



Supplementary files

Gilteritinib (XOSPATA®) in Turkey: Early Access Program Results

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Supplementary Tables

Supplementary Table 1. Side effects with gilteritinib response status

Gilteritinib response (Presence of progression)		Total (n=17)	No (n=11)	Yes (n=6)	
		n (%)	n (%)	n (%)	
Febrile neutropenia	No	13 (76.5)	9 (81.8)	4 (66.7)	0.58
	Yes	4 (23.5)	2 (18.2)	2 (33.3)	
Anemia	No	10 (58.8)	6 (54.5)	4 (66.7)	0.99
	Yes	7 (41.2)	5 (45.5)	2 (33.3)	
Transaminase increase	No	12 (70.6)	7 (63.6)	5 (83.3)	0.6
	Yes	5 (29.4)	4 (36.4)	1 (16.7)	
Hypokalemia	No	16 (94.1)	10 (90.9)	6 (100)	0.99
	Yes	1 (5.9)	1 (9.1)	-	
Thrombocytopenia	No	16 (94.1)	10 (90.9)	6 (100)	0.99
	Yes	1 (5.9)	1 (9.1)	-	
Hypokalemia	No	10 (58.8)	6 (54.5)	4 (66.7)	0.99
	Yes	7 (41.2)	5 (45.5)	2 (33.3)	
ALP Increase	No	15 (88.2)	9 (81.8)	6 (100)	0.51
	Yes	2 (11.8)	2 (18.2)	-	
Nausea/vomiting	No	11 (64.7)	7 (63.6)	4 (66.7)	0.99
	Yes	6 (35.3)	4 (36.4)	2 (33.3)	
Constipation	No	16 (94.1)	10 (90.9)	6 (100)	0.99
	Yes	1 (5.9)	1 (9.1)	-	

Dyspnea	No	16 (94.1)	11 (100)	5 (83.3)	0.35
	Yes	1 (5.9)	-	1 (16.7)	
Peripheral edema	No	13 (76.5)	9 (81.8)	4 (66.7)	0.58
	Yes	4 (23.5)	2 (18.2)	2 (33.3)	
Headache	No	16 (94.1)	11 (100)	5 (83.3)	0.35
	Yes	1 (5.9)	-	1 (16.7)	
Cardiac	No	16 (94.1)	10 (90.9)	6 (100)	0.99
	Yes	1 (5.9)	1 (9.1)	-	
Hypomagnesaemia	No	15 (88.2)	10 (90.9)	5 (83.3)	0.99
	Yes	2 (11.8)	1 (9.1)	1 (16.7)	

ALP: Alkaline phosphatase

($p < 0.05$ significance) Student's t | Mann-Whitney U test, Chi-Square | Exact test

Supplementary Table 2. Comparison of survival curves (log-rank test) and hazard ratios with 95% confidence intervals

	Non-Progressive n (%)	Progressive n (%)	Median/Mean Survival (95% CI)	Hazard Ratio (95% CI)	Log Rank p value
Gender					
Male	4 (100)	0 (0)	813 (813-813)	-	0.11
Female	7 (53.85)	6 (46.15)	487 (285.7-690.3)		
Risk classification by genetics at initial diagnosis					
Intermediate	8 (61.54)	5 (38.46)	514 (313.9-714.9)	1.87 (0.31-11.39)	0.49
Adverse	3 (75)	1 (25)	762 (762-762)		
Presence of mutations other than FLT3					
Yes	4 (57.14)	3 (42.86)	562.3 (275.5-849.1)	1.49 (0.28-7.84)	0.64
No	7 (70)	3 (30)	583.8 (372.1-795.5)		
Number of previous treatment steps					
1-2	7 (58.33)	5 (41.67)	552.2 (363.6-740.8)	1.3 (0.15-10.95)	0.81
3-5	4 (80)	1 (20)	167.6 (110.8-224.4)		
Allogeneic transplantation in previous treatment					
Yes	2 (100)	0 (0)	200 (200-200)	-	0.44
No	9 (60)	6 (40)	540 (365.1-715.8)		
Induction therapy response					
No	5 (55.56)	4 (44.4)	552.9 (267.4-778.4)	2.52 (0.48-13.17)	0.27
Yes	6 (75)	2 (25)	638.3 (432.8-843.7)		
Pre-gilteritinib FLT3 exposure					
Yes	6 (75)	2 (25)	299.3 (204.3-394.2)	1.01 (0.14-7.01)	0.99
No	5 (55.56)	4 (44.44)	566.2 (355.1-777.4)		
Post-transplant gilteritinib maintenance					
No	9 (60)	6 (40)	508.2 (315.3-701.1)	-	0.27
Yes	2 (100)	0 (0)	716 (716-716)		
Febrile neutropenia					
Yes	2 (50)	2 (50)	88 (31-88)	4.86 (0.47-50.96)	0.19
No	9 (69.23)	4 (30.77)	762 (457-762)		
Anemia					
Yes	5 (71.43)	2 (28.57)	528.4 (308.4-748.4)	1.13 (0.18-7.02)	0.91

