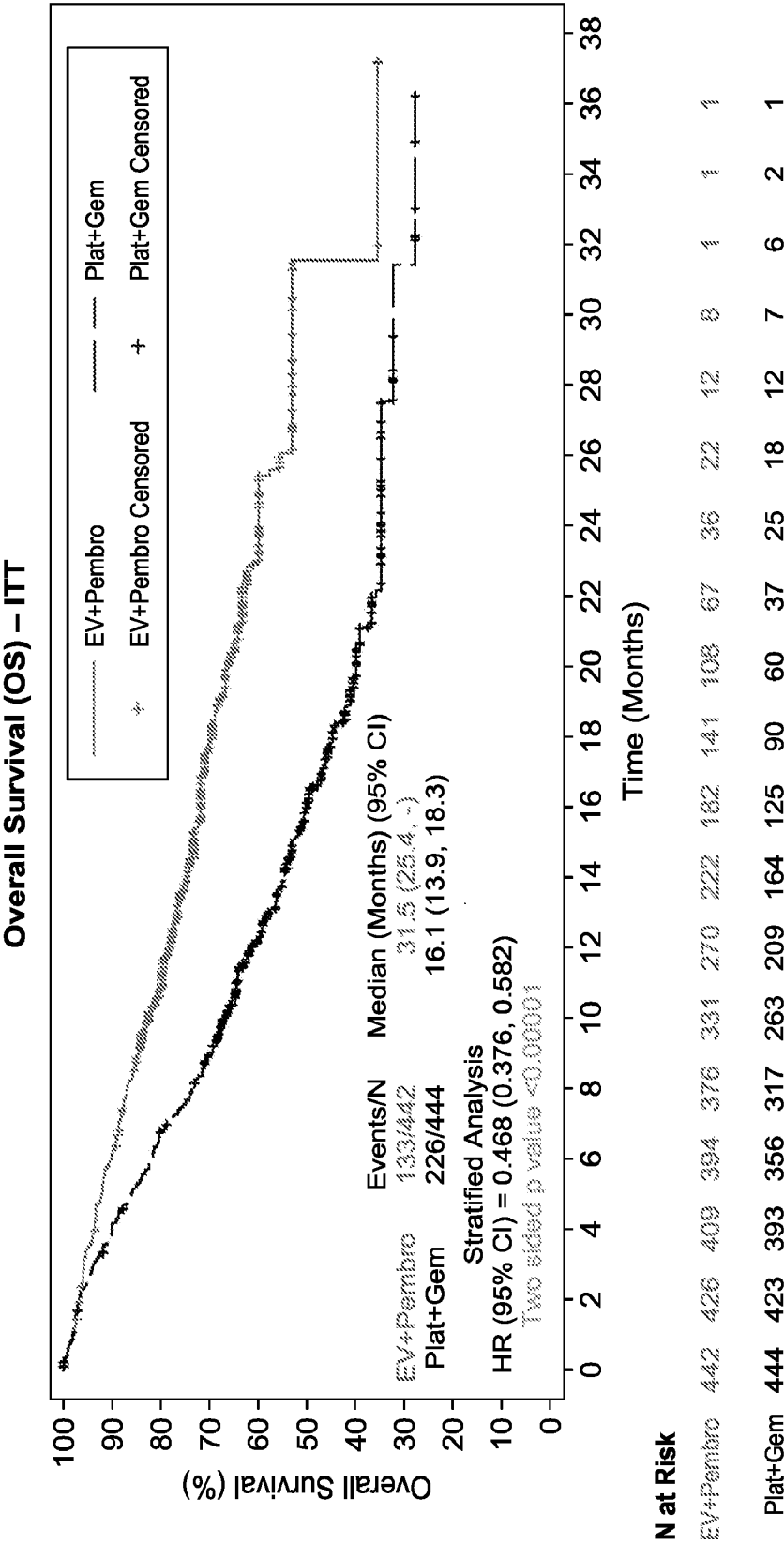


FIG. 21A

Overall Survival (OS) – ITT

	EV + Pembro (N=442)	Plat + Gem (N=444)
No. of events (%)	133 (30.1)	226 (50.9)
HR (95% CI)	0.468 (0.376, 0.582)	
2-sided p-value	<0.00001	
mOS (95% CI), months	31.5 (25.4, -)	16.1 (13.9, 18.3)
OS at 6 months	90.2%	81.9%
OS at 12 months	78.2%	61.4%
OS at 18 months	69.5%	44.7%
Median f/u (range), months	17.2 (0.07, 37.16)	

FIG. 21B

Subgroup Analysis of OS

Subgroup	Median OS, months (Events/N)		Hazard Ratio (95% CI)
	EV+Pembro	Plat+Gem	
Overall	31.5 (133/442)	16.1 (226/444)	0.468 (0.376,0.582)
Age			
<65 years	- (39/144)	19.7 (58/135)	0.461 (0.300,0.709)
≥65 years	31.5 (94/298)	14.6 (168/309)	0.484 (0.375,0.626)
Race			
White	26.1 (104/308)	15.3 (162/290)	0.466 (0.362,0.599)
Other	- (29/134)	19.3 (64/154)	0.458 (0.292,0.721)
Region			
North America	25.6 (40/103)	21.2 (42/85)	0.705 (0.443,1.120)
Europe	- (56/172)	13.9 (110/197)	0.396 (0.280,0.558)
Rest of World	- (37/167)	16.4 (74/162)	0.406 (0.271,0.608)
Sex			
Female	25.4 (32/98)	14.6 (54/108)	0.507 (0.321,0.801)
Male	31.5 (101/344)	16.6 (172/336)	0.468 (0.364,0.601)
ECOG PS			
0	- (44/223)	18.4 (94/215)	0.364 (0.252,0.525)
1-2	25.4 (89/219)	13.1 (131/227)	0.544 (0.413,0.718)
Primary disease site of origin			
Upper tract	- (38/135)	18.4 (45/104)	0.533 (0.341,0.834)
Lower tract	31.5 (94/305)	15.6 (180/339)	0.459 (0.355,0.592)
Liver metastases			
Present	19.1 (43/100)	10.1 (67/99)	0.474 (0.316,0.710)
Absent	- (90/342)	17.9 (159/345)	0.470 (0.363,0.609)
PD-L1 expression			
Low (CPS < 10)	- (53/184)	15.5 (99/185)	0.435 (0.311,0.609)
High (CPS ≥ 10)	31.5 (79/254)	16.6 (125/254)	0.492 (0.368,0.658)
Cisplatin eligibility			
Eligible	31.5 (69/244)	18.4 (106/234)	0.528 (0.389,0.718)
Ineligible	- (64/198)	12.7 (120/210)	0.428 (0.313,0.585)
Metastatic disease site			
Visceral metastases	25.6 (108/318)	13.6 (182/318)	0.470 (0.368,0.600)
Lymph node only	- (22/103)	27.5 (39/104)	0.461 (0.273,0.781)
Renal function			
Normal	26.1 (24/84)	18.4 (44/95)	0.508 (0.300,0.862)
Mild	- (42/165)	16.4 (78/162)	0.437 (0.296,0.646)
Moderate/Severe	31.5 (67/193)	13.3 (104/187)	0.501 (0.365,0.687)

0.1 1 5
 <--- Favors EV+Pembro | Favors Plat+Gem --->

FIG. 22A

SUBSTITUTE SHEET (RULE 26)

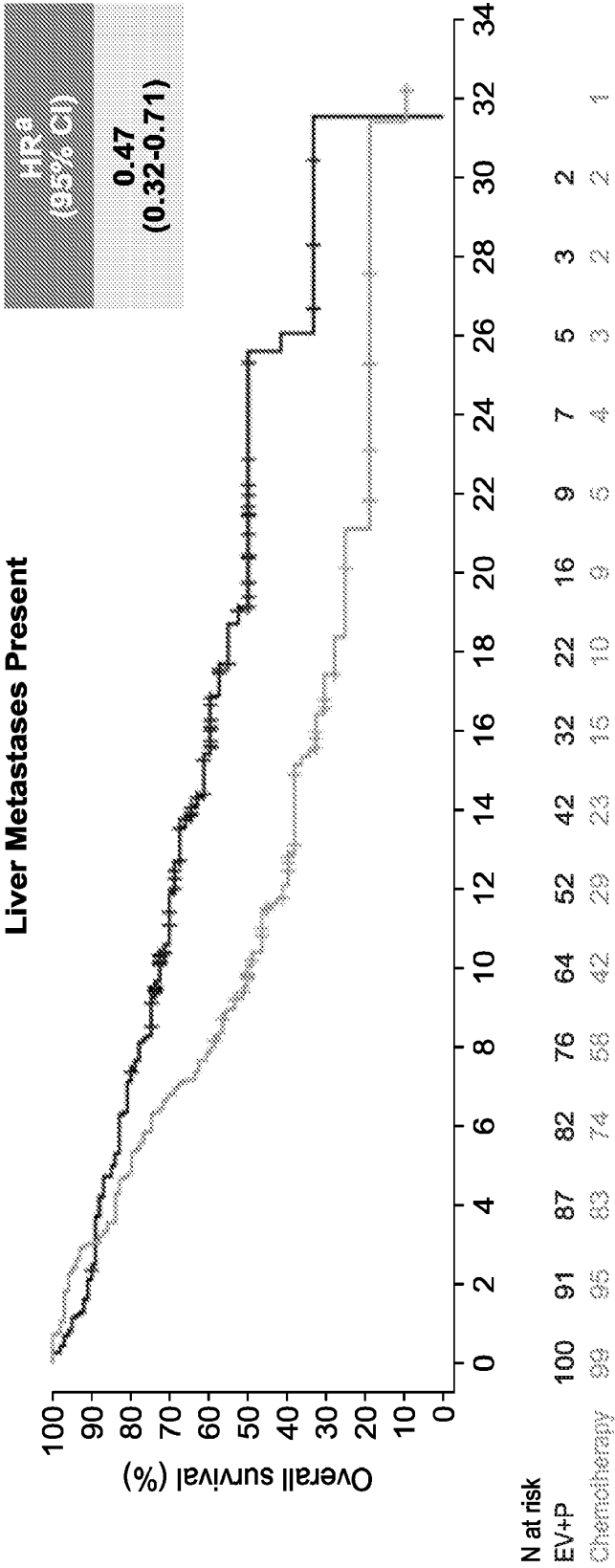


FIG. 22B

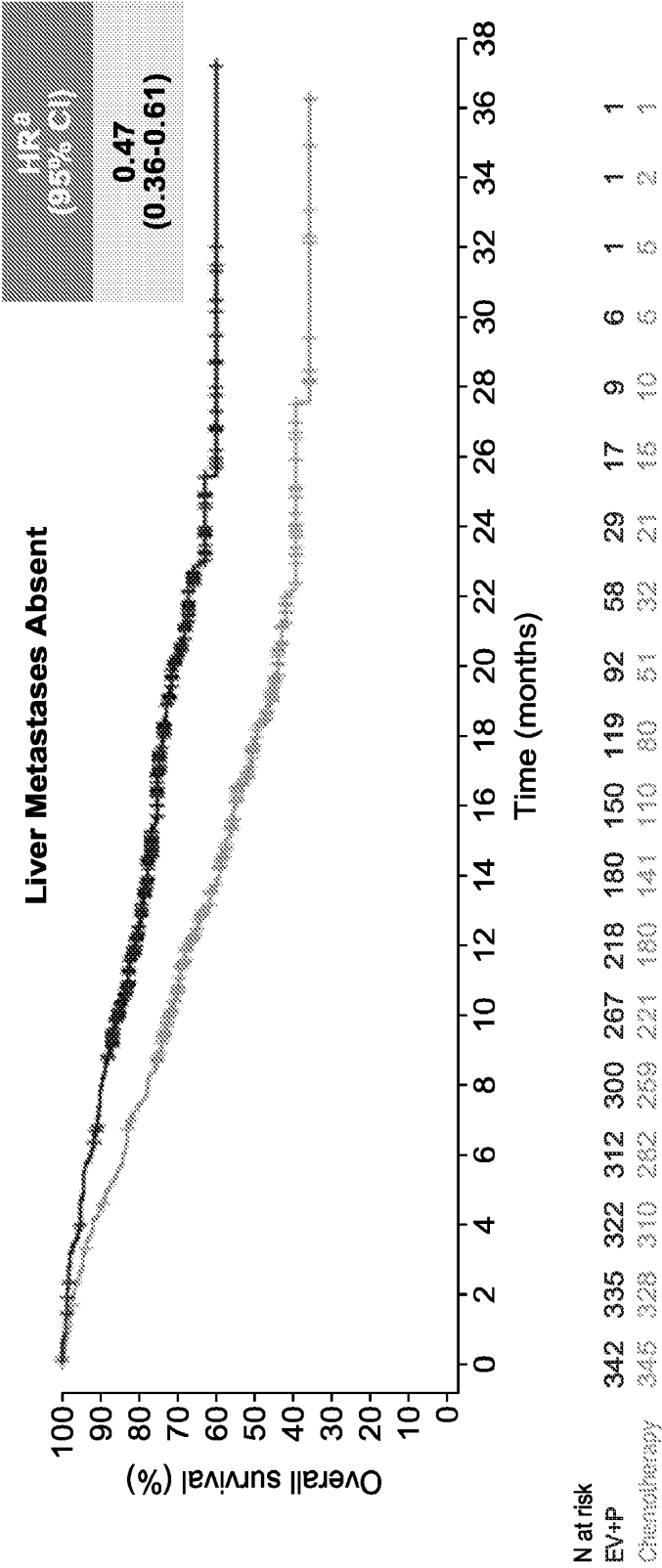


FIG. 22C

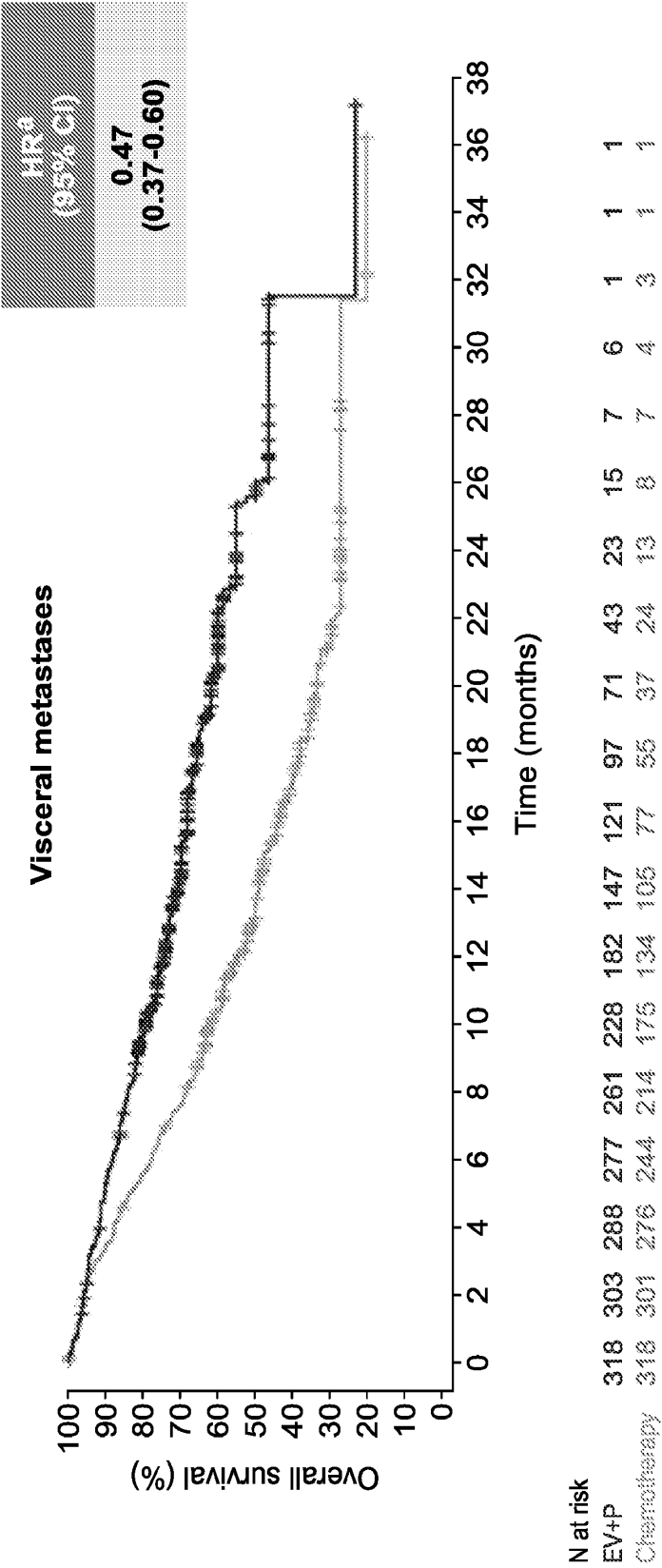


FIG. 22D

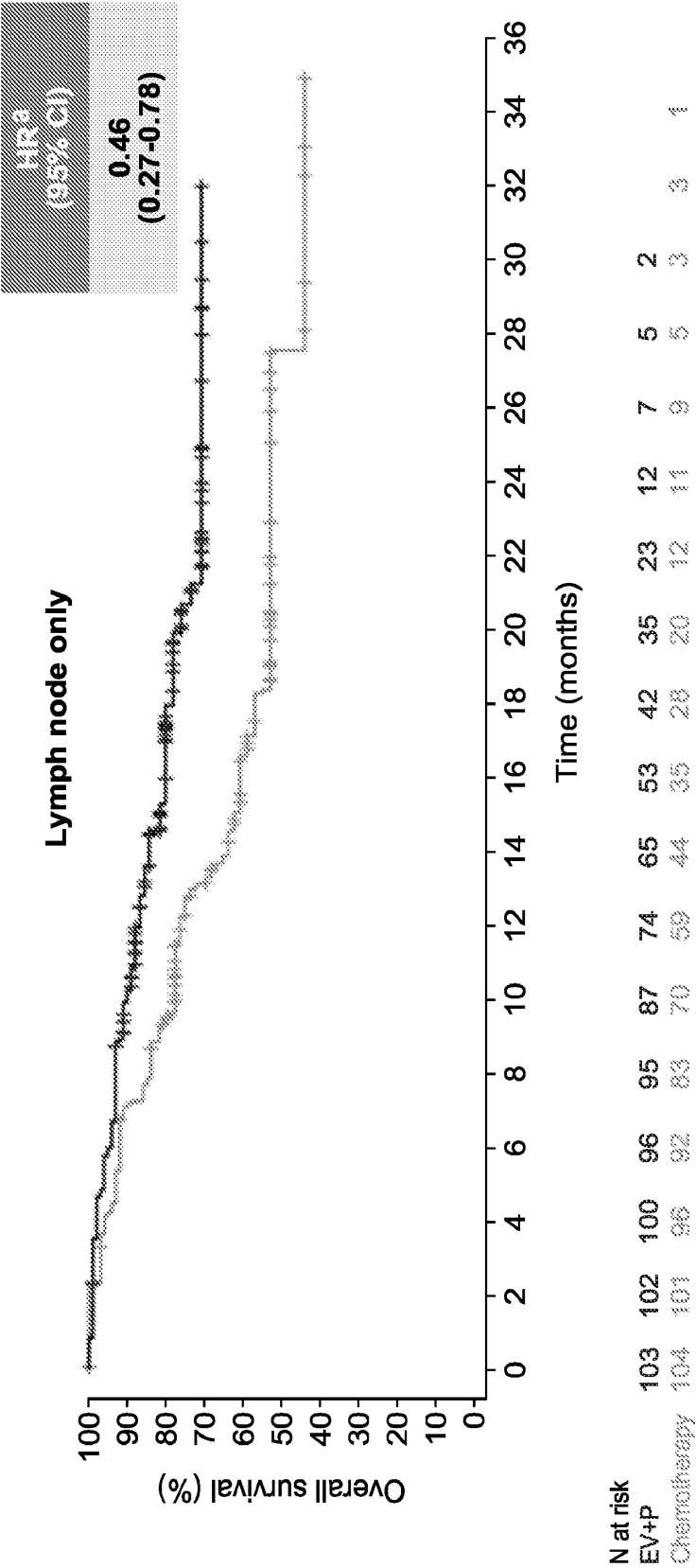


FIG. 22E

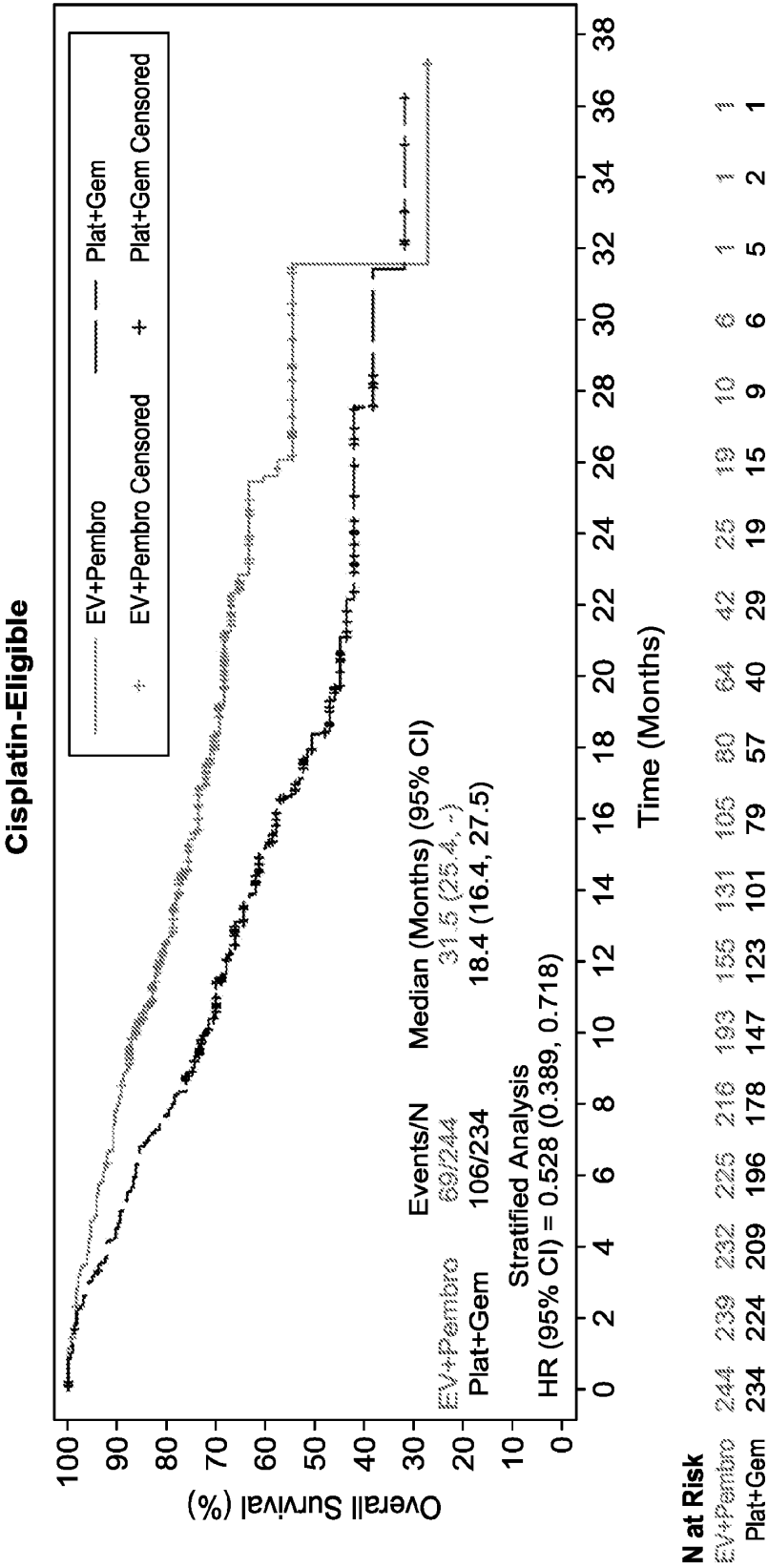
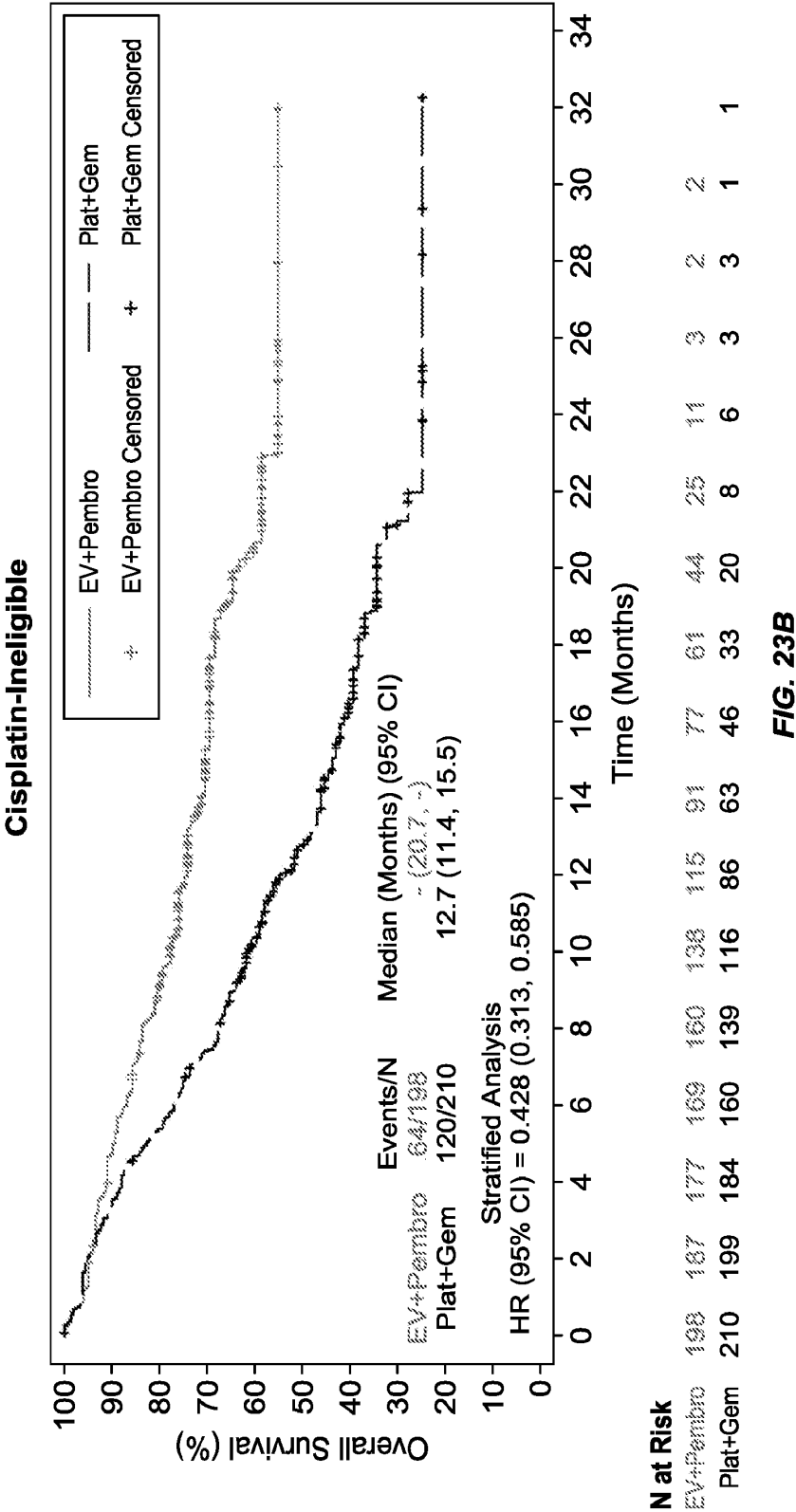


