

Listing 16.2.8.1.7: Treatment-Emergent Marked Laboratory Abnormalities
All Randomized Analysis Set

Lab	Test	Date of Collection		Time	Analysis		Lab	Normal	Fasting	Toxi-
Type	Name	(Study Day)	(hh:mm)	Visit	Visit	Result	Unit	Range	Status	city Flag
Participant ID = 00031-10072		Treatment = BIC 75 mg plus LEN 50 mg		Age/Sex/Race/Ethnicity = 70/M/WH/H						
First Dose = 2022-12-05		Last Dose (Study Day) = Ongoing								
Chemistry	Serum Glucose (Nonfasting)	2023-05-25 (172)	10:15	Unscheduled Week 24		251 (H)	mg/dL	70 - 100	No	G3 *^#
Participant ID = 00407-10018		Treatment = BIC 75 mg plus LEN 25 mg		Age/Sex/Race/Ethnicity = 62/M/WH/H						
First Dose = 2022-10-12		Last Dose (Study Day) = Ongoing								
Chemistry	Serum Glucose (Nonfasting)	2022-09-15 (-27)	14:11	Screening	Baseline	72	mg/dL	70 - 100	No	G0
		2022-11-07 (27)	8:04	Week 4	Week 4	295 (H)	mg/dL	70 - 100	No	G3 *^#
		2022-11-28 (48)	8:24	Unscheduled	Week 4	149 (H)	mg/dL	70 - 100	No	G1 ^
		2022-12-09 (59)	9:11	Unscheduled	Week 12	153 (H)	mg/dL	70 - 100	No	G1 ^
Urinalysis	Urine Glucose	2022-09-15 (-27)	14:11	Screening	Baseline	Trace (H)		NA	No	G1
		2022-10-12 (1)	8:48	Day 1	Baseline	Normal		NA	Yes	G0
		2022-11-07 (27)	8:04	Week 4	Week 4	+4 (H)		NA	No	G3 *^#
		2022-11-28 (48)	8:24	Unscheduled	Week 4	Normal		NA	No	G0
		2022-12-09 (59)	9:11	Unscheduled	Week 12	Normal		NA	No	G0
		2023-01-04 (85)	8:50	Week 12	Week 12	Normal		NA	Yes	G0
		2023-03-28 (168)	9:02	Week 24	Week 24	+3 (H)		NA	Yes	G3 *^#
		2023-06-21 (253)	11:13	Week 36	Week 36	Normal		NA	Yes	G0
Participant ID = 00991-10032		Treatment = SBR		Age/Sex/Race/Ethnicity = 54/M/WH/NH						
First Dose = 2022-10-26		Last Dose (Study Day) = Ongoing								
Urinalysis	Urine Glucose	2022-10-03 (-23)	9:55	Screening	Baseline	+1 (H)		NA	Yes	G1

AS = Asian; BL = Black; F = Female; M = Male; NA = Not Available; (N)H = (Not) Hispanic; NP = Not Permitted; OT = Other; SBR = stable baseline regimen; WH = White. GX = Grade X; H = high; L = low. Severity grades were defined by the Division of AIDS (DAIDS) Toxicity Grading Scale, Version 2.1. Day was the number of study days relative to the date of study Day 1. \$ Imputed last dose date when completely or partially missing. A treatment-emergent marked laboratory abnormality was defined as an increase of at least 3 toxicity grades from baseline at any postbaseline time point, up to and including the last dose date plus 60 days in BIC+LEN groups (or plus 30 days in SBR group). The "Toxicity Flag" includes the toxicity grade and the abnormal characterization, denoted by the following symbols:
^=Treatment-emergent laboratory abnormality;#Treatment-emergent marked laboratory abnormality;*=Maximum postbaseline toxicity grade for a given test.

Data Extracted: CRF Data: 22AUG2023, Lab Data: 22AUG2023, PK Data: 22AUG2023

Source: .../wk_24_p2/version2/prog/l-lbtox.sas v9.4 Output file: l-lbtox-mark.pdf 12APR2024: 9:02

Listing 16.2.8.1.7: Treatment-Emergent Marked Laboratory Abnormalities
All Randomized Analysis Set