No	6 (60)	4 (40)	569.2 (365.9-772.5)		
Transaminase increase					
No	7 (58.33)	5 (41.67)	579 (338.8-819.2)	1.69 (0.25-11.34)	0.59
Yes	4 (80)	1 (20)	519.8 (315.5-724.1)		
Thrombocytopenia					
No	6 (60)	4 (40)	458.6 (218.1-699.1)	1.7 (0.34-8.6)	0.52
Yes	5 (71.43)	2 (28.57)	657.6 (389.6-925.6)		
Peripheral edema					
Yes	2 (50)	2 (50)	88 (31-88)	4.86 (0.46-50.96)	0.19
No	9 (69.23)	4 (30.77)	762 (457-762)		
Last status					
Ex	6 (60)	4 (40)	137.2 (88.3-186.1)	6.29 (0.87-45.25)	0.07
Alive	5 (71.43)	2 (28.57)	721.4 (602.1-840.7)		

FLT3: FMS-like tyrosine kinase 3

Supplementary Table 3. Comparison of survival curves (log-rank test) and hazard ratios with 95% confidence intervals

	EX n (%)	Non-EX n (%)	Median/Mean Survival (95% CI)	Hazard Ratio (95% CI)	Log Rank p value
Gender					
Male	3 (75)	1 (25)	117 (106-117)	1.61 (0.35-7.45)	0.54
Female	7 (53.85)	6 (46.15)	200 (88-200)		
Risk classification by genetics at initial diagnosis					
Intermediate	8 (61.54)	5 (38.46)	129 (88-149)	1.72 (0.45-6.68)	0.44
Adverse	2 (50)	2 (50)	200 (117-200)		
Presence of mutations other than FLT3					
Yes	6 (85.71)	1 (14.29)	226.1 (20.3-431.9)	3.23 (0.85-12.32)	0.09
No	4 (40)	6 (60)	514.5 (288.3-740.6)		
Number of previous treatment steps					
3-5	6 (50)	6 (50)	149 (31-149)	1.83 (0.45-7.46)	0.41
1-2	4 (80)	1 (20)	129 (89-200)		
Allogeneic transplantation in previous treatment					
Yes	1 (50)	1 (50)	200	1.47 (0.25-8.64)	0.67
No	9 (60)	6 (40)	129 (88-149)		
Induction therapy response					
No	7 (77.78)	2 (22.22)	112.2 (62.8-502.7)	2.45 (0.7-8.58)	0.16
Yes	3 (37.5)	5 (62.5)	547.1 (309.2-785.1)		
Pre-gilteritinib FLT3 exposure					
Yes	6 (75)	2 (25)	172.7 (98.6-246.7)	1.91 (0.54-6.82)	0.32
No	4 (44.44)	5 (55.56)	534.6 (263.2-805.8)		
Post-transplant gilteritinib maintenance					
Yes	0 (0)	2 (100)	716	-	0.14
No	10 (66.7)	5 (33.33)	355.2 (160.9-549.6)		
Febrile neutropenia					
Yes	4 (100)	0 (0)	96.25 (47.1-145.4)	7.36 (1.26-43.05)	0.03
No	6 (46.5)	7 (53.85)	530.5 (310.8-750.2)		
Anemia					
Yes	5 (71.43)	2 (28.57)	149 (31-200)	1.62 (0.45-5.86)	0.46

No	5 (50)	5 (50)	129 (21-129)		
Transaminase increase					
No	7 (58.33)	5 (41.67)	117 (88-129)	1.24 (0.33-4.67)	0.75
Yes	3 (60)	2 (40)	200 (31-200)		
Thrombocytopenia					
No	7 (70)	3 (30)	310 (106.1-515.2)	2.24 (0.63-7.96)	0.21
Yes	3 (42.86)	4 (57.14)	529.7 (221.2-838.2)		
Peripheral edema					
Yes	4 (100)	0 (0)	93.5 (45.6-141.4)	10.47 (1.64-66.82)	0.01
No	6 (46.15)	7 (53.85)	531.3 (312.1-750.5)		

FLT3: FMS-like tyrosine kinase 3