FIG. 23A



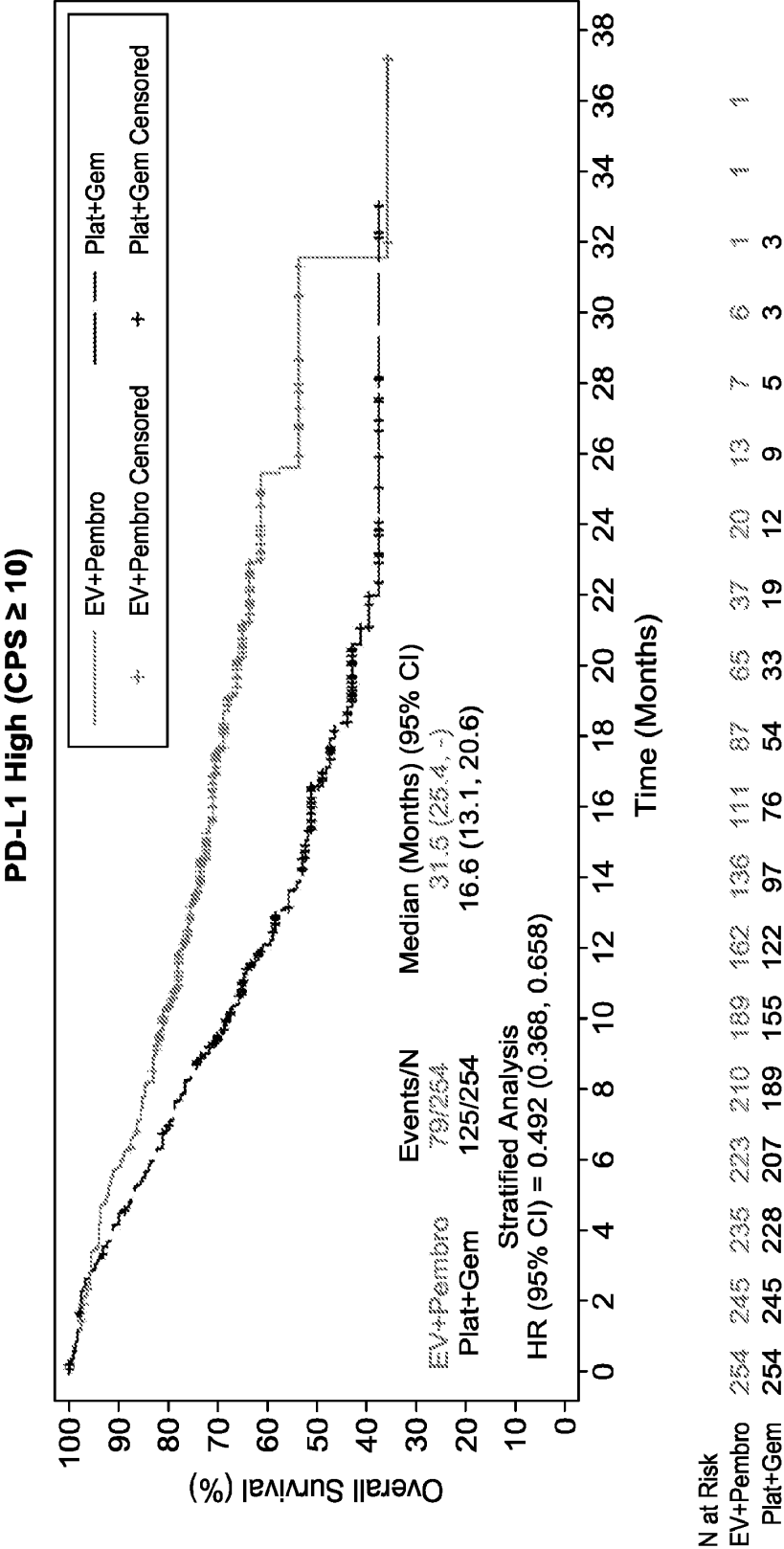


FIG. 24A

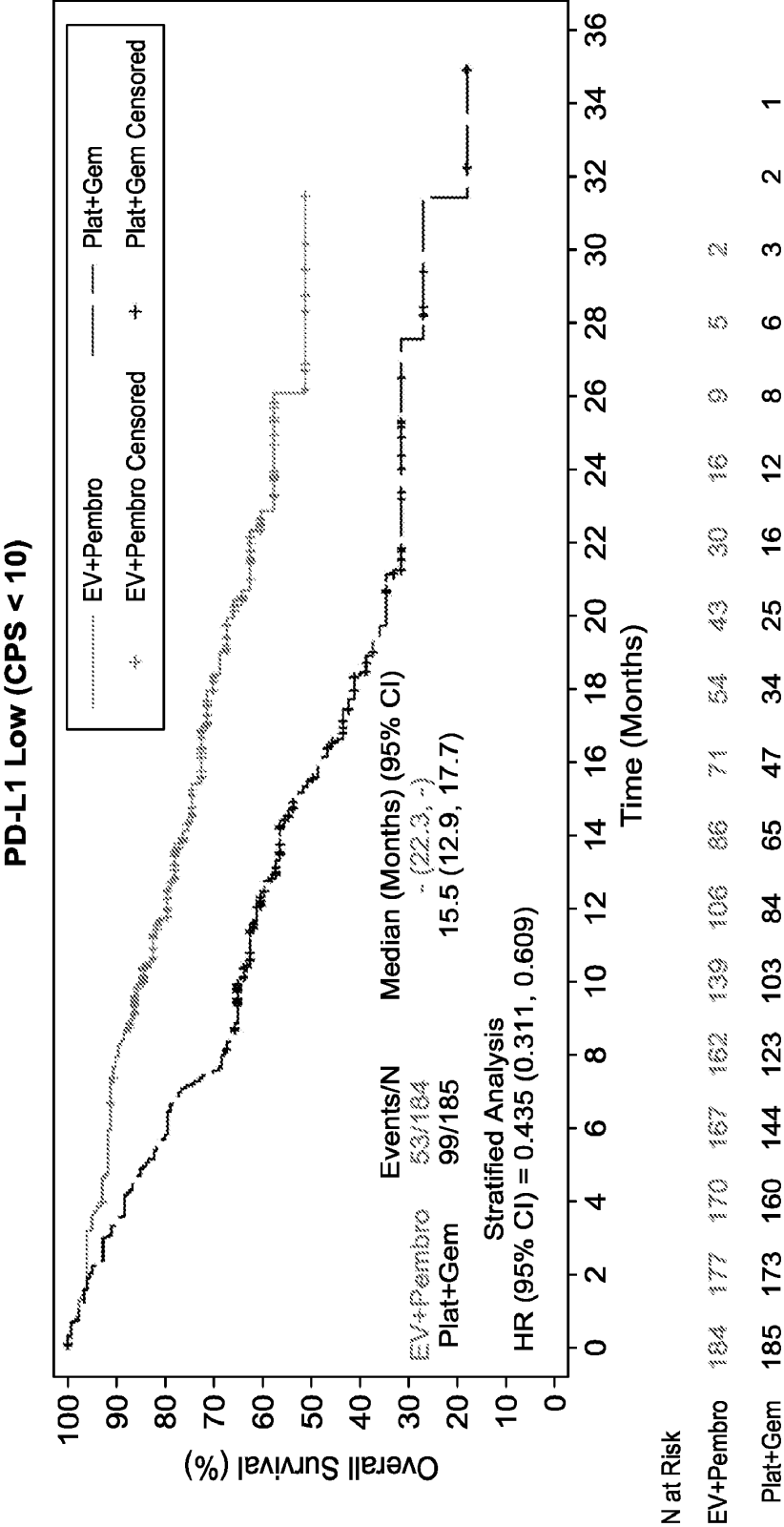


FIG. 24B

**Objective Response Rate (ORR) per RECIST by BICR — Response
Evaluable Set**

	EV + Pembro (N=437)	Plat + Gem (N=441)
Confirmed ORR (CR or PR), n (%)	296 (67.7)	196 (44.4)
95% CI	(63.1, 72.1)	(39.7, 49.2)
2-sided p-value	<0.00001	
Best Overall Response, n (%)		
Complete Response (CR)	127 (29.1)	55 (12.5)
Partial Response (PR)	169 (38.7)	141 (32.0)
Stable Disease (SD)	82 (18.8)	149 (33.8)
Progressive Disease (PD)	38 (8.7)	60 (13.6)
Not Evaluable (NE)	0	4 (0.9)
No Assessment	21 (4.8)	32 (7.3)
Median time to response (range), months	2.10 (1.3, 12.3)	2.10 (1.6, 8.3)

FIG. 25

Subgroup Analysis of ORR per RECIST by BICR

Subgroup	EV+Pembro n/N (%)	Plat+Gem n/N (%)	Absolute Difference % (95% CI)
Overall	296/437 (67.7)	196/441 (44.4)	23.3 (16.8, 29.6)
Age			
<65 years	98/142 (69.0)	70/134 (52.2)	16.8 (5.3, 27.9)
≥65 years	198/295 (67.1)	126/307 (41.0)	26.1 (18.2, 33.6)
Race			
White	204/307 (66.4)	130/289 (45.0)	21.5 (13.6, 29.1)
Other	92/130 (70.8)	66/152 (43.4)	27.3 (15.9, 38.0)
Region			
North America	66/103 (64.1)	42/85 (49.4)	14.7 (0.4, 28.4)
Europe	112/171 (65.5)	91/196 (46.4)	19.1 (8.9, 28.8)
Rest of World	118/163 (72.4)	63/160 (39.4)	33.0 (22.5, 42.8)
Sex			
Female	64/97 (66.0)	44/107 (41.1)	24.9 (11.2, 37.6)
Male	232/340 (68.2)	152/334 (45.5)	22.7 (15.3, 29.9)
ECOG PS			
0	161/222 (72.5)	106/213 (49.8)	22.8 (13.7, 31.5)
1-2	135/215 (62.8)	89/226 (39.4)	23.4 (14.2, 32.3)
Primary disease site of origin			
Upper tract	90/133 (67.7)	42/103 (40.8)	26.9 (14.2, 38.8)
Lower tract	205/302 (67.9)	154/337 (45.7)	22.2 (14.6, 29.5)
Liver metastases			
Present	60/100 (60.0)	41/99 (41.4)	18.6 (4.7, 31.8)
Absent	236/337 (70.0)	155/342 (45.3)	24.7 (17.4, 31.8)
PD-L1 expression			
Low (CPS < 10)	114/180 (63.3)	75/183 (41.0)	22.3 (12.1, 32.1)
High (CPS ≥ 10)	180/253 (71.1)	118/253 (46.6)	24.5 (16.0, 32.6)
Cisplatin eligibility			
Eligible	172/243 (70.8)	123/232 (53.0)	17.8 (9.1, 26.2)
Ineligible	124/194 (63.9)	73/209 (34.9)	29.0 (19.4, 38.0)
Metastatic disease site			
Visceral metastases	202/315 (64.1)	126/318 (39.6)	24.5 (16.8, 31.9)
Lymph node only	79/102 (77.5)	55/103 (53.4)	24.1 (11.1, 36.3)
Renal function			
Normal	58/84 (69.0)	53/95 (55.8)	13.3 (-1.0, 26.9)
Mild	111/163 (68.1)	72/160 (45.0)	23.1 (12.4, 33.3)
Moderate/Severe	127/190 (66.8)	71/186 (38.2)	28.7 (18.7, 38.0)

-50 0 50
 <--- Favors Plat+Gem | Favors EV+Pembro --->

FIG. 26

SUBSTITUTE SHEET (RULE 26)

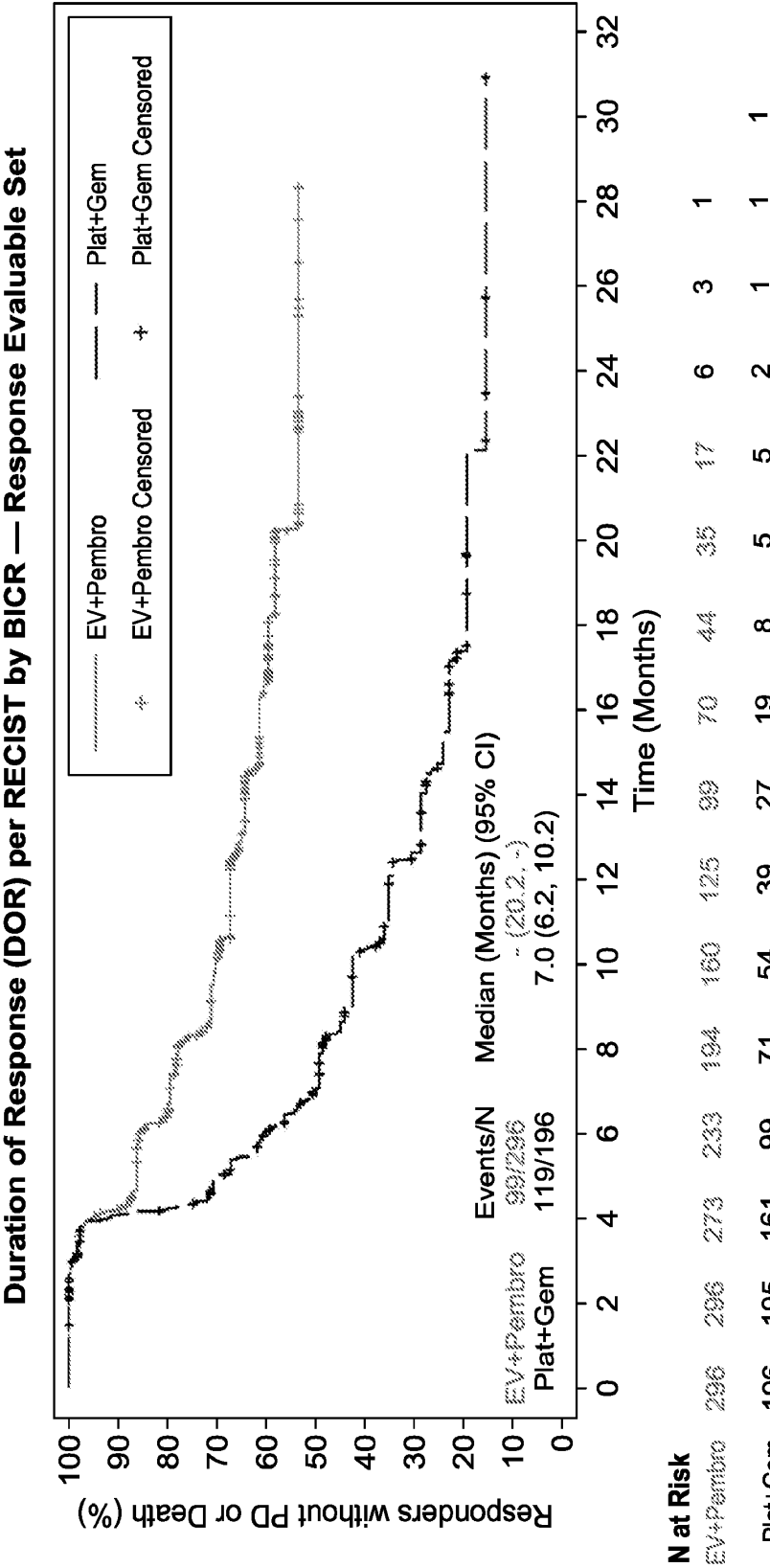


FIG. 27A

**Duration of Response (DOR) per RECIST by BICR –
Response Evaluable Set**

	EV + Pembro (N=437)	Plat + Gem (N=441)
No. of responders	296	196
No. of events (%)	99 (33.4)	119 (60.7)
mDOR (95% CI), months	NR (20.2, -)	7.0 (6.2, 10.2)
DOR at 6 months	85.9%	60.6%
DOR at 12 months	67.3%	35.2%
DOR at 18 months	59.6%	19.3%

FIG. 27B

Overall Summary of Treatment-Emergent Adverse Events (TEAEs)

	Subject Incidence Rate		Event Rate Adjusted for Exposure	
	EV + Pembro (N=440) n (%)	Plat + Gem (N=433) n (%)	EV + Pembro (PY=385.56) E (E/PY)	Plat + Gem (PY=147.82) E (E/PY)
TEAEs	439 (99.8)	427 (98.6)	7442 (19.302)	5034 (34.054)
Treatment-related TEAEs	427 (97.0)	414 (95.6)	4274 (11.085)	3356 (22.703)
Grade 3-5 TEAEs	321 (73.0)	341 (78.8)	854 (2.215)	1069 (7.232)
Treatment-related grade 3-5 TEAEs	246 (55.9)	301 (69.5)	491 (1.273)	792 (5.358)
Serious TEAEs	220 (50.0)	169 (39.0)	440 (1.141)	328 (2.219)
Treatment-related serious TEAEs	122 (27.7)	85 (19.6)	205 (0.532)	139 (0.940)
TEAEs leading to death	19 (4.3)	14 (3.2)	19 (0.049)	14 (0.095)
Treatment-related TEAEs leading to death	4 (0.9)	4 (0.9)	4 (0.010)	4 (0.027)
TEAEs leading to treatment discontinuation				
EV	153 (34.8)	-	153 (0.397)	-
Pembro	117 (26.6)	-	117 (0.303)	-
Any study drug	175 (39.8)	93 (21.5)	196 (0.508)	98 (0.663)
TEAEs leading to dose interruption				
EV	319 (72.5)	-	638 (1.655)	-
Pembro	268 (60.9)	-	467 (1.211)	-
Any study drug	347 (78.9)	279 (64.4)	785 (2.036)	561 (3.795)
TEAEs leading to dose reduction	184 (41.8)	177 (40.9)	224 (0.581)	235 (1.590)
Median number of cycles	12	6		

FIG. 28

TEAEs Occurring in ≥20% of Subjects by Preferred Term

Preferred Term	EV + Pembro (N=440) n (%)	Plat + Gem (N=433) n (%)
Overall	439 (99.8)	427 (98.6)
Peripheral sensory neuropathy	229 (52.0)	44 (10.2)
Pruritus	182 (41.4)	29 (6.7)
Diarrhoea	166 (37.7)	69 (15.9)
Fatigue	155 (35.2)	170 (39.3)
Alopecia	152 (34.5)	34 (7.9)
Rash maculo-papular	146 (33.2)	15 (3.5)
Decreased appetite	145 (33.0)	112 (25.9)
Weight decreased	145 (33.0)	38 (8.8)
Constipation	116 (26.4)	147 (33.9)
Nausea	116 (26.4)	178 (41.1)
Anaemia	108 (24.5)	267 (61.7)
Dysgeusia	93 (21.1)	37 (8.5)
Urinary tract infection	91 (20.7)	83 (19.2)
Asthenia	77 (17.5)	88 (20.3)
Neutropenia	43 (9.8)	181 (41.8)
Thrombocytopenia	19 (4.3)	153 (35.3)

FIG. 29

TEAEs Occuring in ≥15% of Subjects by Preferred Term

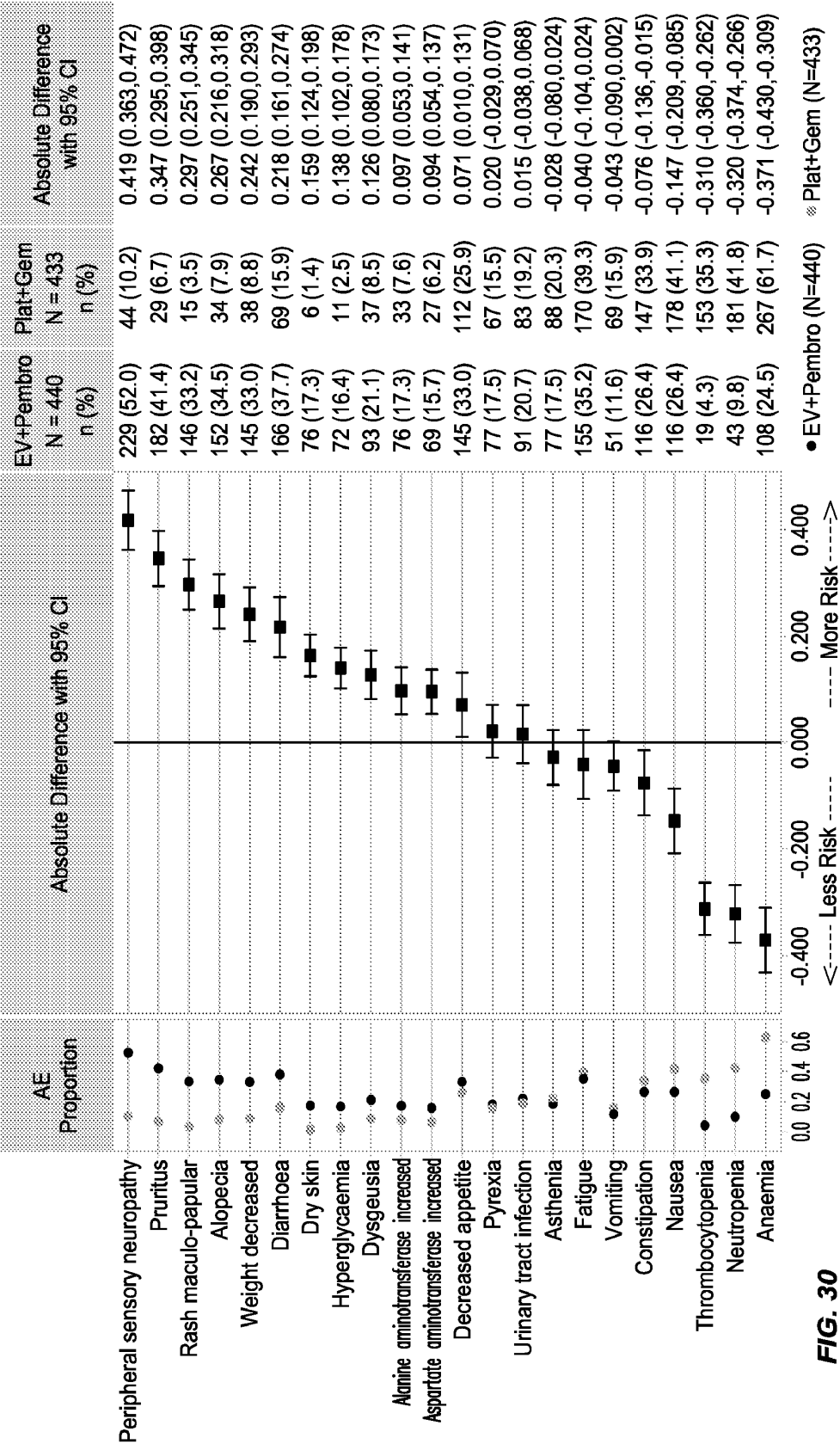


FIG. 30

Grade ≥3 TEAEs Occurring in ≥5% of Subjects by Preferred Term

Preferred Term	EV + Pembro (N=440) n (%)	Plat + Gem (N=433) n (%)
Overall	321 (73.0)	341 (78.8)
Rash maculo-papular	36 (8.2)	0
Hyperglycaemia	32 (7.3)	3 (0.7)
Anaemia	31 (7.0)	148 (34.2)
Acute kidney injury	22 (5.0)	10 (2.3)
Hyponatraemia	22 (5.0)	15 (3.5)
Neutropenia	22 (5.0)	130 (30.0)
Urinary tract infection	22 (5.0)	35 (8.1)
Neutrophil count decreased	11 (2.5)	40 (9.2)
Thrombocytopenia	4 (0.9)	87 (20.1)
Platelet count decreased	0	29 (6.7)

