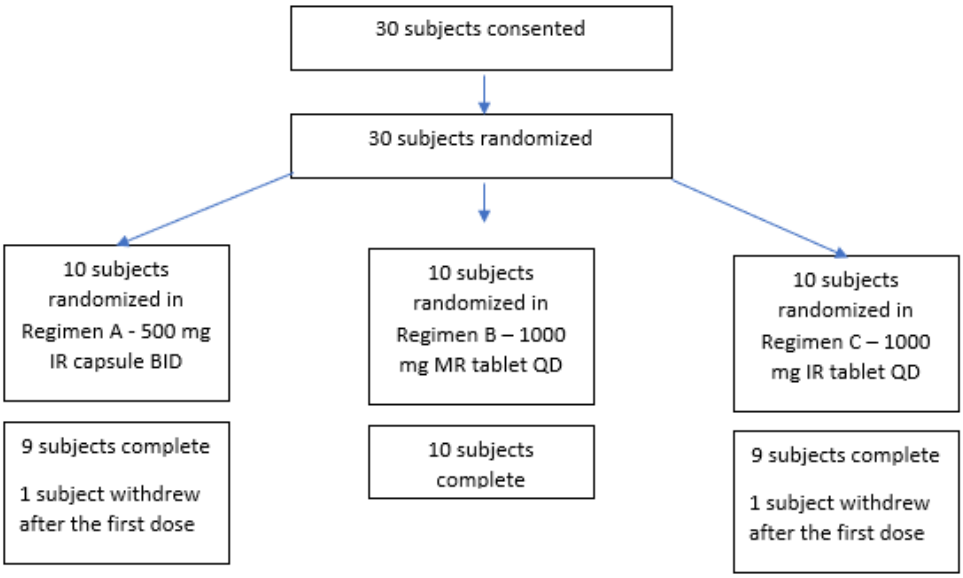
Participants flow :



Demographics:

Table 5 Demographic Characteristics: Safety Analysis Set

		500 mg IR capsule BID (N=10)	1000 mg MR tablet QD (N=10)	1000 mg IR tablet QD (N=10)
Age (years)	Mean	37.8	44.0	33.7
	SD	9.4	9.2	9.7
	Median	38.5	43.5	33.0
	Min	23	26	22
	Max	51	54	49
	n	10	10	10
Ethnicity n (%)	Not Hispanic or Latino	10 (100)	9 (90.0)	10 (100)
	Hispanic or Latino	0	1 (10.0)	0
Race n (%)	Asian	0	2 (20.0)	1 (10.0)
	Black or African American	0	1 (10.0)	2 (20.0)
	White	10 (100)	6 (60.0)	7 (70.0)
	Other	0	1 (10.0)	0
Sex n (%)	Male	10 (100)	10 (100)	10 (100)
Height (cm)	Mean	179.5	173.8	176.5
	SD	7.8	7.2	6.2
	Median	178.0	175.0	176.5
	Min	170	160	167
	Max	197	186	188
	n	10	10	10
Weight (cm)	Mean	83.73	78.34	82.86
	SD	11.28	8.19	12.20
	Median	84.40	78.10	82.90
	Min	68.7	67.6	66.0
	Max	108.0	90.6	100.6
	n	10	10	10
BMI (kg/m²)	Mean	25.93	25.94	26.56
	SD	2.52	2.44	3.27
	Median	26.15	26.10	27.40
	Min	21.6	22.3	20.1
	Max	29.2	29.2	30.0
	n	10	10	10

BMI: body mass index. Source: Table 14.1.3, dated 16 Oct 2020 09:01.