FIG. 31

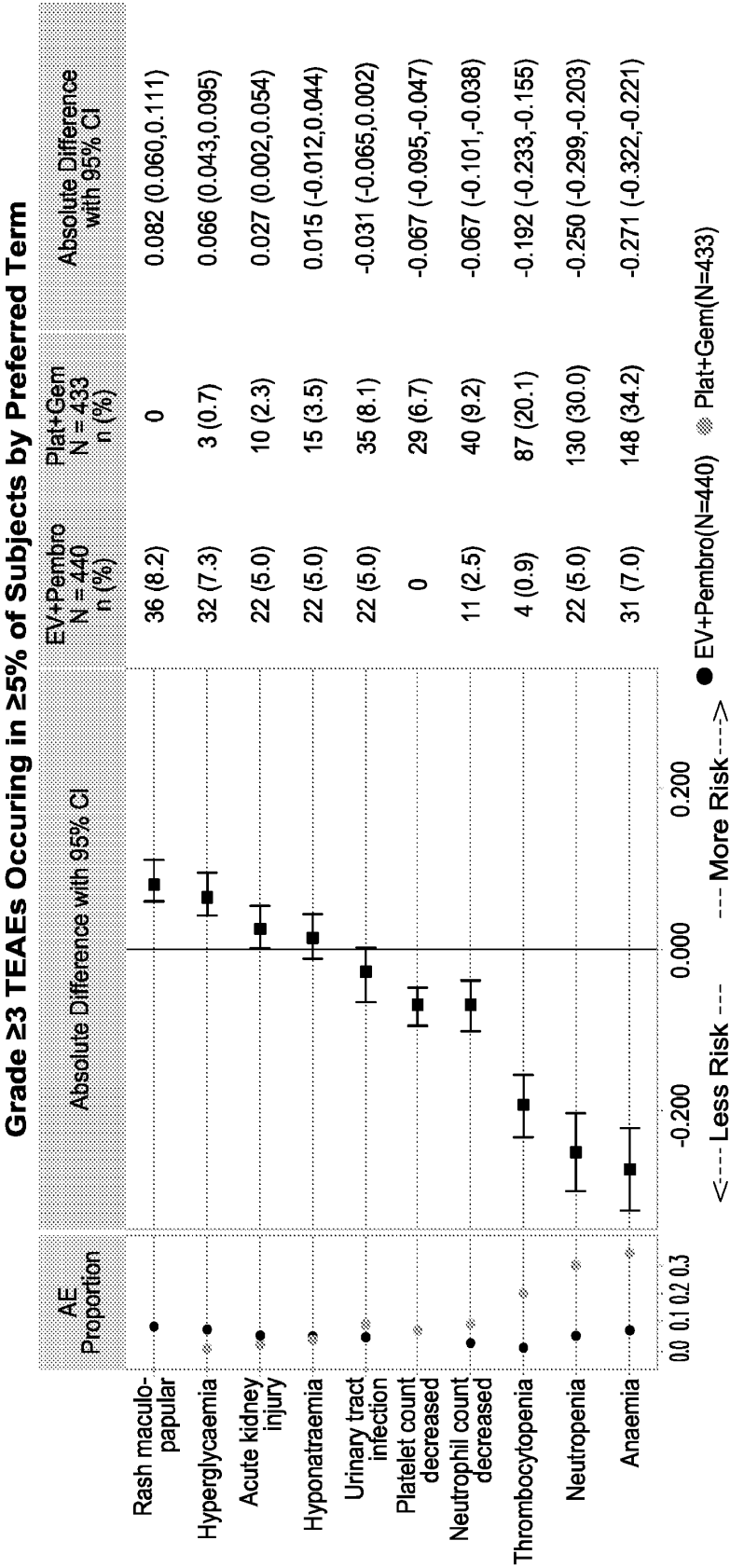


FIG. 32

Serious TEAEs Occurring in ≥2% of Subjects by Preferred Term

Preferred Term	EV + Pembro (N=440) n (%)	Plat + Gem (N=433) n (%)
Overall	220 (50.0)	169 (39.0)
Acute kidney injury	23 (5.2)	11 (2.5)
Urinary tract infection	16 (3.6)	31 (7.2)
Diarrhoea	14 (3.2)	2 (0.5)
Pneumonia	10 (2.3)	5 (1.2)
Pneumonitis	9 (2.0)	0
Pyrexia	9 (2.0)	10 (2.3)
Haematuria	7 (1.6)	10 (2.3)
Febrile neutropenia	4 (0.9)	12 (2.8)
Anaemia	3 (0.7)	17 (3.9)
Thrombocytopenia	0	13 (3.0)

FIG. 33

TEAEs Leading to Death by Preferred Term

EV + Pembro (N=440)	Plat + Gem (N=433)
- Overall 19 (4.3%) 2 (0.5%) for Acute respiratory failure 1 (0.2%) for each PT: - Asthenia, - COVID-19 - Cardiac arrest - Cardiac failure - Cardio-respiratory arrest - Cerebral haemorrhage - Death - Diarrhoea - Immune-mediated lung disease - Multiple organ dysfunction syndrome - Nervous system disorder - Pneumonia - Pneumonia aspiration - Renal failure - Respiratory failure - Sepsis - Sudden death	- Overall 14 (3.2%) 2 (0.5%) for each PT: - General physical health deterioration - Peritonitis - Sepsis 1 (0.2%) for each PT: - Acute right ventricular failure - Cardiac arrest - Cerebrovascular accident - Chronic obstructive pulmonary disease - Febrile neutropenia - Myocardial infarction - Neutropenic sepsis - Shock

FIG. 34

TEAEs Leading to Discontinuation of Any Study Drugs Occurring in ≥1% of Subjects by Preferred Term

Preferred Term	EV + Pembro (N=440) n (%)	Plat + Gem (N=433) n (%)
Overall	175 (39.8)	93 (21.5)
Peripheral sensory neuropathy	49 (11.1)	1 (0.2)
Pneumonitis	9 (2.0)	0
Rash maculo-papular	7 (1.6)	0
Immune-mediated lung disease	6 (1.4)	0
Paraesthesia	6 (1.4)	0
Acute kidney injury	5 (1.1)	10 (2.3)
Diarrhoea	5 (1.1)	1 (0.2)
Anaemia	2 (0.5)	12 (2.8)
Fatigue	2 (0.5)	6 (1.4)
Thrombocytopenia	1 (0.2)	6 (1.4)
Blood creatinine increased	0	8 (1.8)
Neutropenia	0	7 (1.6)

FIG. 35

Adverse Events of Special Interest (AESI) for Enfortumab Vedotin

	EV + Pembro (N=440)		Plat + Gem (N=433)		EV Mono ISS (N=793)	
	All Grade n (%)	≥ Gr 3 n (%)	All Grade n (%)	≥ Gr 3 n (%)	All Grade n (%)	≥ Gr 3 n (%)
Peripheral Neuropathy	293 (66.6)	34 (7.7)	60 (13.9)	0	422 (53.2)	41 (5.2)
Skin reactions	304 (69.1)	71 (16.1)	68 (15.7)	1 (0.2)	452 (57.0)	108 (13.6)
Hyperglycemia	85 (19.3)	38 (8.6)	15 (3.5)	4 (0.9)	133 (16.8)	60 (7.6)
Ocular disorders	128 (29.1)	0	16 (3.7)	0	277 (34.9)	3 (0.4)
Dry eye	107 (24.3)	0	9 (2.1)	0	239 (30.1)	3 (0.4)
Corneal disorders	14 (3.2)	0	0	0	46 (5.8)	0
Blurred vision	34 (7.7)	0	7 (1.6)	0	84 (10.6)	0
Infusion-related reactions	13 (3.0)	0	9 (2.1)	0	50 (6.3)	7 (0.9)

FIG. 36

Pembrolizumab Adverse Events of Special Interest (AEOSI) Occurring in >2 subjects in EV+Pembro

	EV + Pembro (N=440)		Plat + Gem (N=433)		Pembro RSD (N=7631)	
	All Grade n (%)	≥ Gr 3 n (%)	All Grade n (%)	≥ Gr 3 n (%)	All Grade n (%)	≥ Gr 3 n (%)
Adrenal Insufficiency	7 (1.6)	2 (0.5)	0	0	74 (1.0)	35 (0.5)
Colitis	12 (2.7)	7 (1.6)	0	0	159 (2.1)	89 (1.2)
Gastritis	9 (2.0)	0	3 (0.7)	0	pending	pending
Hepatitis	14 (3.2)	8 (1.8)	2 (0.5)	0	80 (1.0)	63 (0.8)
Hyperthyroidism	20 (4.5)	1 (0.2)	2 (0.5)	0	398 (5.2)	9 (0.1)
Hypophysitis	3 (0.7)	0	0	0	52 (0.7)	25 (0.3)
Hypothyroidism	47 (10.7)	2 (0.5)	3 (0.7)	0	939 (12.3)	8 (0.1)
Infusion reactions	6 (1.4)	0	6 (1.4)	1 (0.2)	165 (2.2)	16 (0.2)
Myocarditis	3 (0.7)	1 (0.2)	0	0	9 (0.1)	8 (0.1)
Myositis	4 (0.9)	1 (0.2)	2 (0.5)	2 (0.5)	34 (0.4)	8 (0.1)
Nephritis	4 (0.9)	1 (0.2)	0	0	37 (0.5)	21 (0.3)
Pancreatitis	5 (1.1)	4 (0.9)	1 (0.2)	1 (0.2)	28 (0.4)	18 (0.2)
Pneumonitis	42 (9.5)	16 (3.6)	1 (0.2)	1 (0.2)	324 (4.2)	109 (1.4)
Severe skin reactions	75 (17.0)	52 (11.8)	2 (0.5)	0	130 (1.7)	105 (1.4)

FIG. 37

Key Demographics and Baseline Characteristics

	EV+P (N=198)	Chemotherapy (N=210)
Male sex, n (%)	143 (72.2)	158 (75.2)
Age (yrs), median (range)	71.0 (40,87)	72.5 (47,91)
Race, n (%)		
White	137 (69.2)	149 (71.0)
Asian	49 (24.7)	40 (19.0)
Geographic location, n (%)		
North America	45 (22.7)	34 (16.2)
Europe	70 (35.4)	98 (46.7)
Rest of World	83 (41.9)	78 (37.1)
ECOG PS, n (%)		
0	85 (42.9)	85 (40.5)
1	102 (51.5)	114 (54.3)
2	11 (5.6)	10 (4.8)
Primary tumor location, n (%)		
Upper tract ^a	72 (36.4)	59 (28.1)
Lower tract ^b	126 (63.6)	150 (71.4)
Unknown	0	1 (0.5)
Metastatic category, n (%)		
Visceral metastases ^c	142 (71.7)	166 (79.0)
Bone	33 (16.7)	54 (25.7)
Liver	50 (25.3)	53 (25.2)
Lung	80 (40.4)	76 (36.2)
Lymph node only disease	44 (22.2)	35 (16.7)
Not applicable ^d	12 (6.1)	9 (4.3)
PD-L1 expression^e, n/N (%)		
High (CPS $\geq$ 10)	116/196 (59.2)	117/209 (56.0)
Low (CPS < 10)	80/196 (40.8)	92/209 (44.0)

FIG. 38

SUBSTITUTE SHEET (RULE 26)

Summary of Disposition		
	EV+P (N=198)	Chemotherapy (N=210)
Patients randomized, n (%)	198 (100)	210 (100)
Patients who received any amount of study drug, n (%)	197 (99.5)	205 (97.6)
Patients on treatment	62 (31.3)	0
Patients on study, n (%)	126 (63.6)	84 (40.0)
Primary reason for study treatment discontinuation ^a , n (%)		
Completed treatment	1 (0.5) ^b	102 (48.6)
Progressive disease	64 (32.3)	44 (21.0)
Adverse event	46 (23.2)	36 (17.1)
Physician/patient decision	18 (9.1)	22 (10.5)
Other ^c	6 (3.0)	1 (0.5)

FIG. 39

Reasons for Cisplatin Ineligibility ^a			
	EV+P (N=198)	Chemotherapy (N=210)	Total (N=408)
Cisplatin ineligible at randomization (n)	194	197	391
GFR <60 mL/min, n (%)	164 (84.5)	163 (82.7)	327 (83.6)
≥ Grade 2 hearing loss, n (%)	29 (14.9)	29 (14.7)	58 (14.8)
ECOG PS of 2, n (%)	9 (4.6)	8 (4.1)	17 (4.3)
NYHA Class III heart failure, n (%)	4 (2.1)	7 (3.6)	11 (2.8)
Patients meeting more than one criterion, n (%)	12 (6.2)	10 (5.1)	22 (5.6)

FIG. 40

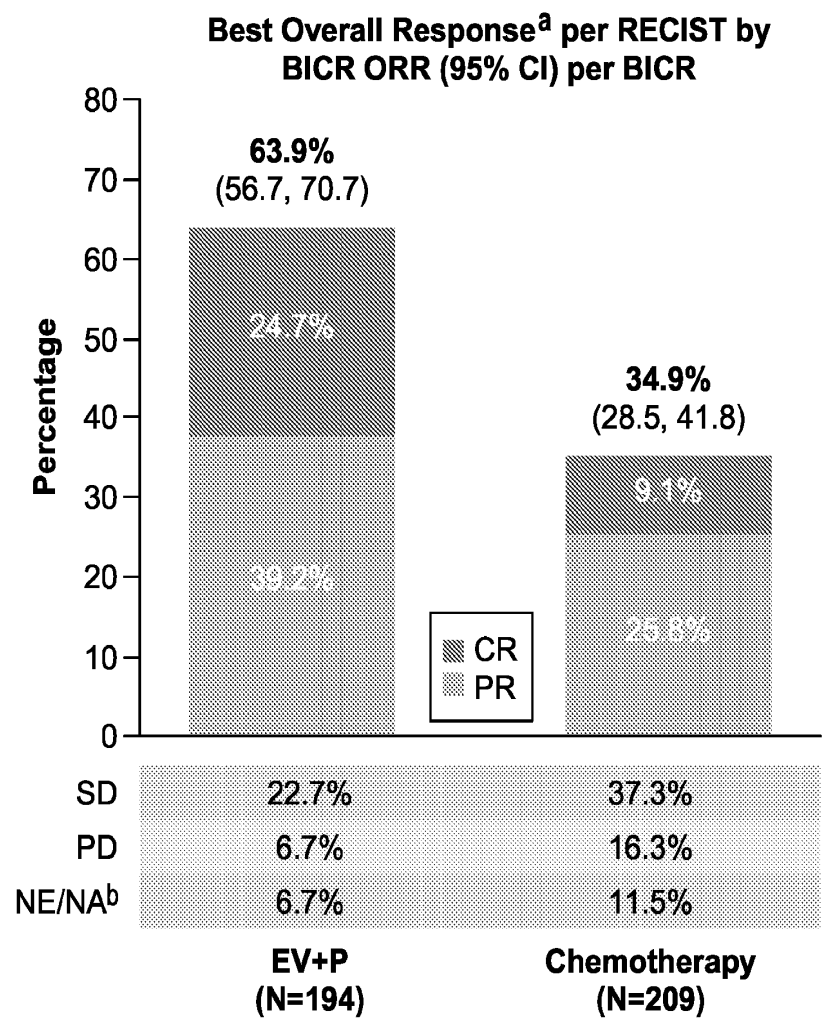


FIG. 41A

Time to Objective Response		
Any objective response ^a	EV+P (n=124)	Chemotherapy (n=73)
Median TTR ^b (Q1, Q3), months	2.1 (2.0, 2.2)	2.1 (2.0, 2.3)

FIG. 41B

Duration of Objective Response per BICR

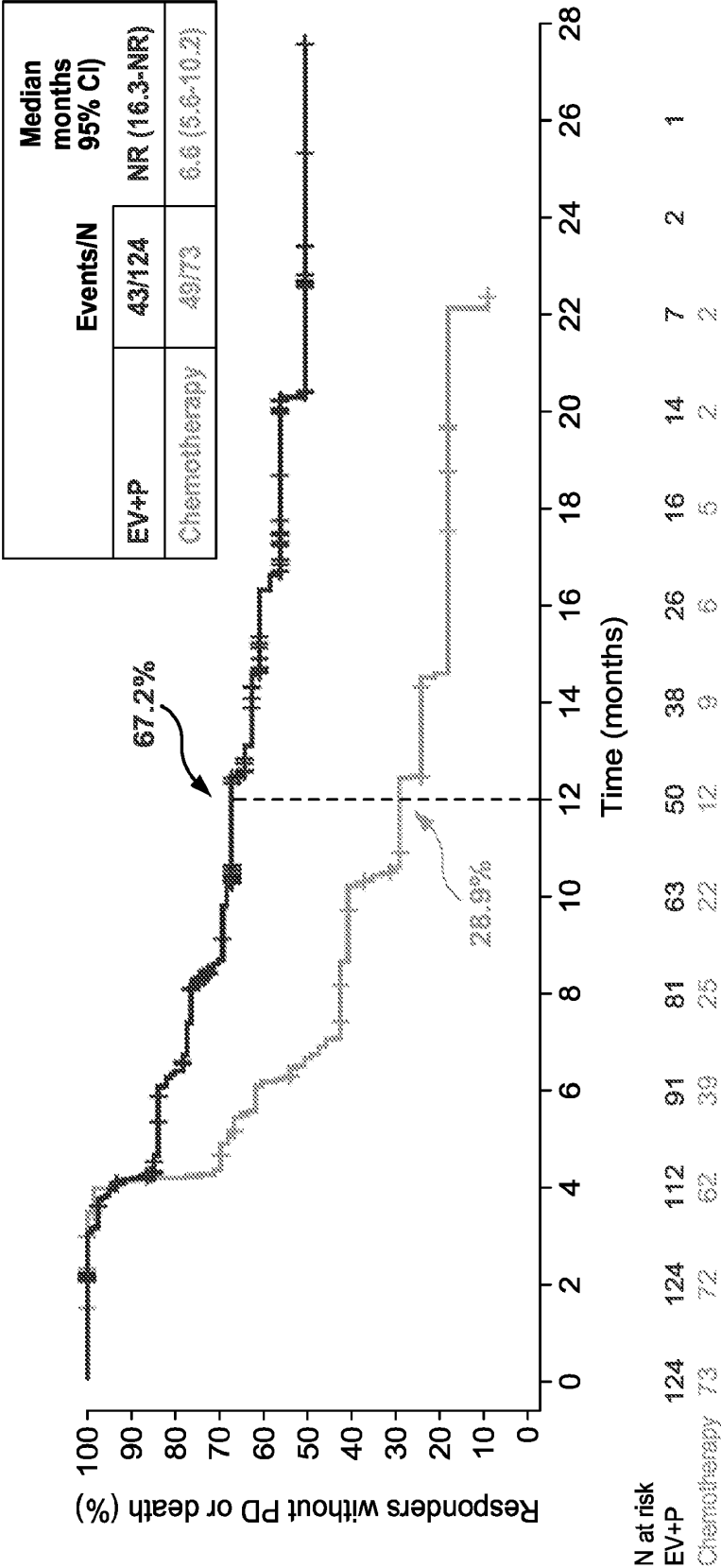
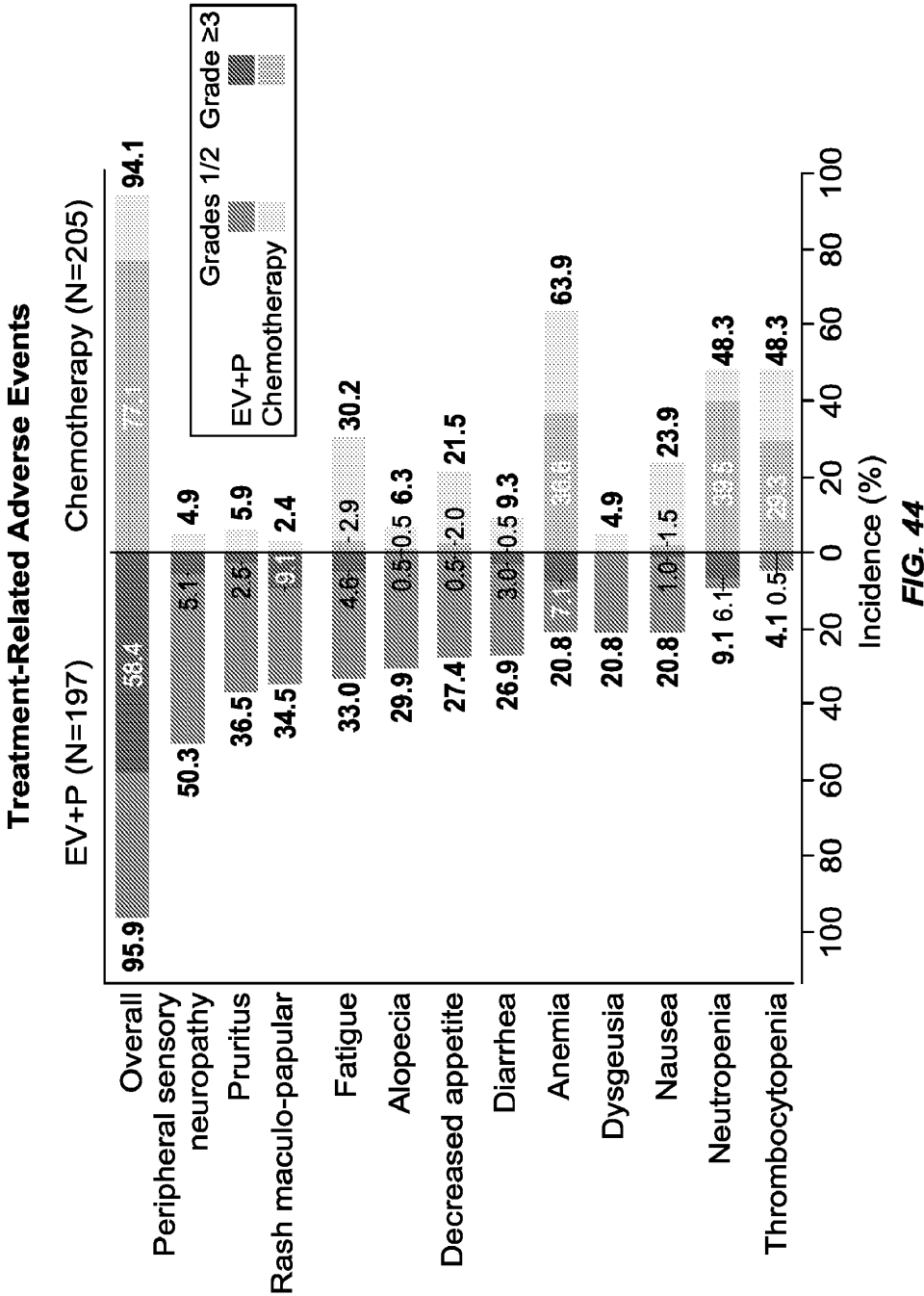


FIG. 42

Summary of Subsequent Therapy		
	EV+P (N=198) n (%)	Chemotherapy (N=210) n (%)
Patients receiving any subsequent cancer-related therapy ^a		
First subsequent systemic therapy		
Platinum-based therapy ^b	38 (19.2)	7 (3.3)
Cisplatin-based therapy	10 (5.1)	2 (1.0)
Carboplatin-based therapy	27 (13.6)	4 (1.9)
PD-1/L1 inhibitor-containing therapy	4 (2.0)	114 (54.3)
Maintenance therapy	0	56 (26.7)
Avelumab maintenance	0	52 (24.8)
PD-1/L1 inhibitor-containing therapy following progression	4 (2.0)	58 (27.6)
Other	4 (2.0)	11 (5.2)

FIG. 43



EV Treatment-Related Adverse Events of Special Interest

	EV+P (N=197) n (%)		Chemotherapy (N=205) n (%)	
	Any grade	Grade ≥3	Any grade	Grade ≥3
Skin reactions	132 (67.0)	32 (16.2)	30 (14.6)	1 (0.5)
Peripheral neuropathy	123 (62.4)	16 (8.1)	14 (6.8)	0
Sensory events	114 (57.9)	12 (6.1)	13 (6.3)	0
Motor events	21 (10.7)	5 (2.5)	1 (0.5)	0
Ocular disorders	32 (16.2)	0	6 (2.9)	0
Dry eye	28 (14.2)	0	5 (2.4)	0
Hyperglycemia	21 (10.7)	8 (4.1)	2 (1.0)	0
Infusion-related reactions	5 (2.5)	0	5 (2.4)	0

FIG. 45

**Pembrolizumab Treatment-Emergent
Adverse Events of Special Interest***

AEOSIs any grades in ≥1% of patients	EV+P (N=197) n (%)		Chemotherapy (N=205) n (%)	
	Any grade	Grade ≥3	Any grade	Grade ≥3
Severe skin reactions	35 (17.8)	29 (14.7)	1 (0.5)	0
Hypothyroidism	25 (12.7)	1 (0.5)	2 (1.0)	0
Pneumonitis	17 (8.6)	4 (2.0)	0	0
Hyperthyroidism	11 (5.6)	1 (0.5)	1 (0.5)	0
Hepatitis	8 (4.1)	4 (2.0)	2 (1.0)	0
Gastritis	4 (2.0)	0	1 (0.5)	0
Adrenal insufficiency	3 (1.5)	1 (0.5)	0	0
Nephritis	3 (1.5)	0	0	0
Arthritis	2 (1.0)	0	0	0
Colitis	2 (1.0)	0	0	0
Hypophysitis	2 (1.0)	0	0	0
Infusion reactions	2 (1.0)	0	4 (2.0)	1 (0.5)
Myocarditis	2 (1.0)	1 (0.5)	0	0
Myositis	2 (1.0)	0	0	0

FIG. 46

Key Demographics and Baseline Characteristics

	EV+P (N=244)	Chemotherapy (N=234)
Male sex , n (%)	201 (82.4)	178 (76.1)
Age (yrs), median (range)	66.0 (37,85)	65.0 (22,85)
Race , n (%)		
White	171 (70.1)	141 (60.3)
Asian	50 (20.5)	52 (22.2)
Geographic location , n (%)		
North America	58 (23.8)	51 (21.8)
Europe	102 (41.8)	99 (42.3)
Rest of World	84 (34.4)	84 (35.9)
ECOG PS , n (%)		
0	138 (56.6)	130 (55.6)
1	102 (41.8)	102 (43.6)
2	4 (1.6)	1 (0.4)
Primary tumor location , n (%)		
Upper tract ^a	63 (25.8)	45 (19.2)
Lower tract ^b	179 (73.4)	189 (80.8)
Unknown	2 (0.8)	0
Metastatic category , n (%)		
Visceral metastases ^c	176 (72.1)	152 (65.0)
Bone	48 (19.7)	48 (20.5)
Liver	50 (20.5)	46 (19.7)
Lung	90 (36.9)	81 (34.6)
Lymph node only disease	59 (24.2)	69 (29.5)
Not applicable ^d	9 (3.7)	13 (5.6)
PD-L1 expression^e , n/N (%)		
High (CPS $\geq$ 10)	138/242 (57.0)	137/230 (59.6)
Low (CPS < 10)	104/242 (43.0)	93/230 (40.4)

FIG. 47

SUBSTITUTE SHEET (RULE 26)

Summary of Disposition

	EV+P (N=244)	Chemotherapy (N=234)
Patients randomized, n (%)	244 (100)	234 (100)
Patients who received any amount of study drug, n (%)	243 (99.6)	228 (97.4)
Patients on treatment	82 (33.6)	0
Patients on study, n (%)	170 (69.7)	119 (50.9)
Primary reason for study treatment discontinuation ^a , n (%)		
Completed treatment	7 (2.9) ^b	142 (60.7)
Progressive disease	89 (36.5)	29 (12.4)
Adverse event	51 (20.9)	26 (11.1)
Physician/Patient decision	13 (5.3)	30 (12.8)
Other ^c	1 (0.4)	1 (0.4)

FIG. 48

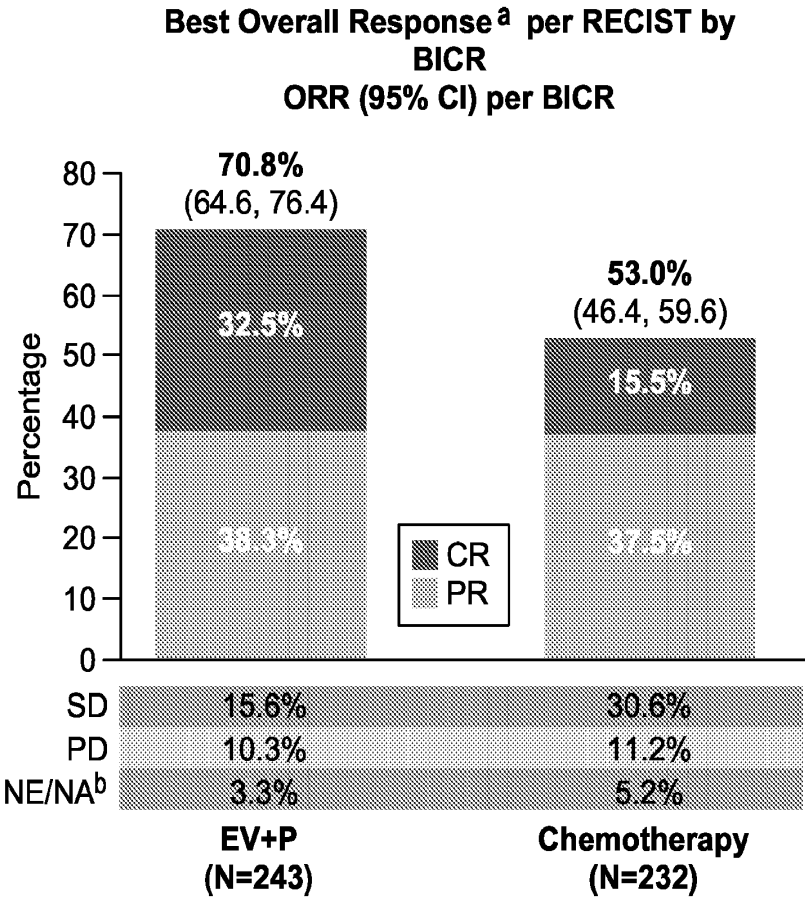


FIG. 49A

Time to Objective Response

Any objective response ^a	EV+P (n=172)	Chemotherapy (n=123)
Median TTR ^b (Q1, Q3), months	2.1 (2.0, 2.2)	2.1 (2.0, 2.2)

FIG. 49B

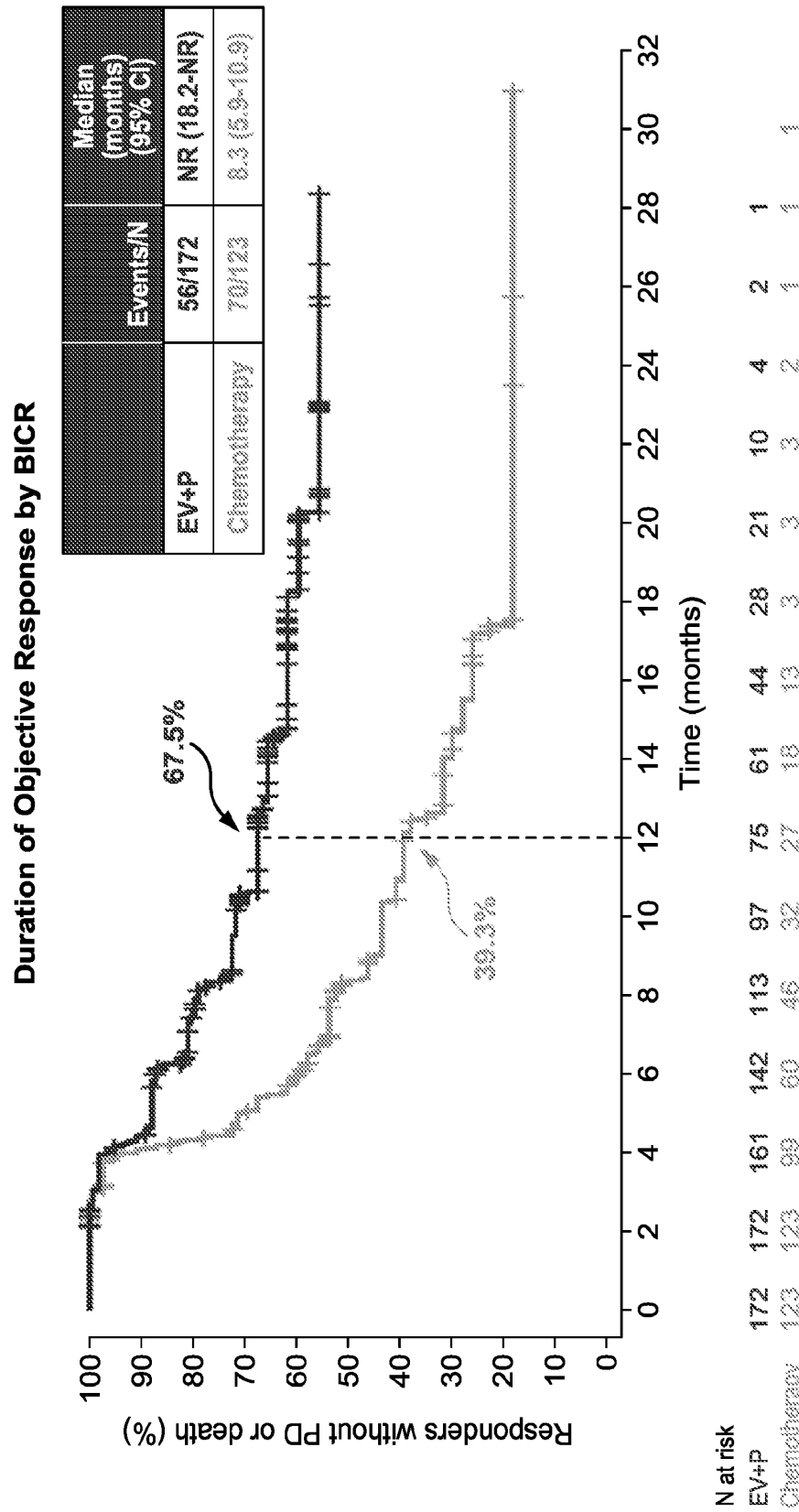


FIG. 50

Summary of Subsequent Therapy

	EV+P (N=244) n (%)	Chemotherapy (N=234) n (%)
Patients receiving any subsequent cancer-related therapy ^a	85 (34.8)	173 (73.9)
First subsequent systemic therapy		
Platinum-based therapy ^b	72 (29.5)	10 (4.3)
Cisplatin-based therapy	43 (17.6)	6 (2.6)
Carboplatin-based therapy	29 (11.9)	4 (1.7)
PD-1/L1 inhibitor-containing therapy	3 (1.2)	146 (62.4)
Maintenance therapy	0	87 (37.2)
Avelumab maintenance	0	83 (35.5)
PD-1/L1 inhibitor-containing therapy following progression	3 (1.2)	59 (25.2)
Other	7 (2.9)	6 (2.6)

FIG. 51

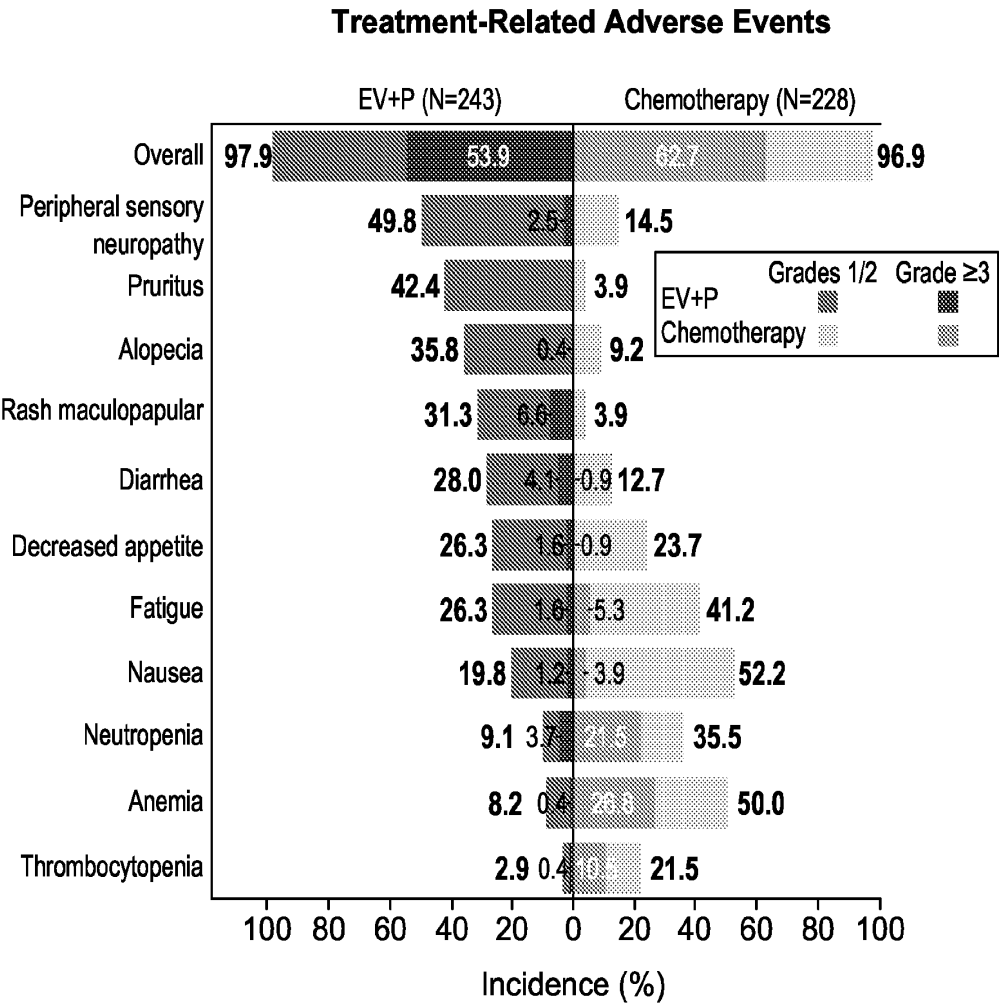


FIG. 52

EV Treatment-Related Adverse Events of
Special Interest

	EV+P (N=243) n (%)		Chemotherapy (N=228) n (%)	
	Any grade	Grade ≥3	Any grade	Grade ≥3
Skin reactions	162 (66.7)	36 (14.8)	30 (13.2)	0
Peripheral neuropathy	155 (63.8)	14 (5.8)	39 (17.1)	0
Sensory events	146 (60.1)	7 (2.9)	38 (16.7)	0
Motor events	23 (9.5)	7 (2.9)	4 (1.8)	0
Ocular disorders	62 (25.5)	0	6 (2.6)	0
Dry eye	54 (22.2)	0	3 (1.3)	0
Hyperglycemia	36 (14.8)	19 (7.8)	1 (0.4)	0
Infusion-related reactions	4 (1.6)	0	4 (1.8)	0

FIG. 53

Pembrolizumab Treatment-Emergent
Adverse Events of Special Interest*

AEOSIs any grades in ≥1% of patients	EV+P (N=243) n (%)		Chemotherapy (N=228) n (%)	
	Any grade	Grade ≥3	Any grade	Grade ≥3
Severe skin reactions	40 (16.5)	23 (9.5)	1 (0.4)	0
Pneumonitis	25 (10.3)	12 (4.9)	1 (0.4)	1 (0.4)
Hypothyroidism	22 (9.1)	1 (0.4)	1 (0.4)	0
Colitis	10 (4.1)	7 (2.9)	0	0
Hyperthyroidism	9 (3.7)	0	1 (0.4)	0
Hepatitis	6 (2.5)	4 (1.6)	0	0
Gastritis	5 (2.1)	0	2 (0.9)	0
Adrenal insufficiency	4 (1.6)	1 (0.4)	0	0
Infusion reactions	4 (1.6)	0	2 (0.9)	0
Pancreatitis	4 (1.6)	3 (1.2)	0	0

FIG. 54

PFS per RECIST by BICR for Asian subgroup: ITT
Analysis Set

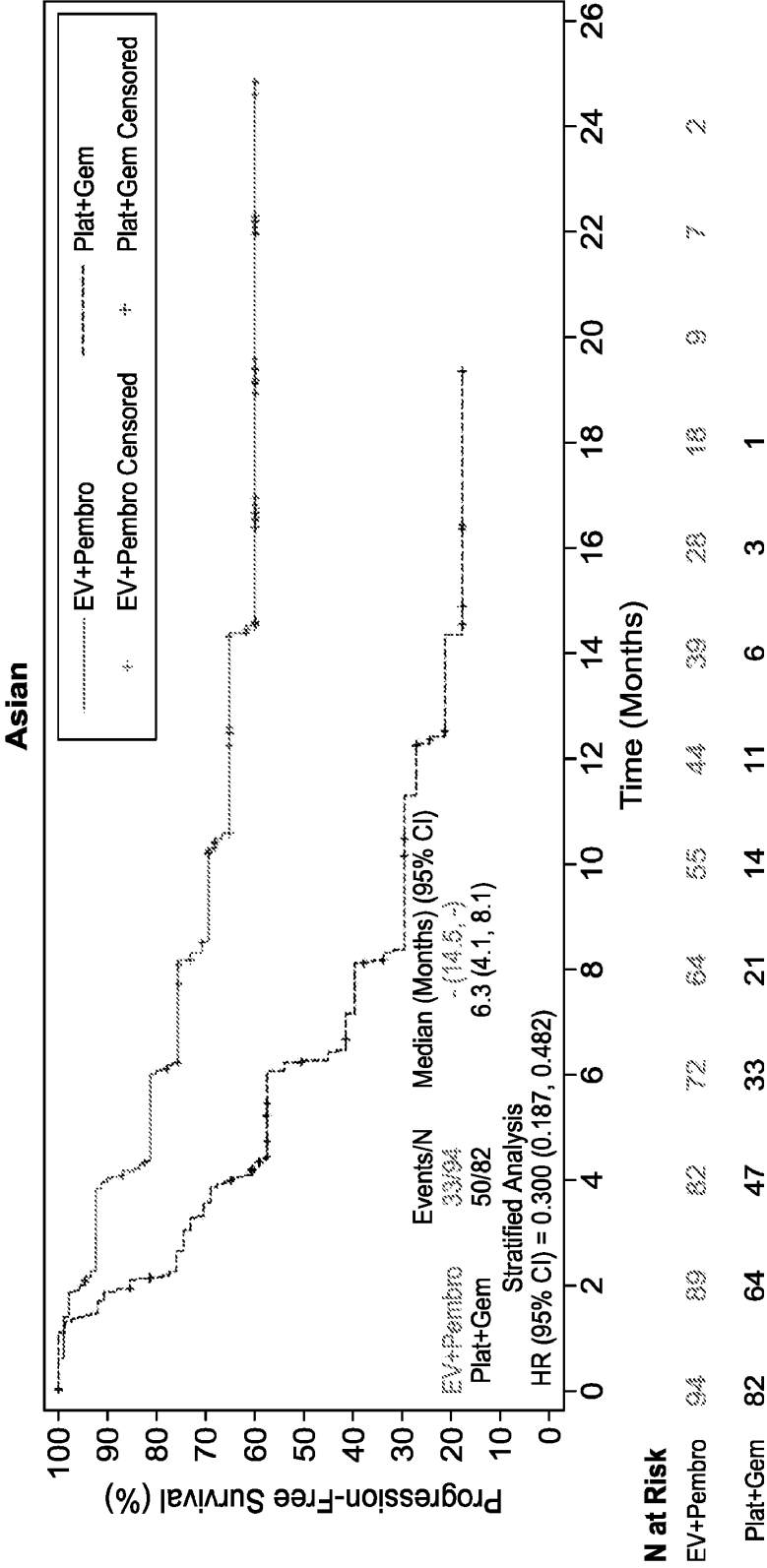


FIG. 55

OS for Asian subgroup: ITT Analysis Set

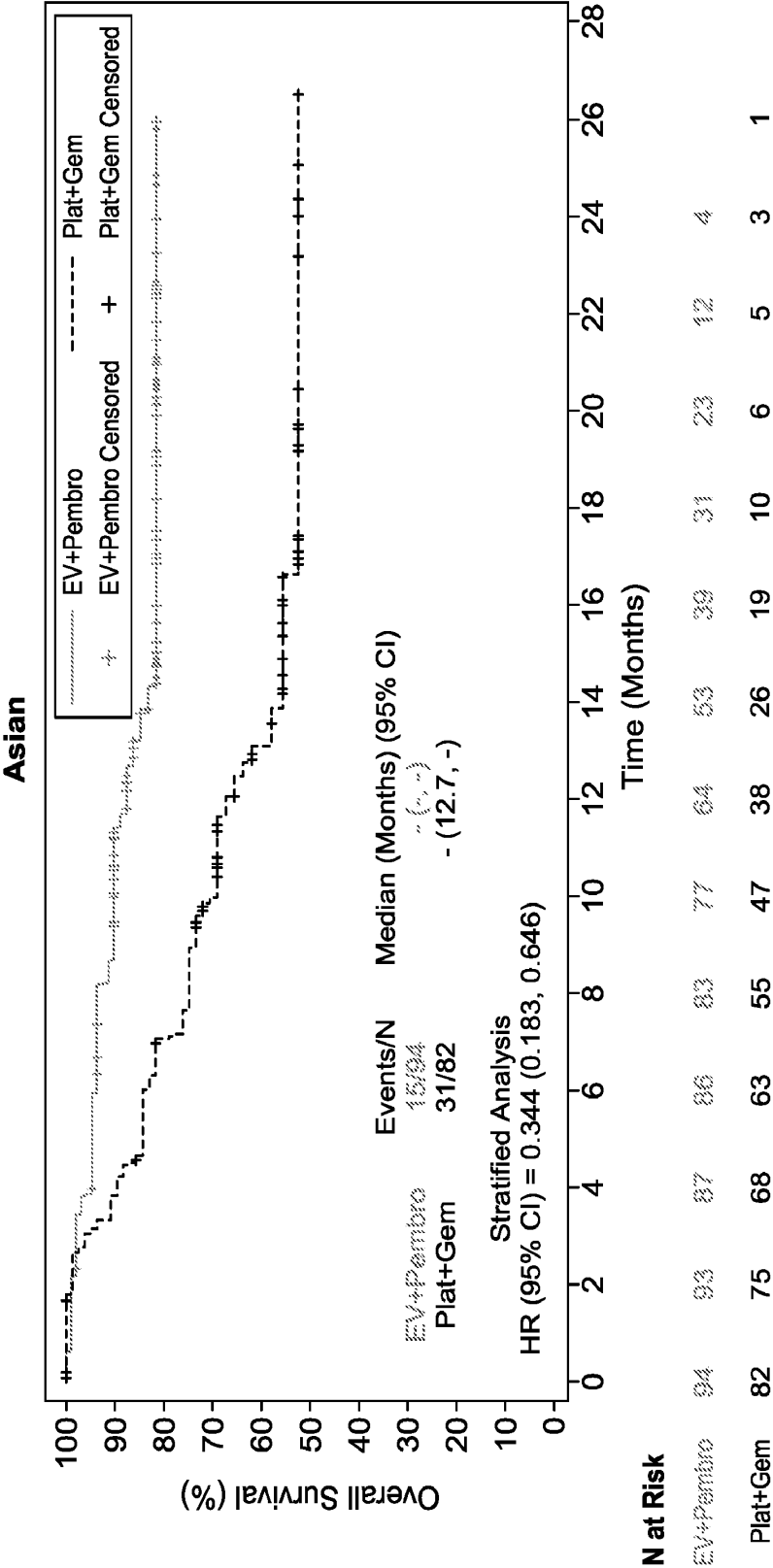


FIG. 56

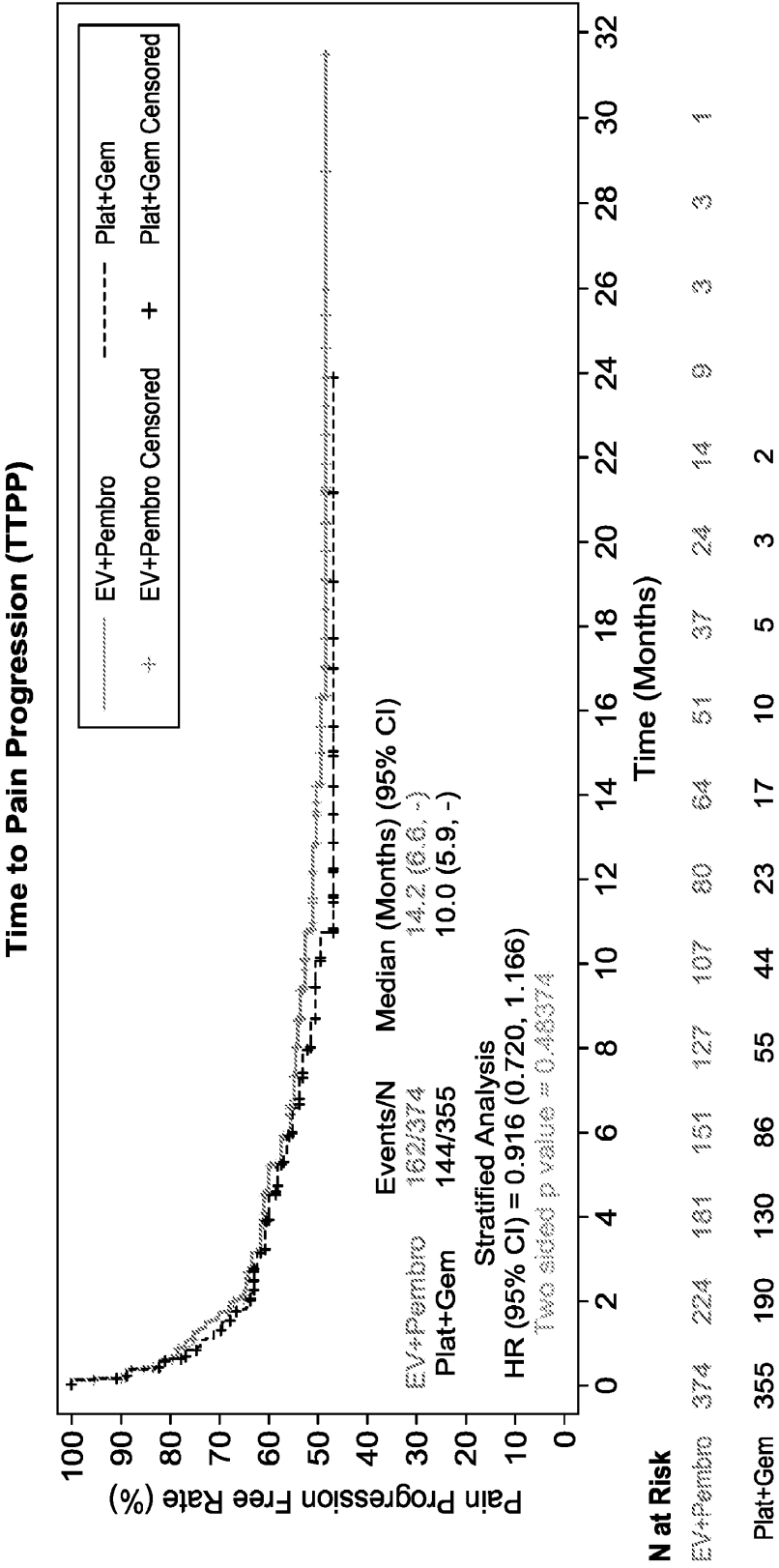


FIG. 57A

Time to Pain Progression (TTPP)