Main results :

Table 47: Main PK parameters of QGC001 from study QGC001/1QG5

Formulation Dose	Day 1			Day 7		
	IR capsules 500 mg BID	MR tablets 1000 mg QD	IR tablets 1000 mg QD	IR capsules 500 mg BID	MR tablets 1000 mg QD	IR tablets 1000 mg QD
T_{max} (h)	4.00 (0.50-4.02) [n=10]	3.01 (1.00-6.00) [n=10]	0.50 (0.50-6.00) [n=10]	4.00 (2.00-6.00) [n=9]	4.00 (1.00-6.00) [n=10]	1.02 (1.00-4.10) [n=9]
C_{max} (ng/mL)	41.7 (92.5) [n=10]	40.4 (76.6) [n=10]	60.0 (78.9) [n=10]	56.5 (58.8) [n=9]	62.8 (96.1) [n=10]	75.2 (57.6) [n=9]
AUC_{0-4} (ng.h/mL)	81.2 (78.4) [n=10]	79.1 (51.4) [n=9]	116.2 (59.4) [n=10]	118 (42.5) [n=9]	86.3 (66.1) [n=10]	191 (49.4) [n=8]
AUC_{0-12} (ng.h/mL)	156 (97.5) [n=4]	201 (95.5) [n=4]	195 (66.0) [n=8]	288 (71.8) [n=5]	320 (90.1) [n=5]	366 (45.6) [n=8]
AUC_{0-24} (ng.h/mL)	NC	211 (94.1) [n=4]	219 (70.8) [n=8]	NC	335 (89.6) [n=5]	384 (43.6) [n=8]
AUC_{0-tau} (ng.h/mL)	156 (97.5) [n=4]	211 (94.1) [n=4]	219 (70.8) [n=8]	288 (71.8) [n=5]	335 (89.6) [n=5]	384 (43.6) [n=8]
$AUC_{0-24est}$ (ng.h/mL)	NC	-	-	576 (71.8) [n=5]	NC	NC
$t_{1/2}$ (h)	NC	NC	NC	1.83 (19.2) [n=4]	1.78 (23.0) [n=4]	2.34 (37.9) [n=6]
AR C_{max}	-	-	-	1.39 (53.6) [n=9]	1.55 (76.0) [n=10]	1.45 (30.5) [n=9]
AR AUC	-	-	-	0.94 (37.1) [n=2]	1.28 (78.4) [n=3]	1.83 (65.1) [n=6]

PK parameters are expressed as geometric mean (CV%) values except T_{max} which expressed as median [min;max] values. AUC_{0-tau} represents the area under the curve over the dosing interval from time 0 to tau (0 to 12 h for IR 500 mg capsules BID and 0 to 24 h for IR and MR 1000 mg tablets QD). $AUC_{0-24est}$ was calculated for IR formulation only and corresponds to $2*AUC_{0-12}$. AR C_{max} and AR AUC are the accumulation ratio for Day 1 vs Day 7 based on C_{max} or AUC respectively. NC = not calculated.

Safety :

	500 mg IR capsule BID (N=10)		1000 mg MR tablet QD (N=10)		1000 mg IR tablet QD (N=10)	
	n (%)	Events n	n (%)	Events n	n (%)	Events n
Subjects reporting TEAEs	3 (30.0)	8	3 (30.0)	4	5 (50.0)	10
Skin and subcutaneous tissue disorders	2 (20.0)	2	0	0	4 (40.0)	6
Pruritus	0	0	0	0	3 (30.0)	3
Rash	1 (10.0)	1	0	0	1 (10.0)	1
Rash maculo-papular	1 (10.0)	1	0	0	1 (10.0)	1
Erythema	0	0	0	0	1 (10.0)	1
Gastrointestinal disorders	1 (10.0)	2	1 (10.0)	1	2 (20.0)	3
Abdominal pain upper	0	0	1 (10.0)	1	1 (10.0)	1
Diarrhoea	0	0	0	0	1 (10.0)	2
Nausea	1 (10.0)	2	0	0	0	0
Nervous system disorders	2 (20.0)	4	2 (20.0)	2	0	0
Headache	2 (20.0)	4	1 (10.0)	1	0	0
Tension headache	0	0	1 (10.0)	1	0	0
General disorders and administration site conditions	0	0	1 (10.0)	1	1 (10.0)	1
Chest discomfort	0	0	1 (10.0)	1	0	0
Feeling hot	0	0	0	0	1 (10.0)	1

Subjects in Cohorts 1, 2 and 3 were to receive firibastat (QGC001) for 7 days as 500 mg IR capsule BID, 1000 mg MR tablet QD and 1000 mg IR tablet QD, respectively.
Source: data taken from Table 14.3.2, dated 16 Oct 2020 09:01.