	EV + Pembro (N=376)	Plat + Gem (N=355)
No. of events (%)	162 (43.3)	144 (40.6)
HR (95% CI)	0.916 (0.720, 1.166)	
2-sided p-value	0.48374	
mTTPP (95% CI), months	14.2 (6.6, -)	10.0 (5.9, -)
Subjects without pain progression		
at 6 months	55.7%	55.2%
at 12 months	51.0%	46.9%

FIG. 57B

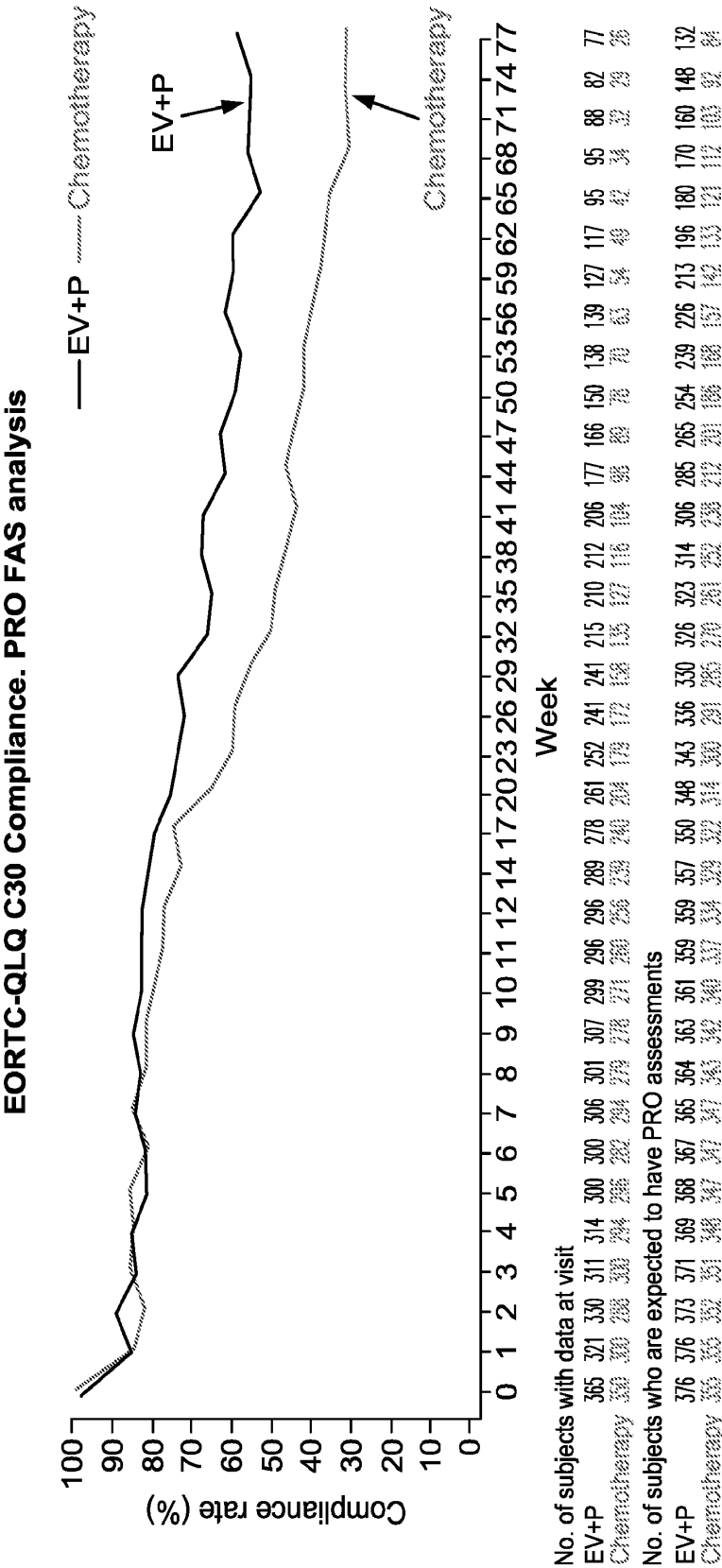


FIG. 58

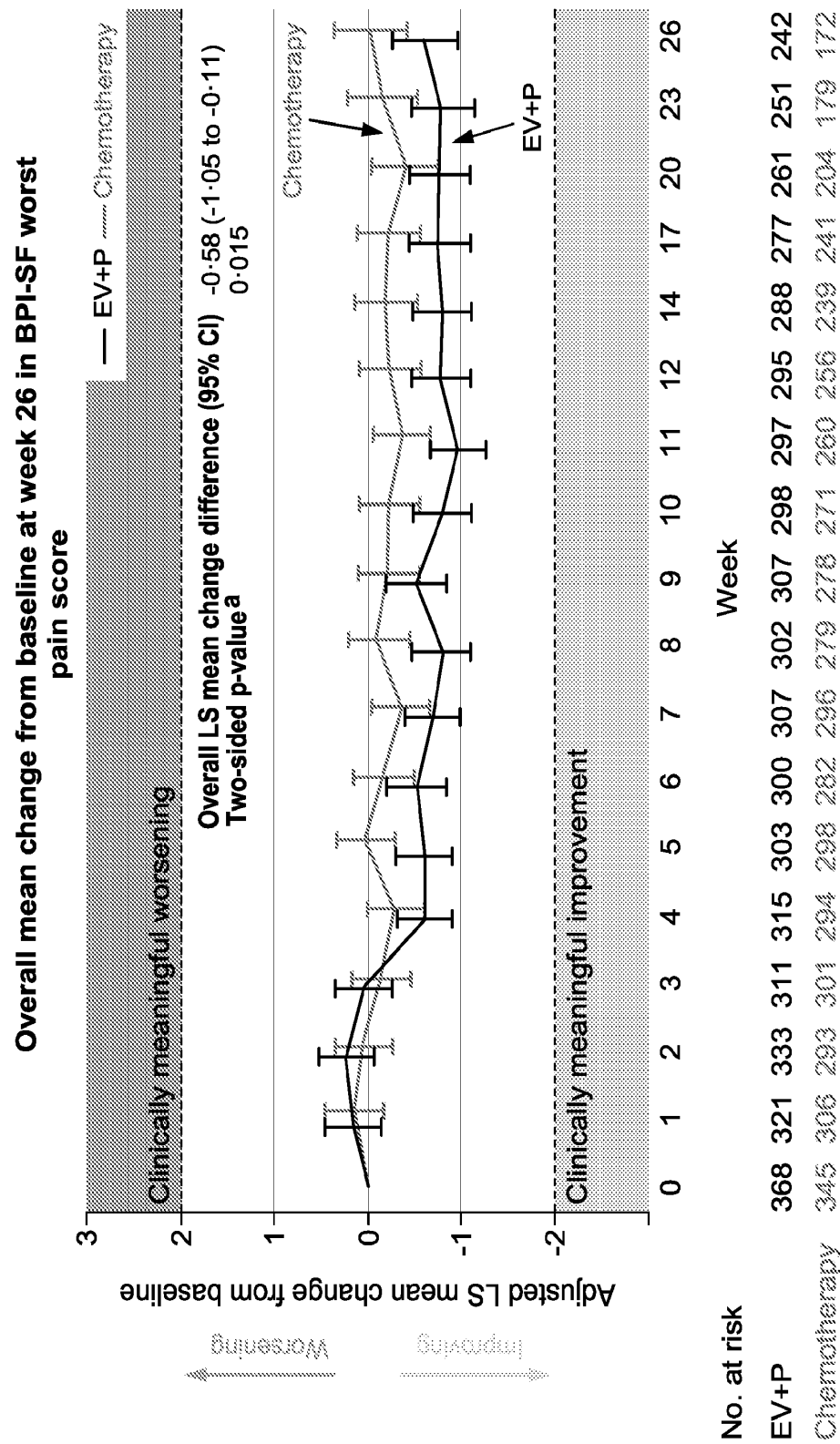


FIG. 59

LS mean change from baseline in BPI-SF scale scores through week 26

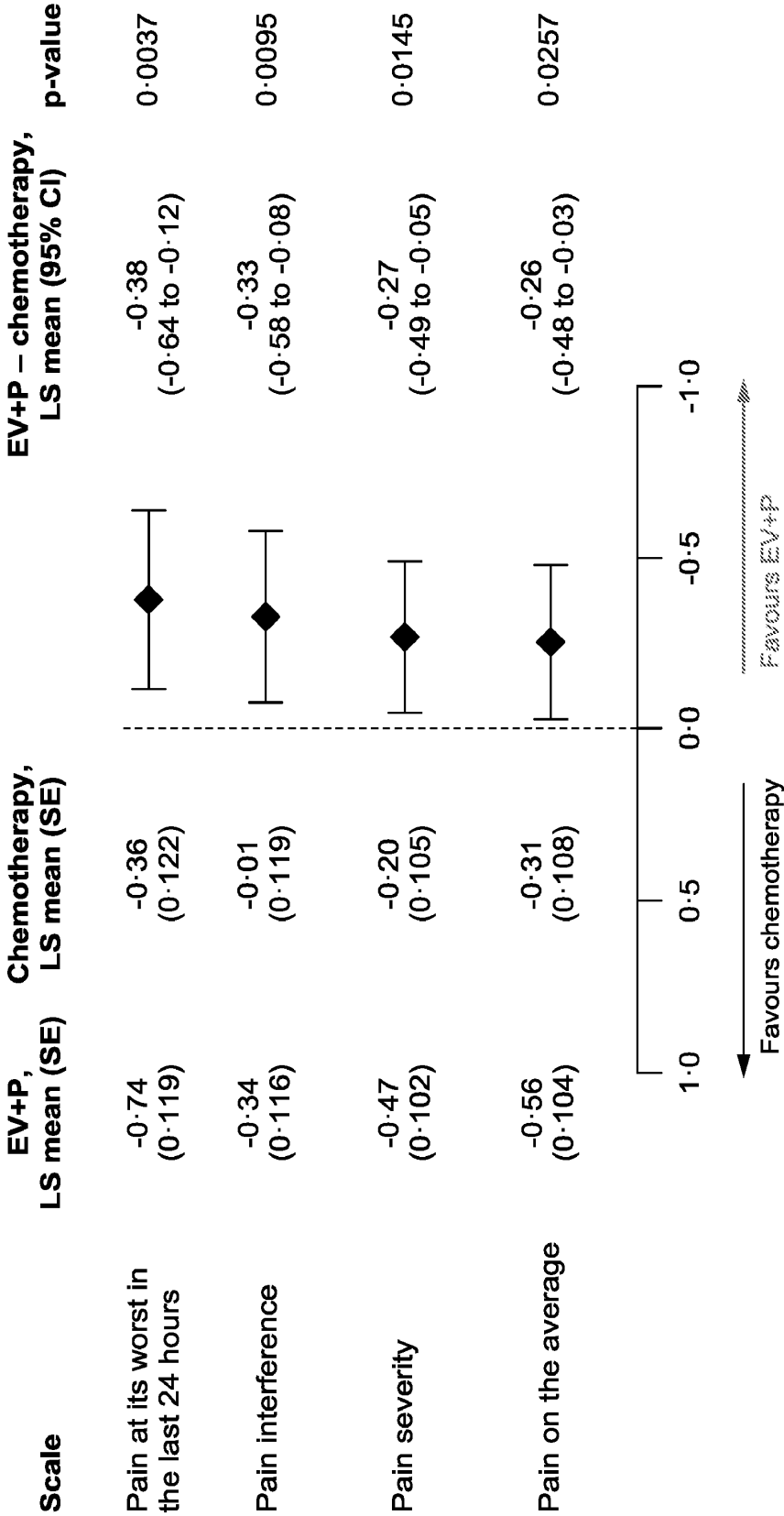


FIG. 60

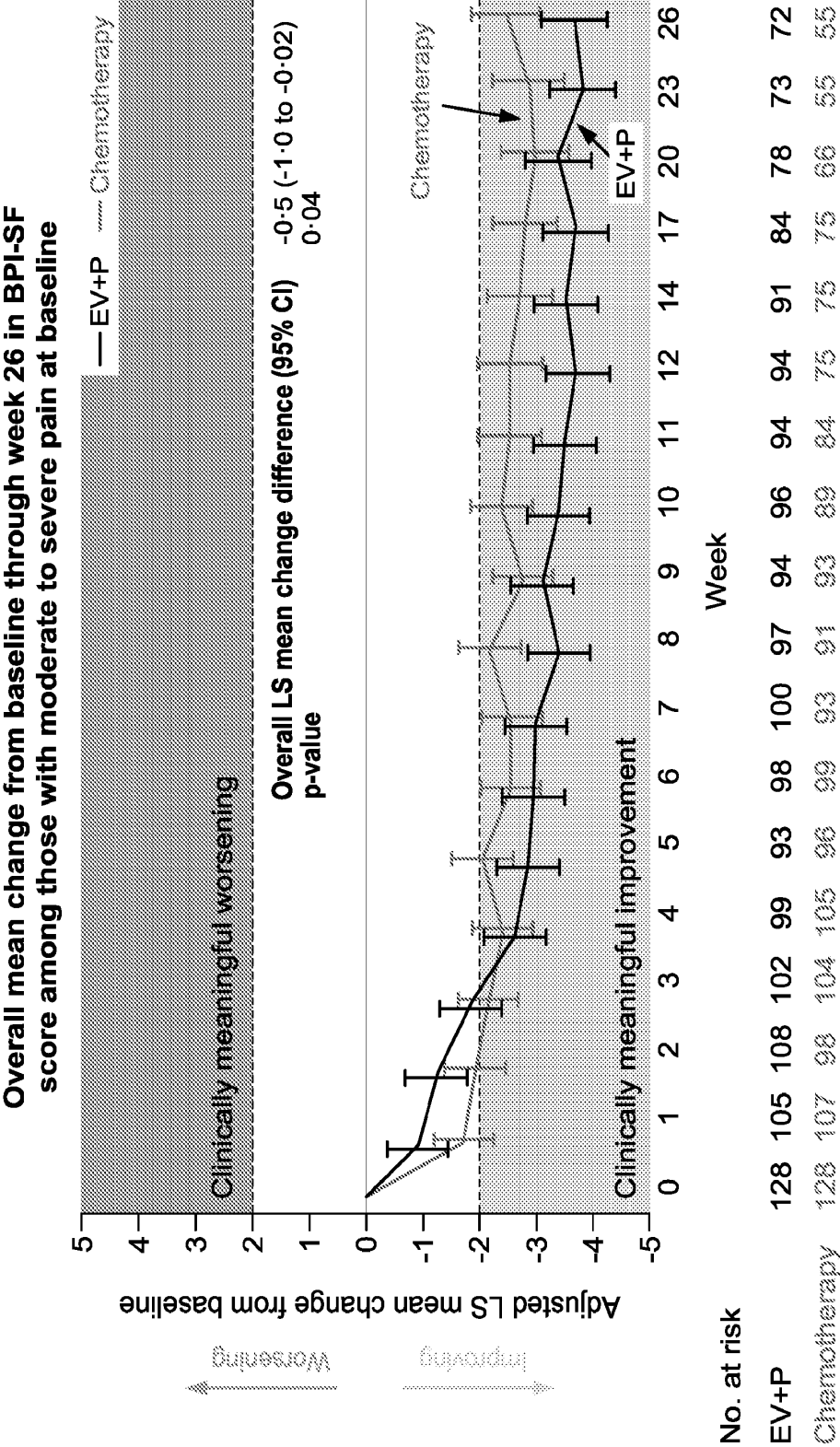


FIG. 61

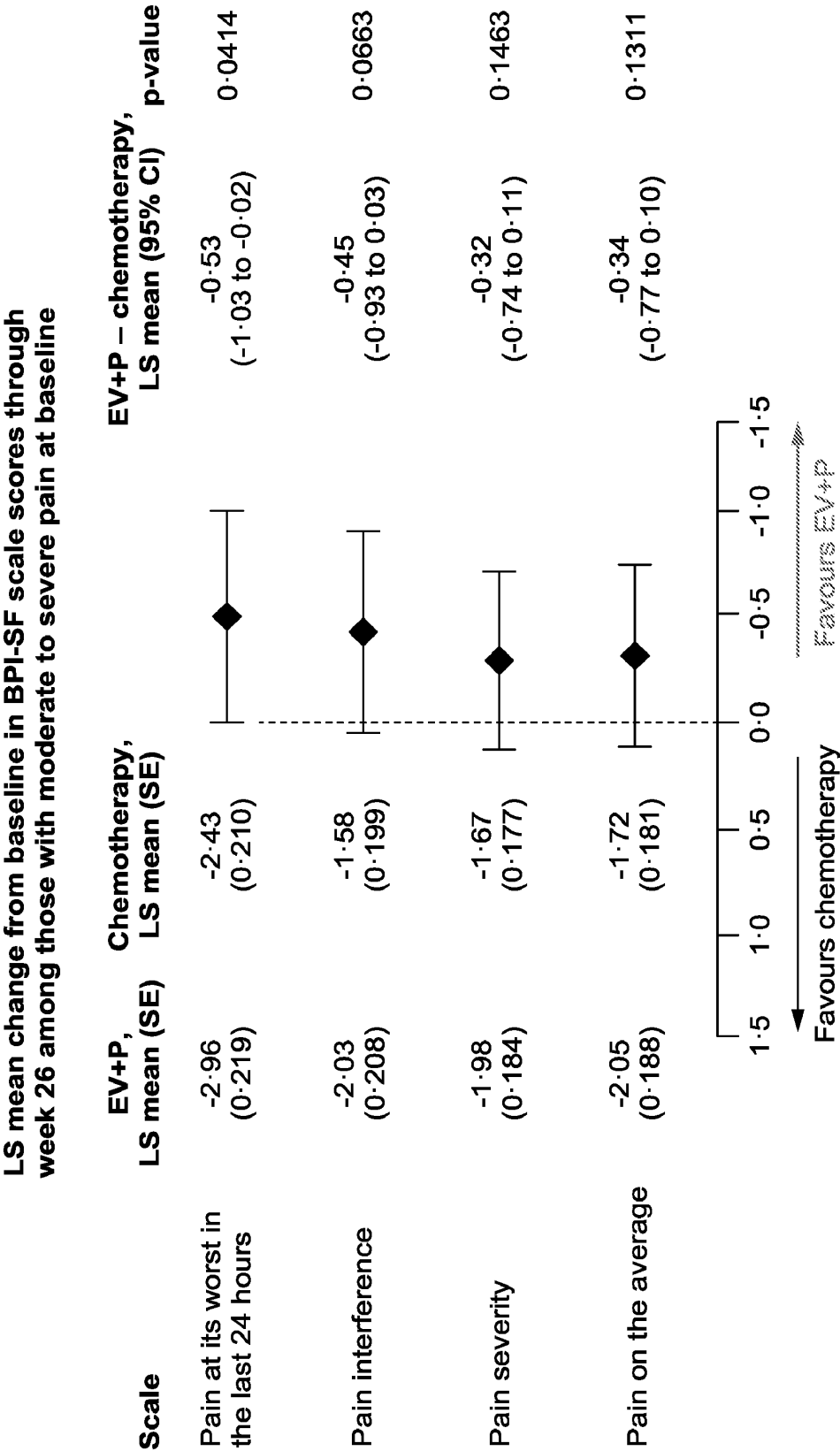


FIG. 62

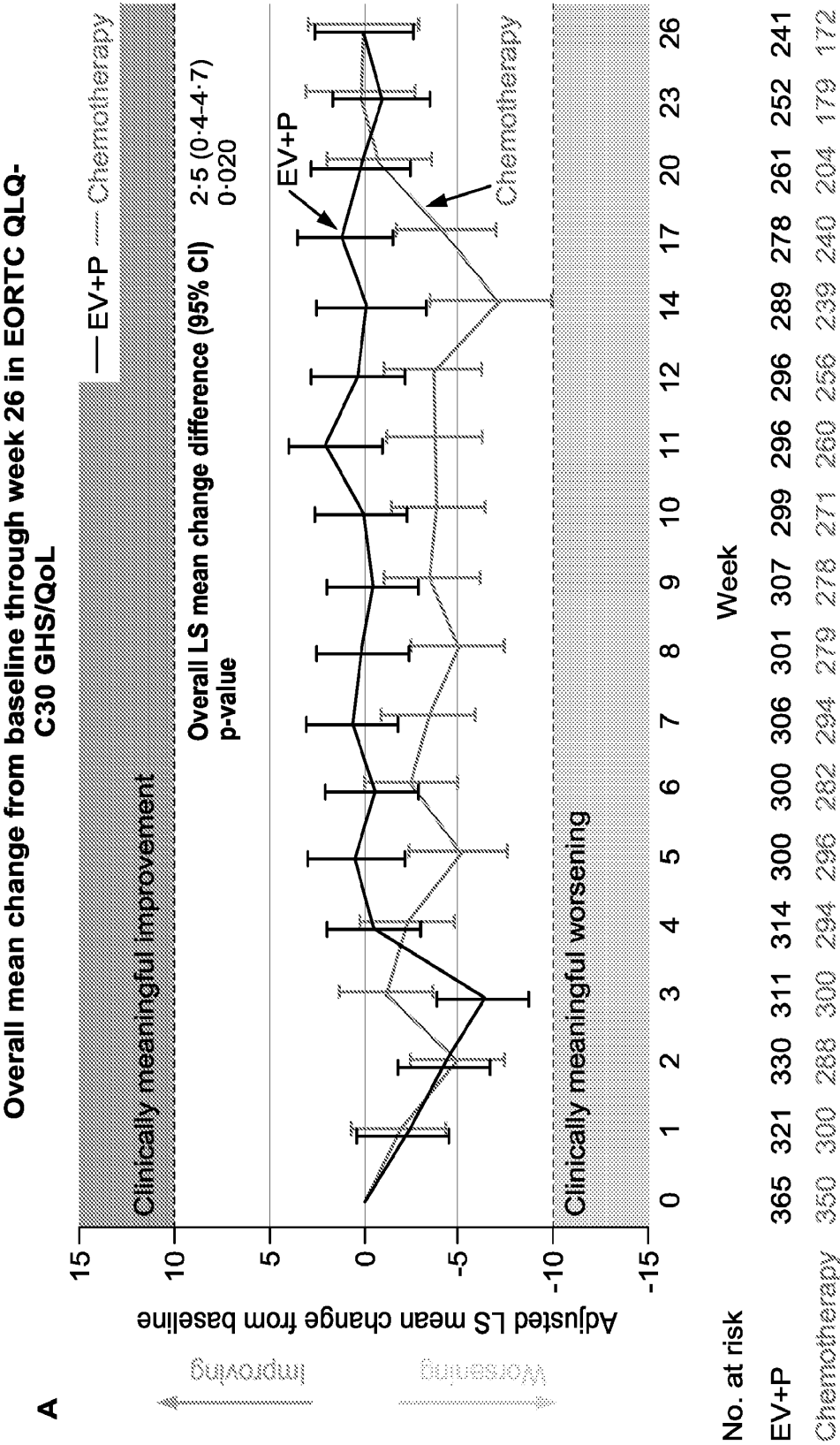
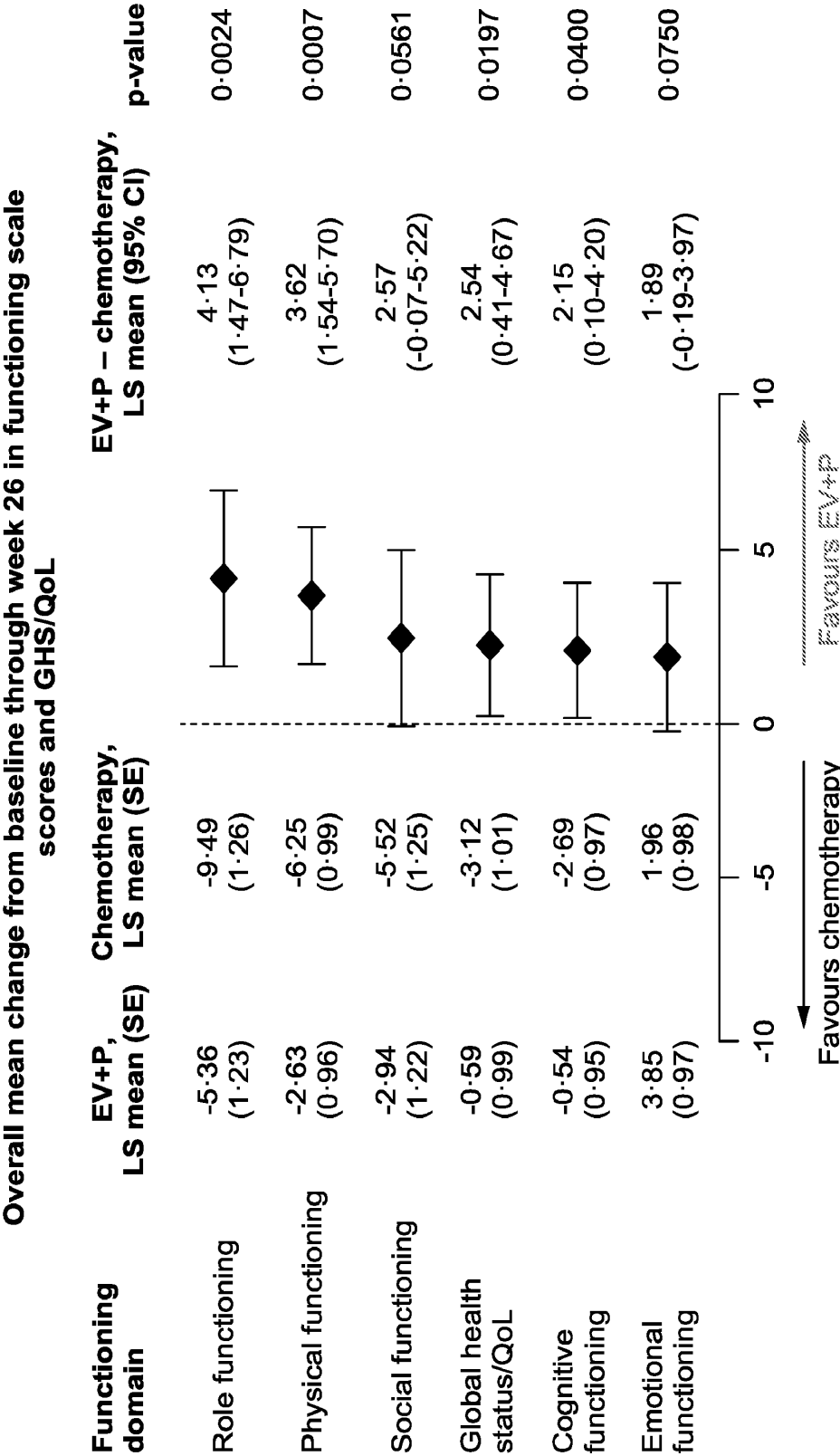
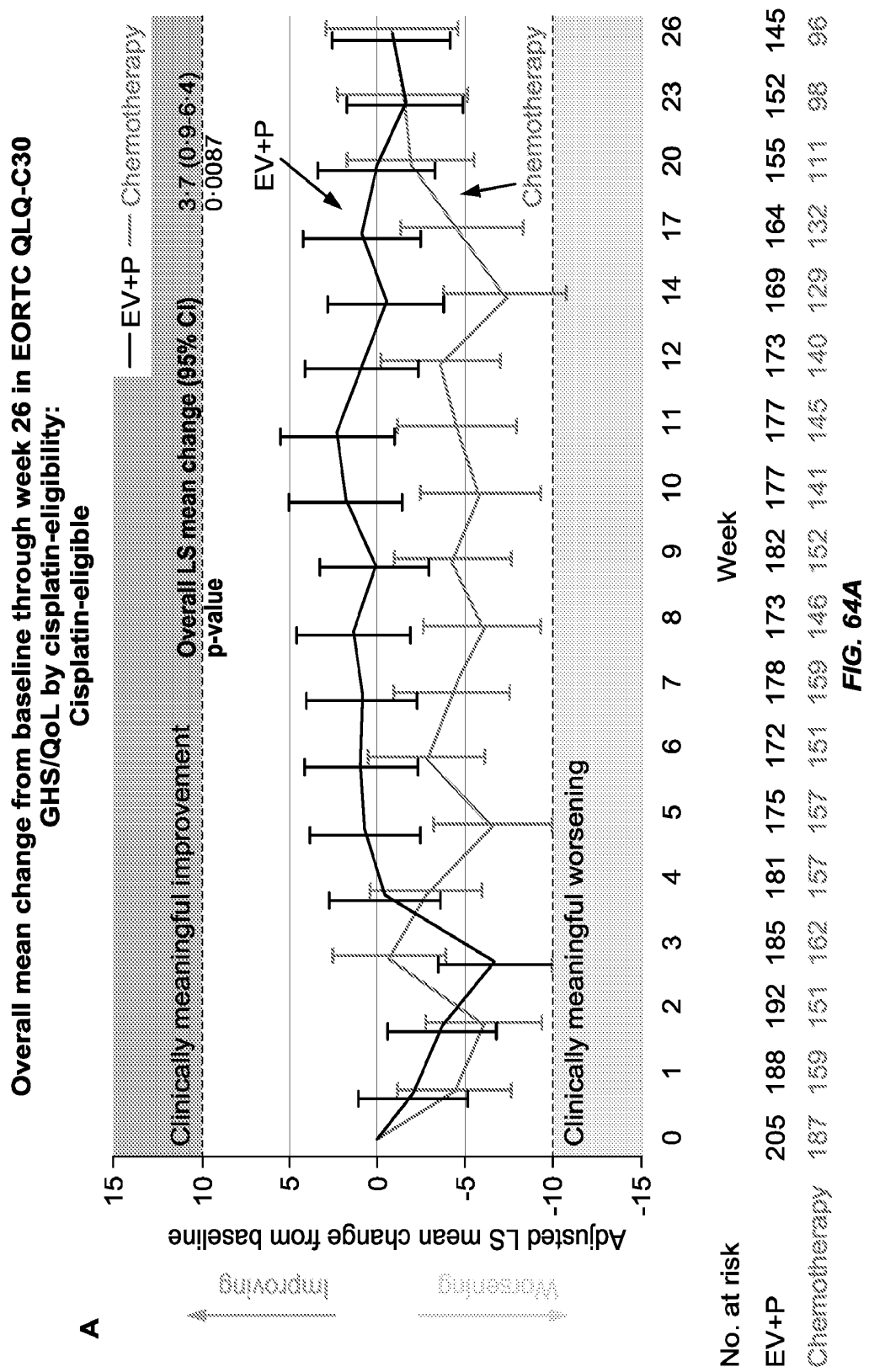
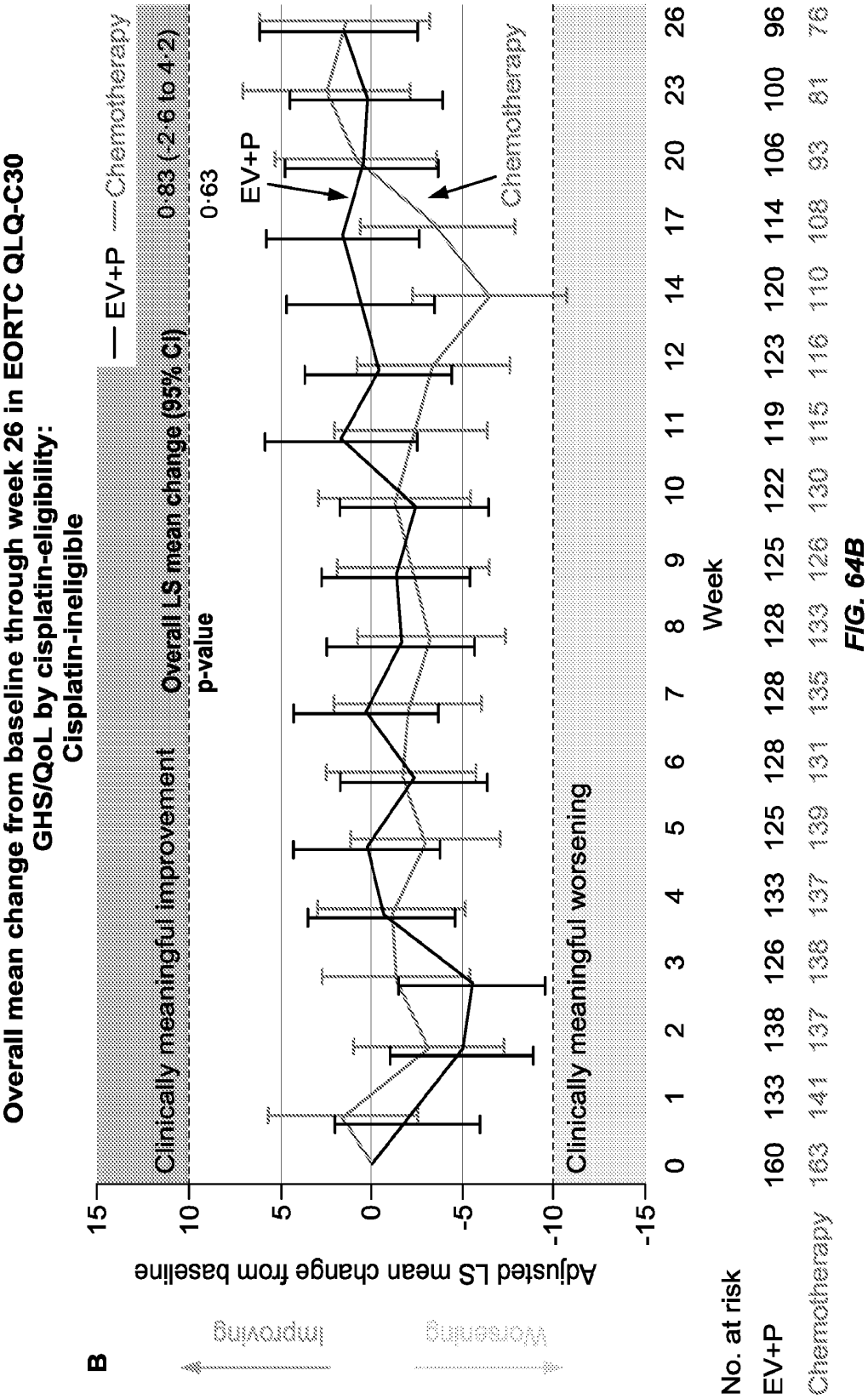


FIG. 63A







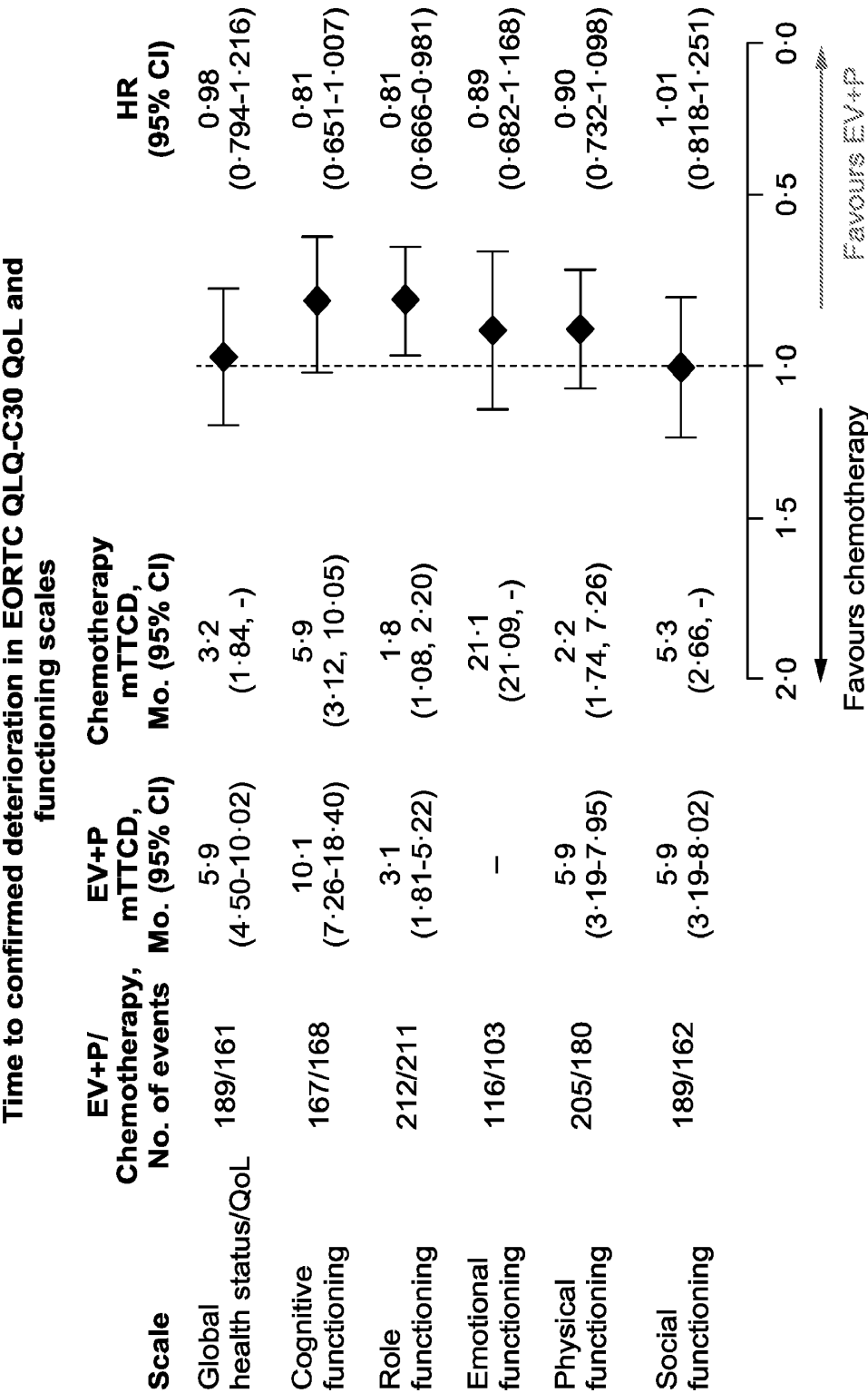


FIG. 65

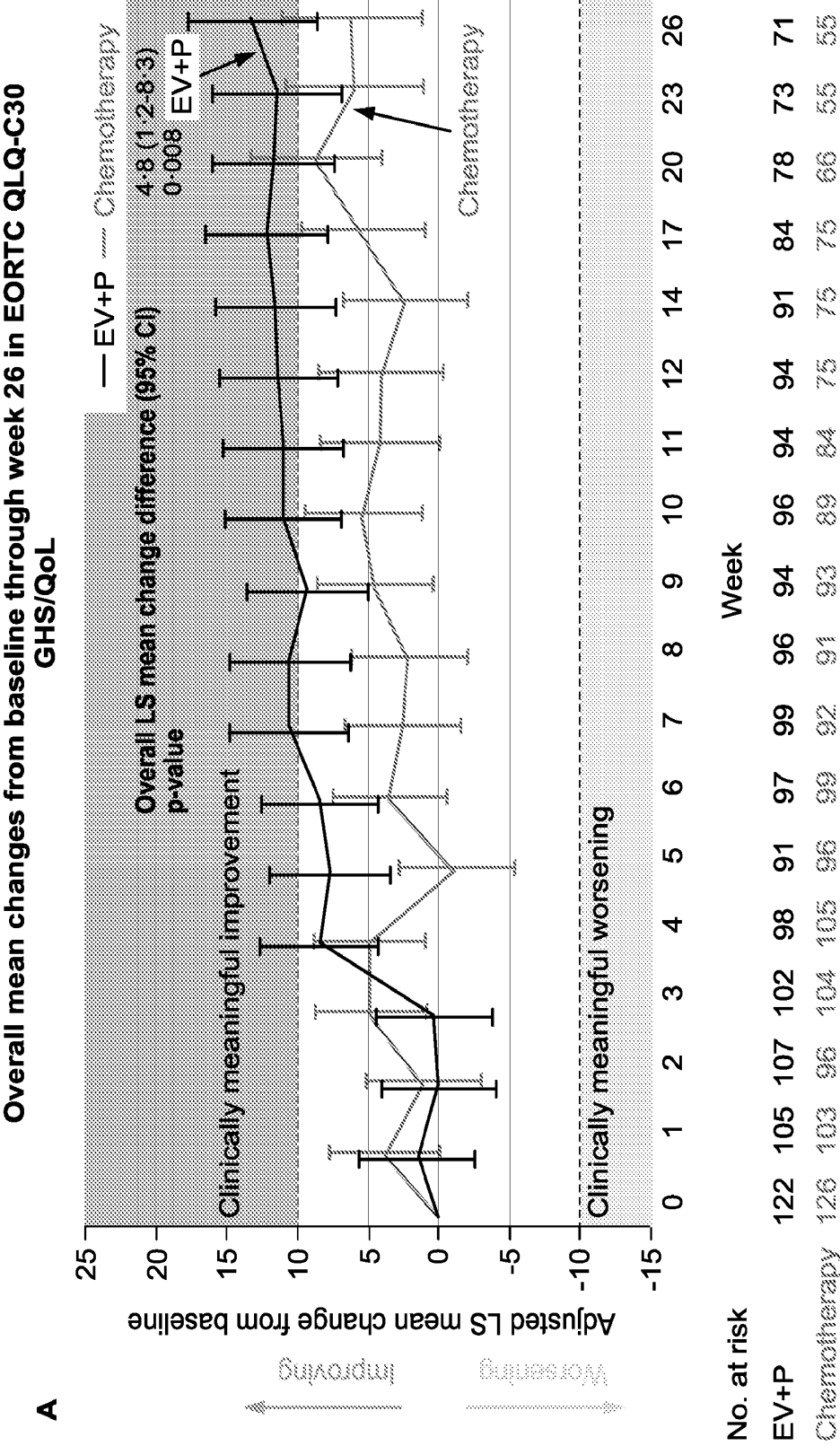


FIG. 66A

B Overall mean changes from baseline through week 26 in functioning scale scores in patients with moderate/severe pain at baseline

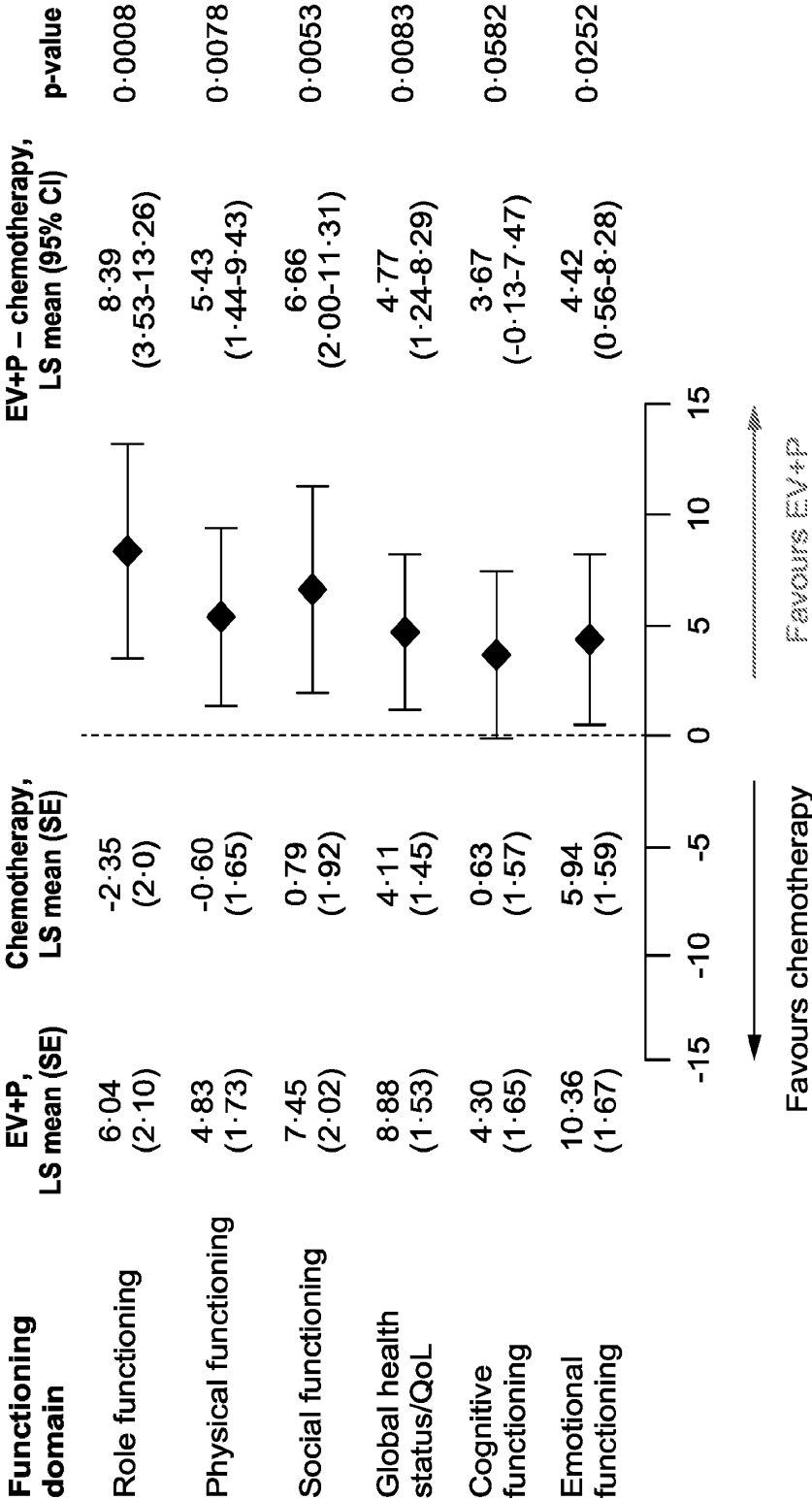
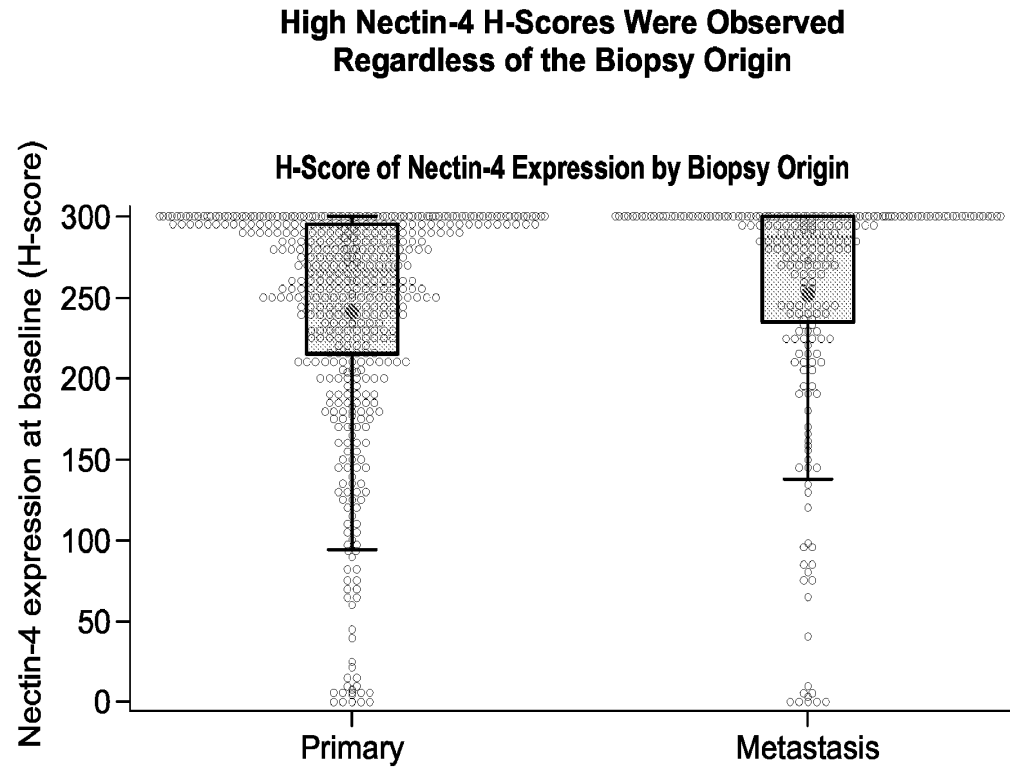


FIG. 66B



Biopsy origin	Primary (n=554)	Metastasis (n=246)
H-score, median (IQR)	267 (215-295)	287 (235-300)

FIG. 67

**Distribution of Nectin-4 H-Scores Was
Skewed Toward High Expression**

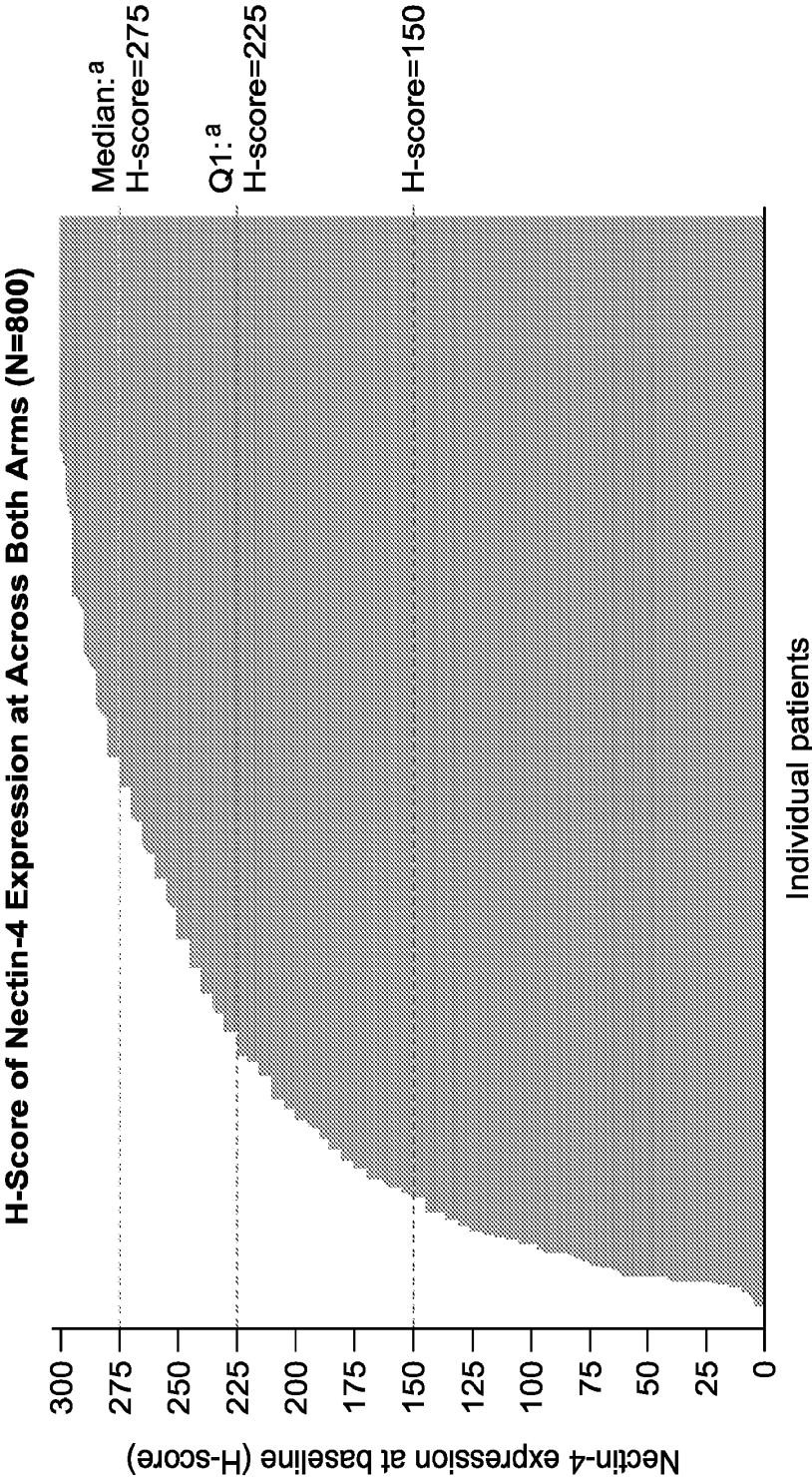


FIG. 68A

Distribution of Nectin-4 H-Scores Was Skewed Toward High Expression

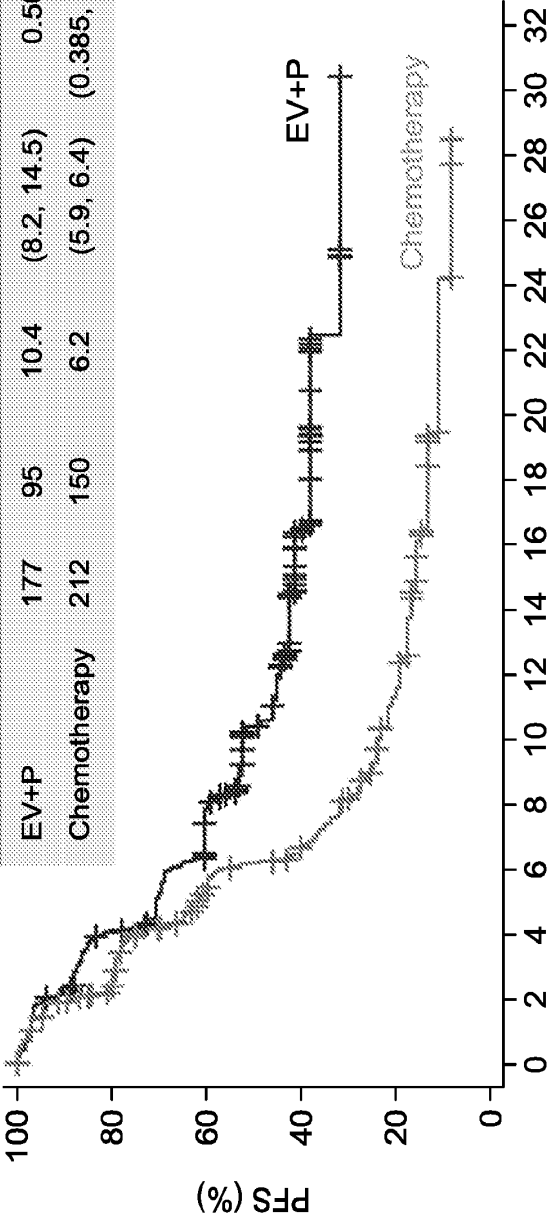
Variable	EV+P (n=394)	Chemotherapy (n=406)
H-score, median (IQR)	280 (230-298)	270 (215-297)
Subgroup, H-score, n (%)		
<150	38 (9.6)	50 (12.3)
≥150 to <225	50 (12.7)	56 (13.8)
≥225	306 (77.7)	300 (73.9)
Patients with H-score 0, n (%)	3 (0.8)	6 (1.5)

FIG. 68B

Consistent PFS Benefit With EV+P in Both
<275 and ≥275 Nectin-4 H-Score Subgroups

Nectin-4 H-score <275

	N	Events (months)	Median	95% CI	Stratified HR (95% CI)
EV+P	177	95	10.4	(8.2, 14.5)	0.503
Chemotherapy	212	150	6.2	(5.9, 6.4)	(0.385, 0.657)



No. at risk	177	165	138	111	94	72	54	40	28	19	11	9	5	1	1	1
EV+P																
Chemotherapy	212	173	142	97	51	33	24	19	14	10	4	4	4	2	1	1

FIG. 69A

Consistent PFS Benefit With EV+P in Both
<275 and ≥275 Nectin-4 H-Score Subgroups

Nectin-4 H-score ≥275

	N	Events	Median (months)	95% CI	Stratified HR (95% CI)
EV+P	217	106	15.3	(10.5, —)	0.410
Chemotherapy	194	130	6.4	(6.2, 8.1)	(0.313, 0.537)

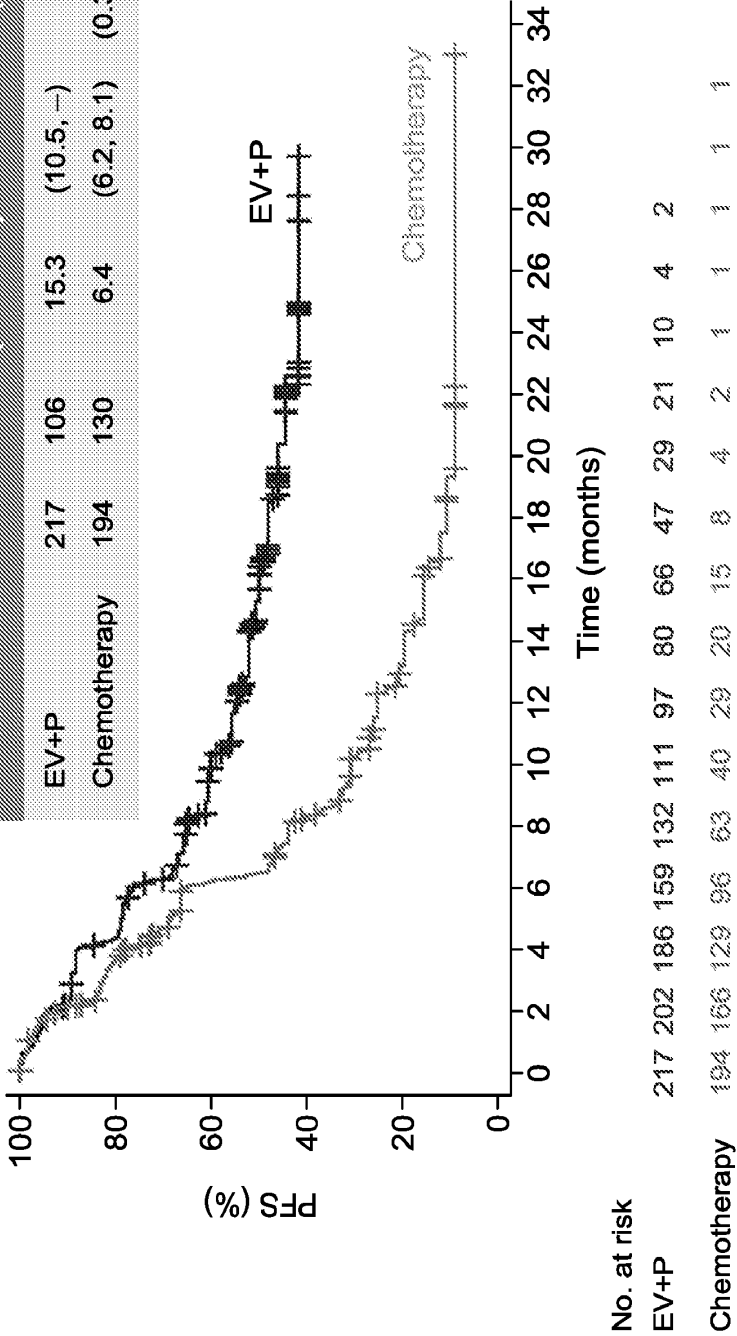


FIG. 69B

Consistent OS Benefit With EV+P in Both
<275 and ≥275 Nectin-4 H-Score Subgroups

Nectin-4 H-score <275

	N	Events	Median (months)	95% CI	Stratified HR (95% CI)
EV+P	177	57	26.1	(22.3, -)	0.518
Chemotherapy	212	108	13.9	(11.6, 19.7)	(0.372, 0.721)

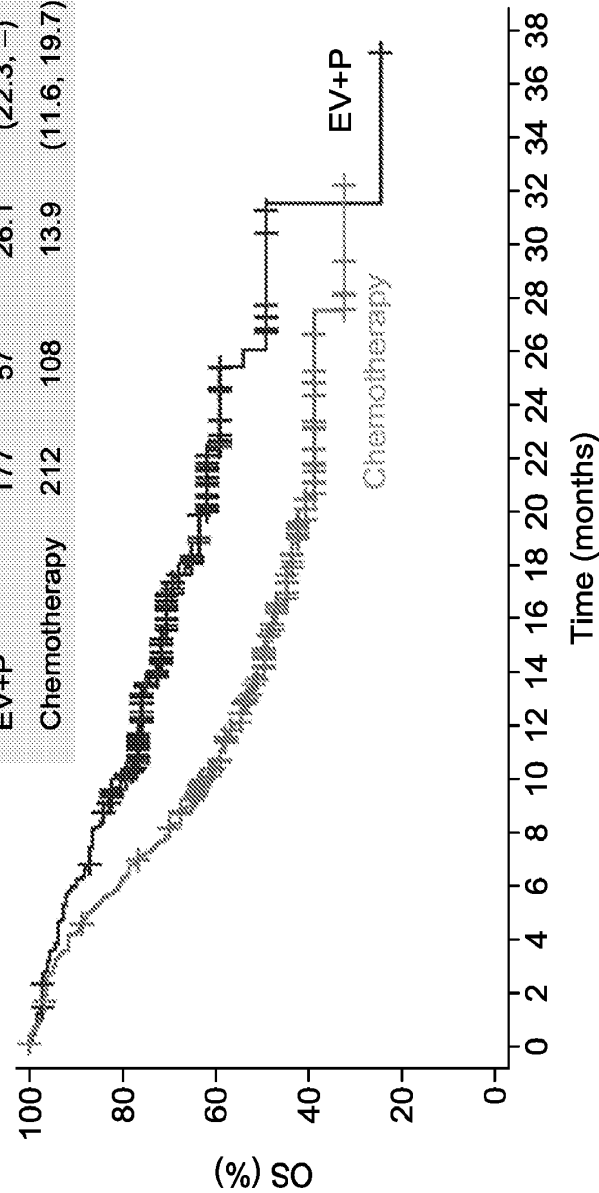


FIG. 70A

Consistent OS Benefit With EV+P in Both
<275 and ≥275 Nectin-4 H-Score Subgroups

Nectin-4 H-score ≥275

	N	Events	Median (months)	95% CI	Stratified HR (95% CI)
EV+P	217	62	—	(25.6, —)	0.426
Chemotherapy	194	95	17.1	(14.7, 19.3)	(0.305, 0.595)

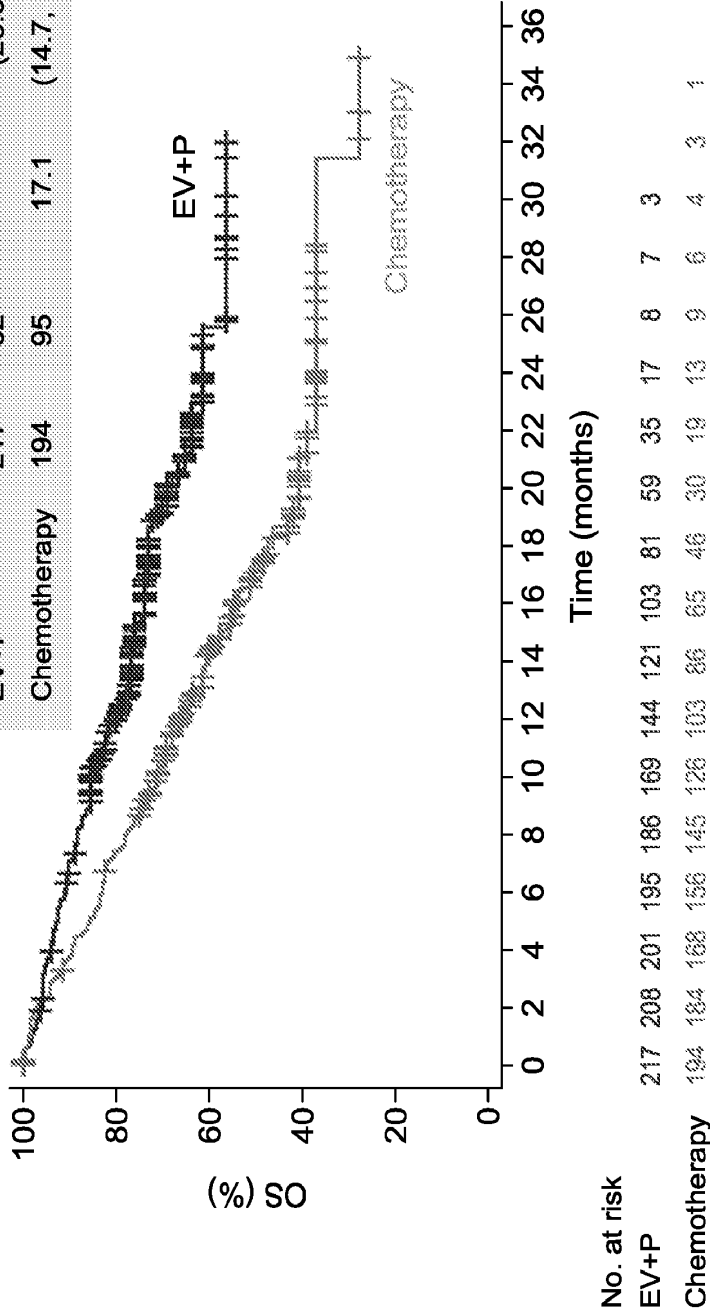
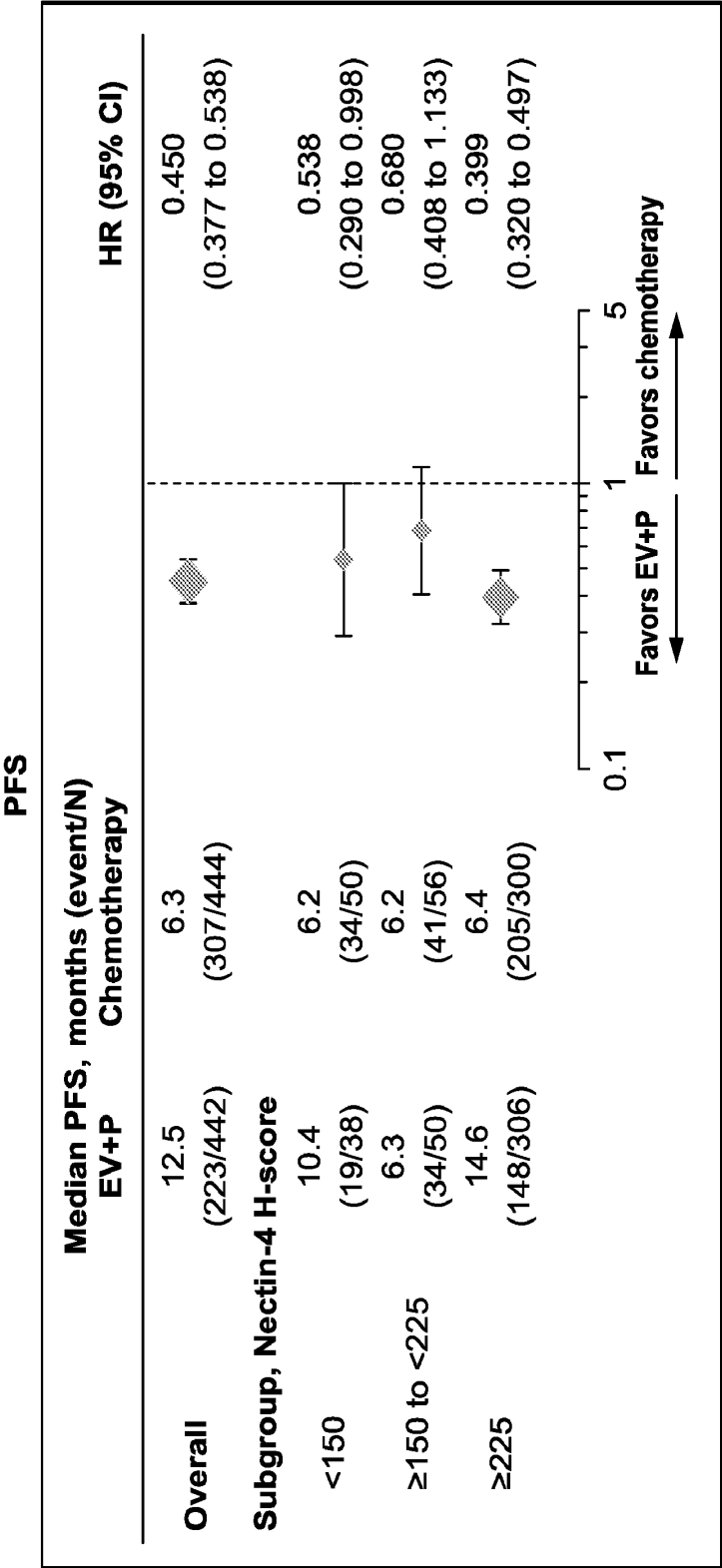


FIG. 70B

Consistent PFS Benefit with EV+P Across
Nectin-4 H-Score Subgroups

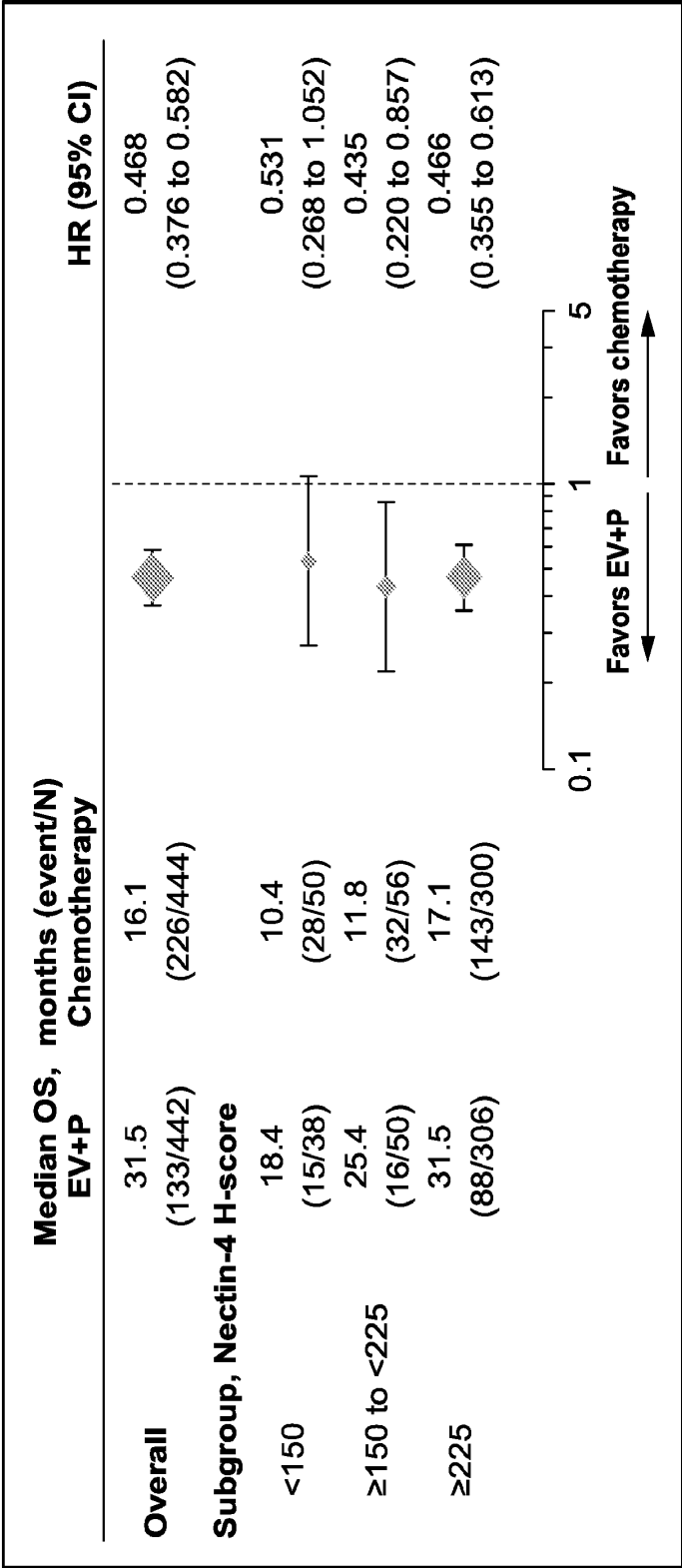


The size of diamonds is relative to the size of the population in each subgroup.

FIG. 71A

Consistent OS Benefit with EV+P Across
Nectin-4 H-Score Subgroups

OS



The size of diamonds is relative to the size of the population in each subgroup.

FIG. 71B

Consistent ORR Benefit with EV+P Across All Nectin-4 Subgroups

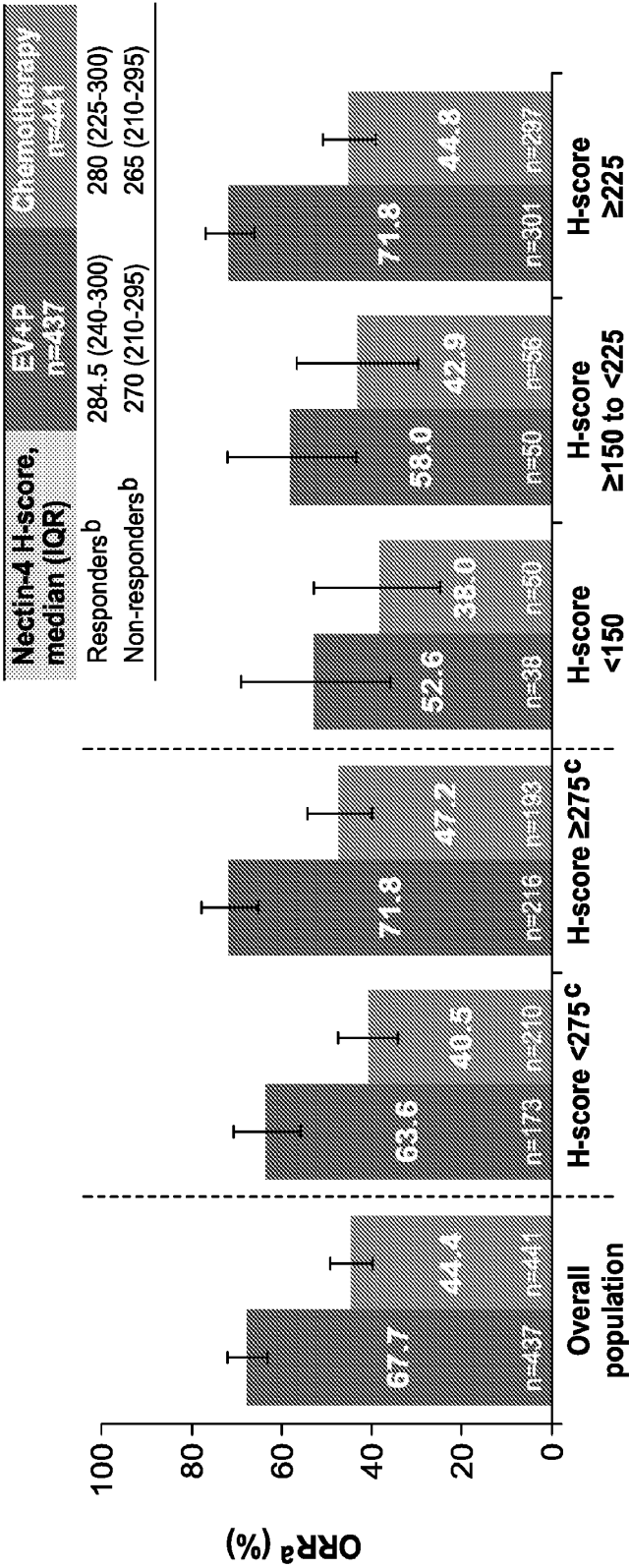


FIG. 72

Nectin-4 and PD-L1 Expression Distribution

	EV+P (N=442)		Chemotherapy (N=444)	
	PD-L1 Low (CPS <10) ^a n=184	PD-L1 High (CPS ≥10) ^a n=254	PD-L1 Low (CPS <10) ^a n=185	PD-L1 High (CPS ≥10) ^a n=254
Nectin-4 H-score, n(%)				
<275 ^b	70 (15.8)	107 (24.2)	86 (19.4)	126 (28.4)
≥275 ^b	97 (21.9)	120 (27.1)	84 (18.9)	109 (24.5)
Missing	17 (3.8)	27 (6.1)	15 (3.4)	19 (4.3)

FIG. 73

Consistent PFS Benefit with EV+P Across Nectin-4
and PD-L1 Subgroups

Nectin-4 H-score <275 / PD-L1 Low

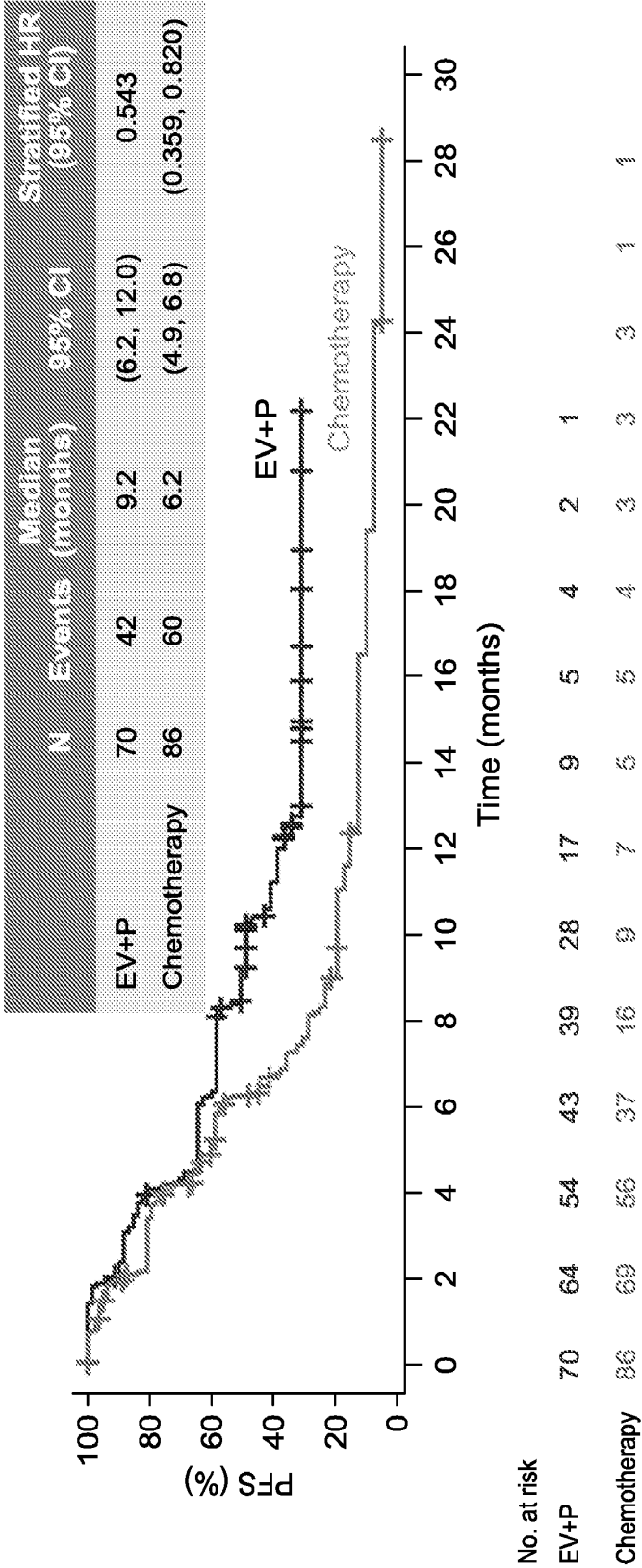


FIG. 74A

Consistent PFS Benefit with EV+P Across Nectin-4
and PD-L1 Subgroups

Nectin-4 H-score <275 / PD-L1 High

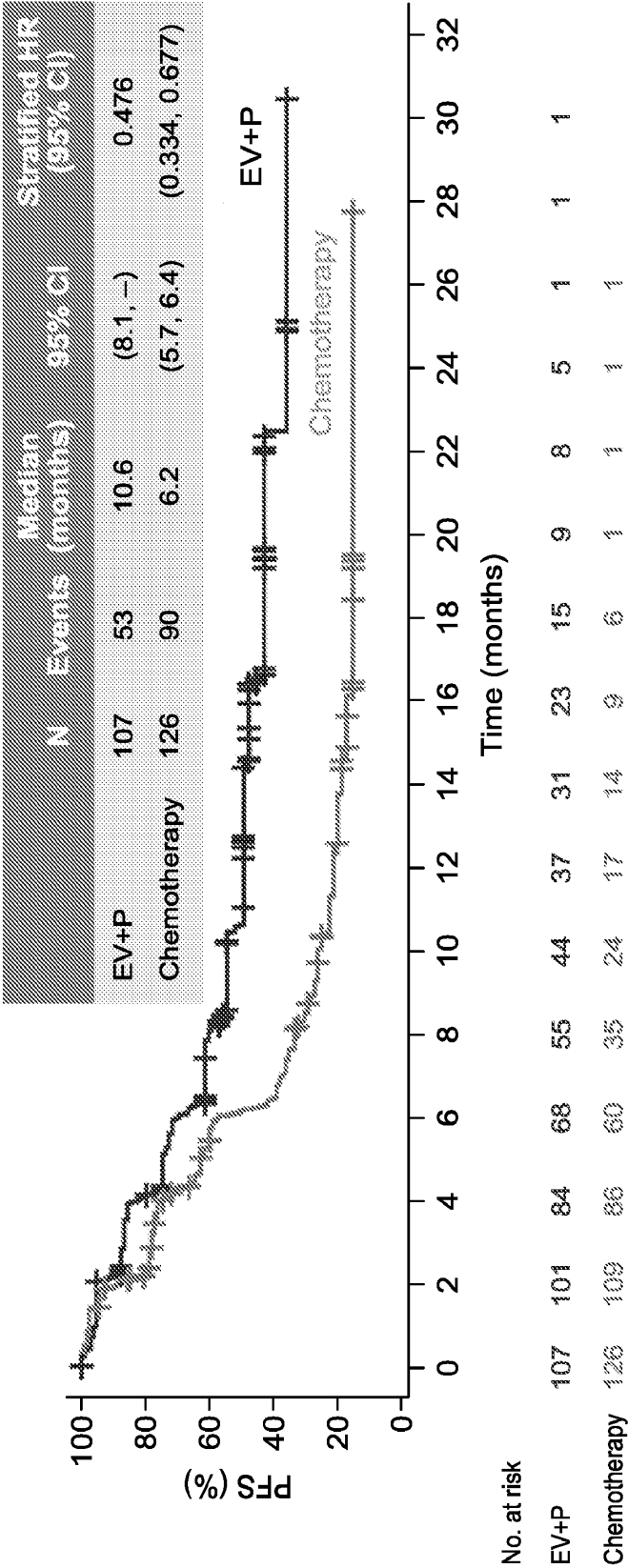


FIG. 74B

Consistent PFS Benefit with EV+P Across Nectin-4
and PD-L1 Subgroups

Nectin-4 H-score ≥ 275 / PD-L1 Low

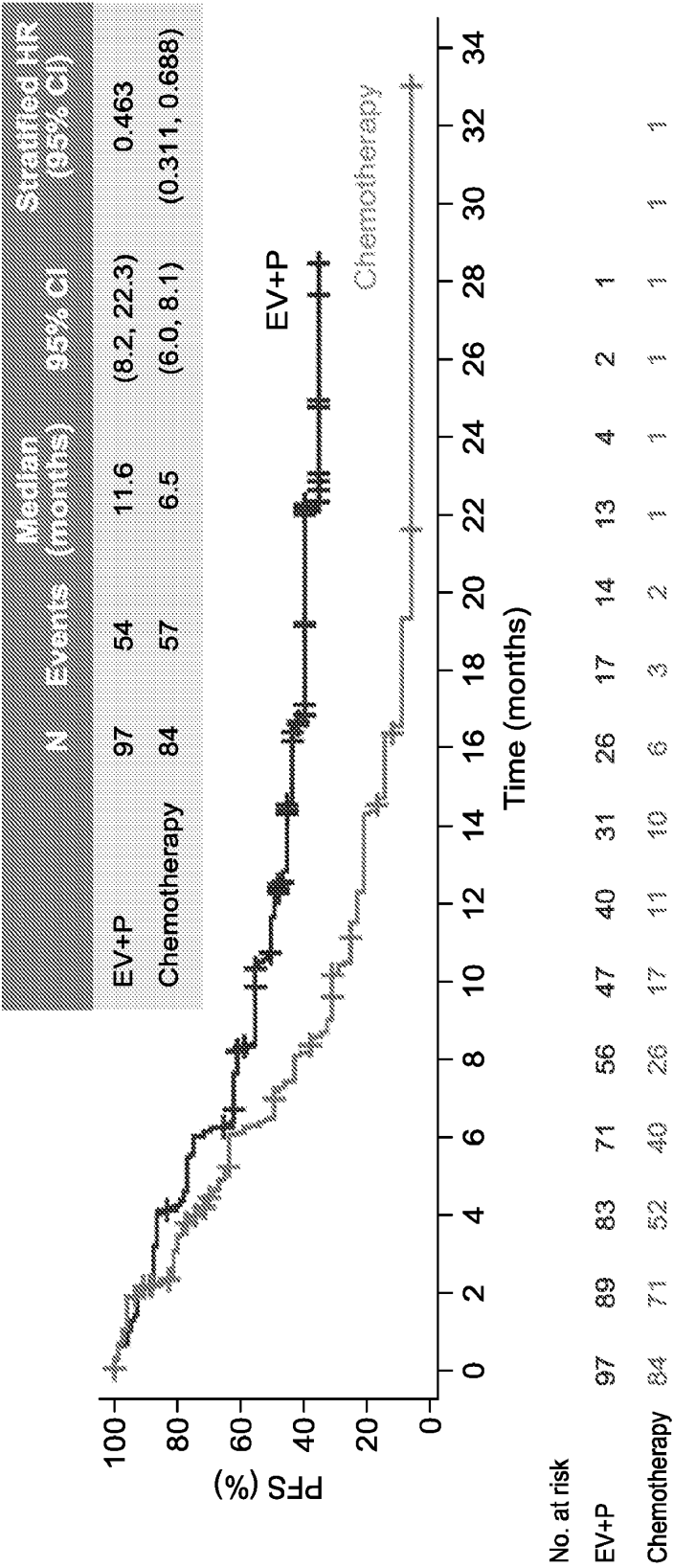
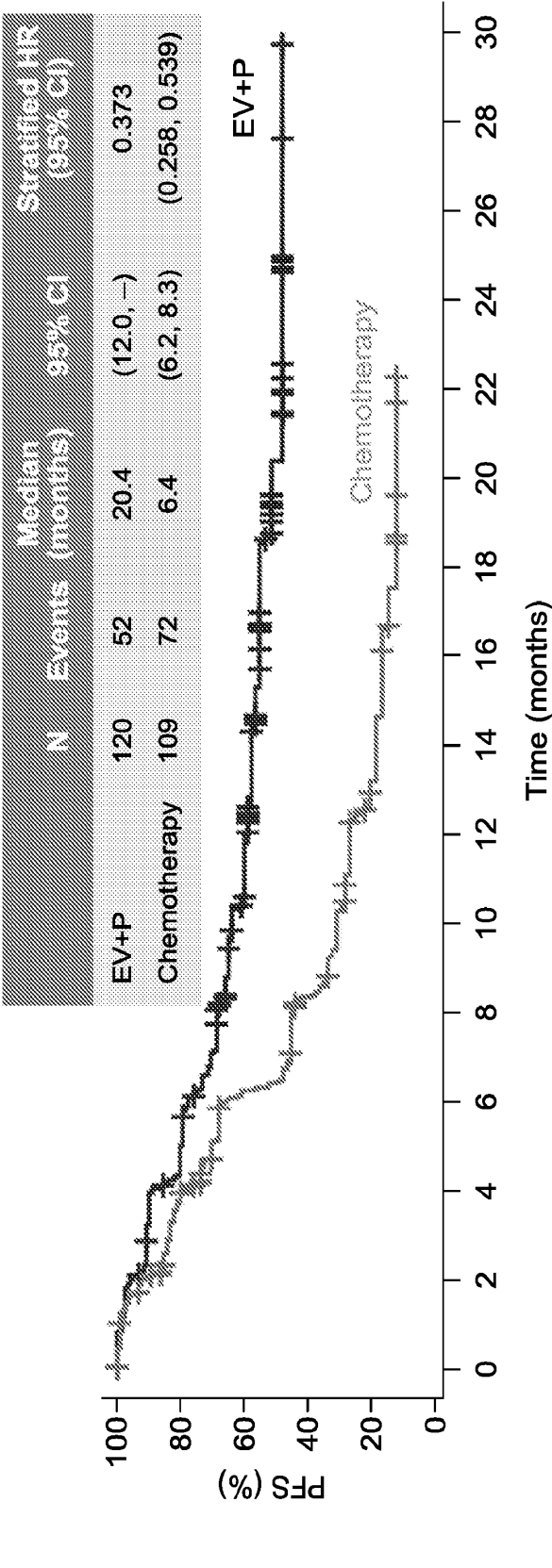


FIG. 74C

Consistent PFS Benefit with EV+P Across Nectin-4
and PD-L1 Subgroups

Nectin-4 H-score ≥ 275 / PD-L1 High



No. at risk

EV+P 120 113 103 88 76 64 57 49 40 30 15 8 6 2 1

Chemotherapy 109 94 76 55 37 23 18 10 9 5 2 1

FIG. 74D

Consistent OS Benefit with EV+P Across Nectin-4
and PD-L1 Subgroups

Nectin-4 H-score <275 / PD-L1 Low

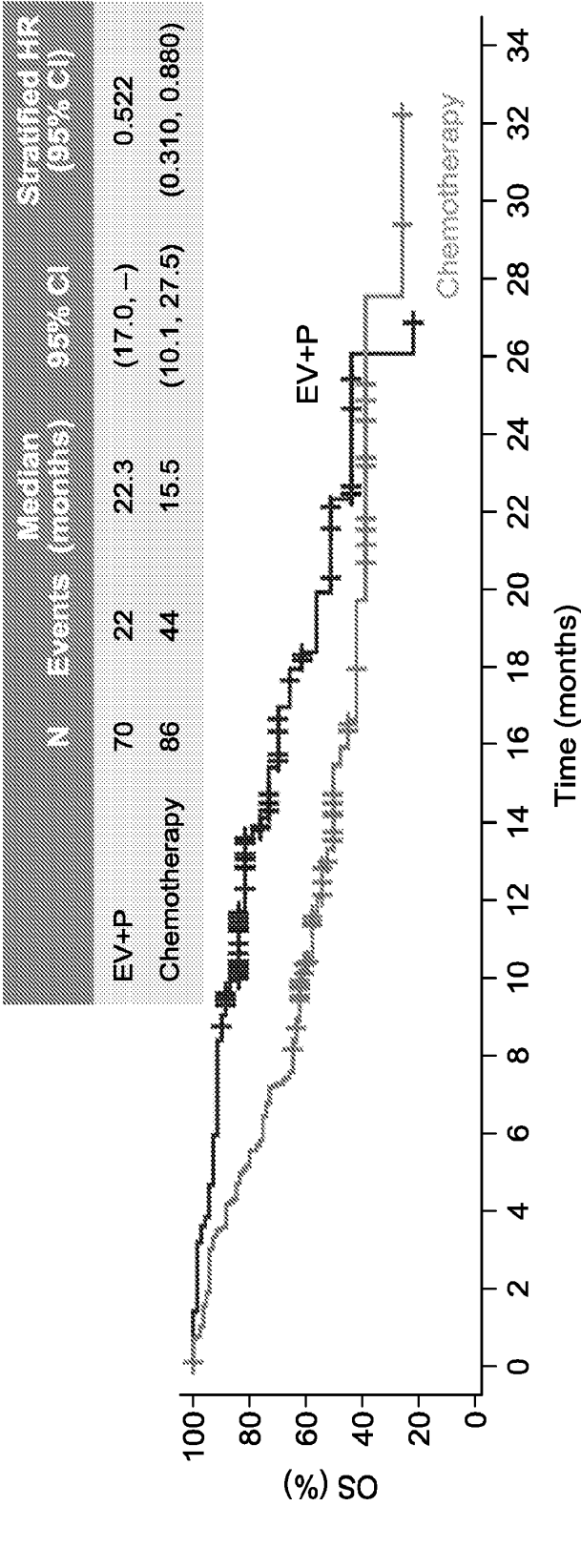


FIG. 75A

No. at risk

	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34
EV+P	70	69	66	64	64	53	37	26	19	14	10	8	4	2				
Chemotherapy	86	80	75	64	55	44	32	23	17	13	12	8	6	3	2	1	1	

Consistent OS Benefit with EV+P Across Nectin-4
and PD-L1 Subgroups

Nectin-4 H-score <275 / PD-L1 High

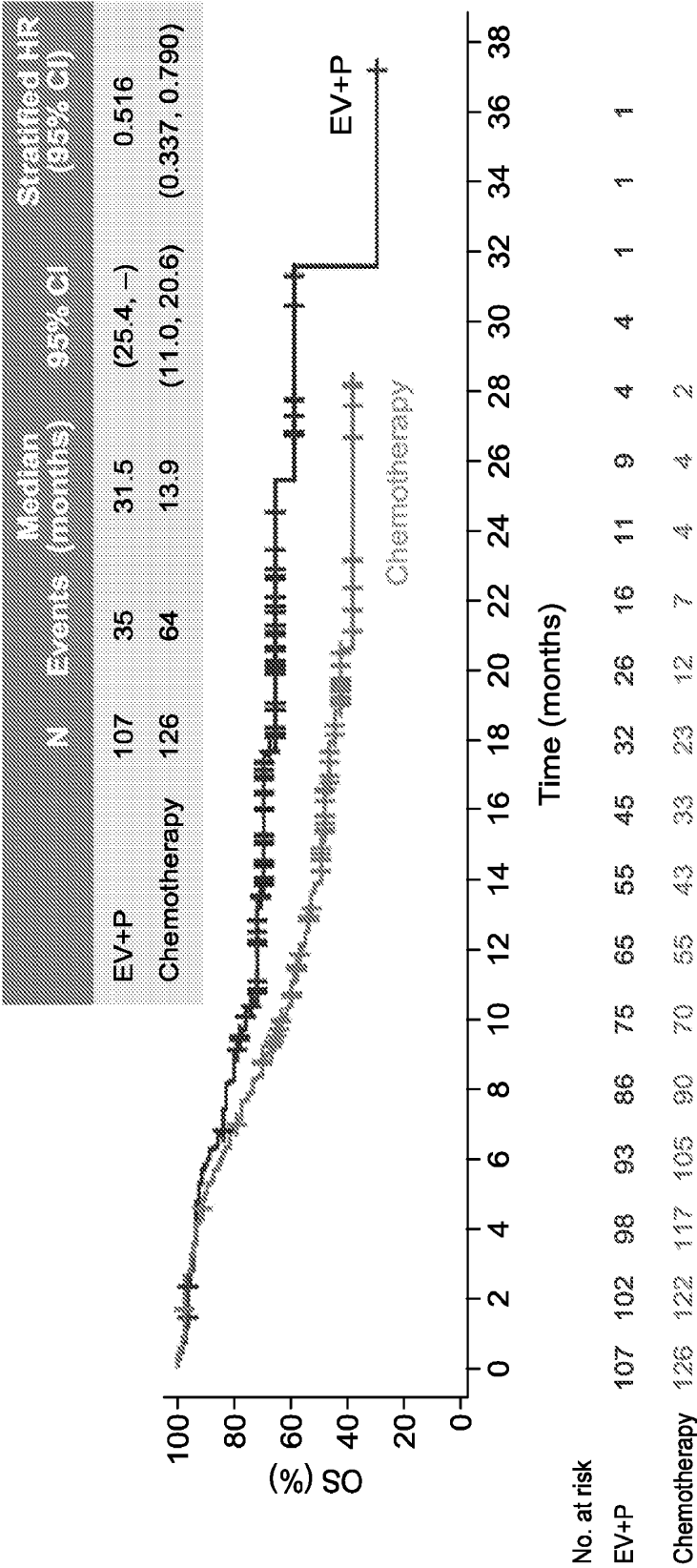
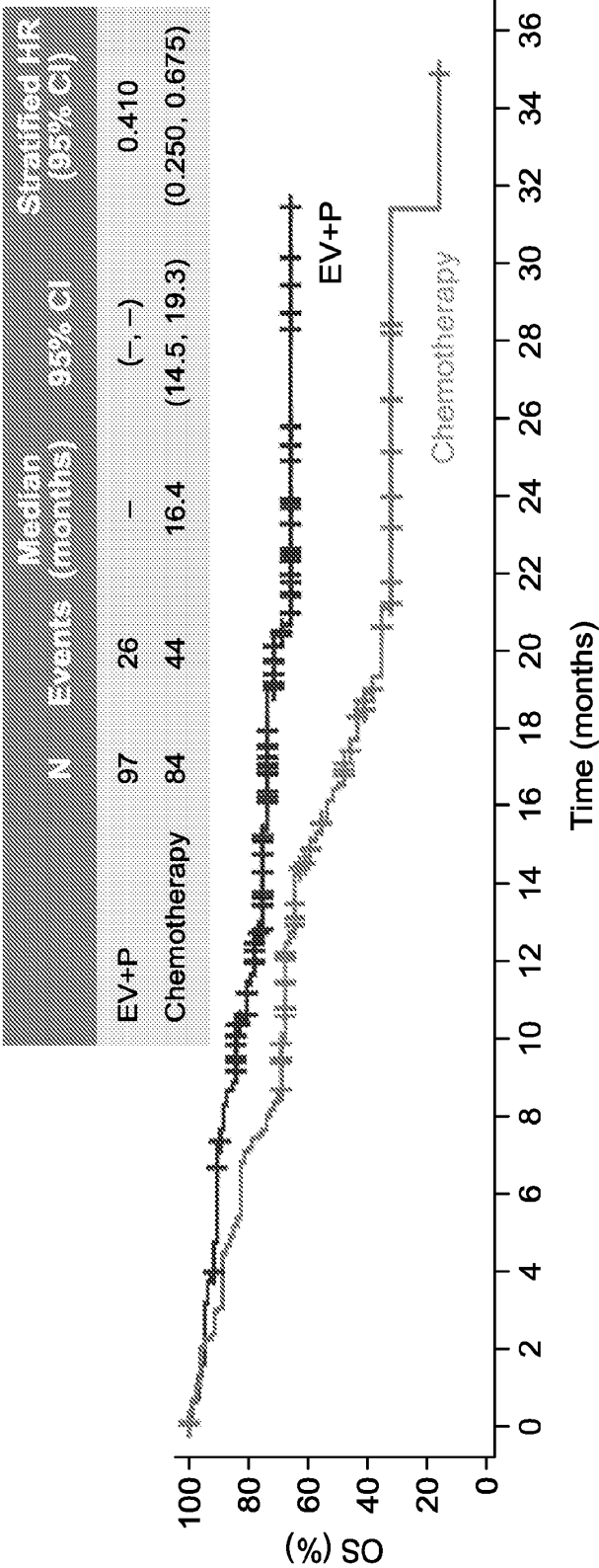


FIG. 75B

Consistent OS Benefit with EV+P Across Nectin-4
and PD-L1 Subgroups

Nectin-4 H-score ≥275 / PD-L1 Low



No. at risk																	
EV+P	97	92	88	87	83	74	60	51	46	35	28	17	9	5	5	2	
Chemotherapy	84	78	72	67	59	51	46	38	28	19	12	8	6	5	4	2	1

FIG. 75C

Consistent OS Benefit with EV+P Across Nectin-4
and PD-L1 Subgroups

Nectin-4 H-score ≥275 / PD-L1 High

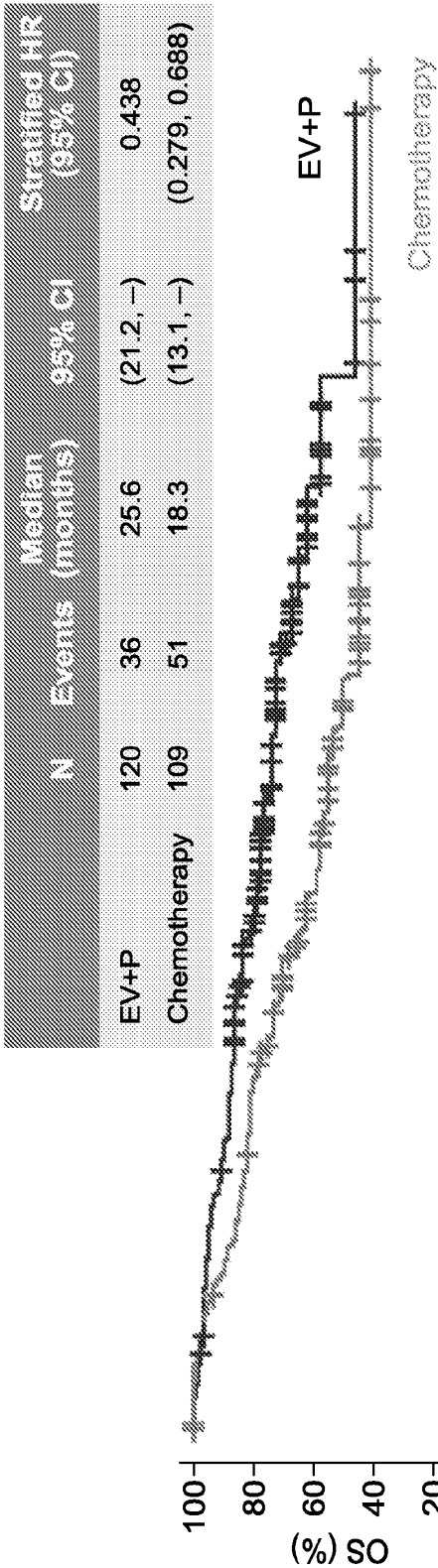


FIG. 75D