Lab	Test	Date of Collection		Time	Analysis	Lab		Normal	Fasting	Toxi-	
Type	Name	(Study Day)	(hh:mm)	Visit	Visit	Result	Unit	Range	Status	city	
										Flag	
Urinalysis	Urine Glucose	2022-10-26 (1)	8:05	Day 1	Baseline	Normal		NA	Yes	G0	
		2022-11-21 (27)	9:06	Week 4	Week 4	+3 (H)		NA	No	G3	^*#
		2022-11-28 (34)	8:40	Unscheduled	Week 4	Normal		NA	No	G0	
		2023-01-18 (85)	7:48	Week 12	Week 12	Normal		NA	Yes	G0	
		2023-04-12 (169)	7:58	Week 24	Week 24	Normal		NA	Yes	G0	
		2023-07-05 (253)	7:55	Week 36	Week 36	+1 (H)		NA	Yes	G1	^
Participant ID = 01598-10015 Treatment = BIC 75 mg plus LEN 50 mg Age/Sex/Race/Ethnicity = 66/M/WH/H											
First Dose = 2022-10-11 Last Dose (Study Day) = Ongoing											
Urinalysis	Urine Glucose	2022-09-08 (-33)	10:10	Screening	Baseline	Normal		NA	Yes	G0	
		2022-10-11 (1)	9:00	Day 1	Baseline	Normal		NA	Yes	G0	
		2022-11-08 (29)	9:00	Week 4	Week 4	+4 (H)		NA	Yes	G3	^*#
		2023-01-03 (85)	9:12	Week 12	Week 12	+4 (H)		NA	Yes	G3	^*#
		2023-03-30 (171)	9:30	Week 24	Week 24	+4 (H)		NA	Yes	G3	^*#
		2023-06-20 (253)	9:15	Week 36	Week 36	+4 (H)		NA	Yes	G3	^*#
Participant ID = 01966-10022 Treatment = BIC 75 mg plus LEN 50 mg Age/Sex/Race/Ethnicity = 61/M/WH/NH											
First Dose = 2022-10-17 Last Dose (Study Day) = Ongoing											
Chemistry	Lipase	2022-09-15 (-32)	9:00	Screening	Baseline	202 (H)	U/L	0 - 120	Yes	G2	
		2022-10-17 (1)	8:31	Day 1	Baseline	71	U/L	0 - 120	Yes	G0	
		2022-11-15 (30)	8:42	Week 4	Week 4	75	U/L	0 - 120	Yes	G0	
		2023-01-10 (86)	8:25	Week 12	Week 12	51	U/L	0 - 120	Yes	G0	
		2023-04-10 (176)	8:40	Week 24	Week 24	75	U/L	0 - 120	Yes	G0	

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Lab Type	Test Name	Date of Collection (Study Day)	Time (hh:mm)	Visit	Analysis Visit	Lab Result	Unit	Normal Range	Fasting Status	Toxi-city Flag
Chemistry	Lipase	2023-06-26 (253)	8:40	Week 36	Week 36	420 (H)	U/L	0 - 120	Yes	G3 **^#
Participant ID = 02058-10029 Treatment = BIC 75 mg plus LEN 25 mg Age/Sex/Race/Ethnicity = 59/M/WH/NH First Dose = 2022-10-24 Last Dose (Study Day) = Ongoing										
Chemistry	Lipase	2022-09-28 (-26)	14:49	Screening	Baseline	165 (H)	U/L	0 - 100	No	G2
		2022-10-24 (1)	9:49	Day 1	Baseline	78	U/L	0 - 100	No	G0
		2022-11-15 (23)	8:55	Week 4	Week 4	173 (H)	U/L	0 - 100	Yes	G2 ^
		2023-01-16 (85)	8:56	Week 12	Week 12	364 (H)	U/L	0 - 100	Yes	G3 **^#
		2023-04-04 (163)	9:42	Week 24	Week 24	78	U/L	0 - 100	Yes	G0
		2023-06-27 (247)	8:30	Week 36	Week 36	74	U/L	0 - 100	Yes	G0
Participant ID = 02106-10009 Treatment = BIC 75 mg plus LEN 50 mg Age/Sex/Race/Ethnicity = 64/F/BL/NH First Dose = 2022-09-29 Last Dose (Study Day) = Ongoing										
Urinalysis	Urine Glucose	2022-09-14 (-15)	11:48	Screening	Baseline	Normal		NA	No	G0
		2022-09-29 (1)	10:08	Day 1	Baseline	Normal		NA	Yes	G0
		2022-10-27 (29)	9:07	Week 4	Week 4	Normal		NA	Yes	G0
		2022-12-19 (82)	11:24	Week 12	Week 12	Normal		NA	Yes	G0
		2023-03-13 (166)	10:35	Week 24	Week 24	+3 (H)		NA	Yes	G3 **^#
		2023-06-12 (257)	10:50	Week 36	Week 36	+4 (H)		NA	Yes	G3 **^#
Participant ID = 02728-10065 Treatment = BIC 75 mg plus LEN 25 mg Age/Sex/Race/Ethnicity = 58/M/AS/NH First Dose = 2022-11-18 Last Dose (Study Day) = Ongoing										

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Lab Type	Test Name	Date of Collection (Study Day)	Time (hh:mm)	Visit	Analysis Visit	Lab Result	Unit	Normal Range	Fasting Status	Toxicity Flag
Chemistry	Serum Glucose (Nonfasting)	2023-05-04 (168)	10:00	Unscheduled	Week 24	255 (H)	mg/dL	70 - 100	No	G3 *^#
Participant ID = 04170-10110 Treatment = SBR Age/Sex/Race/Ethnicity = 65/M/WH/NH First Dose = 2023-01-11 Last Dose (Study Day) = Ongoing										
Chemistry	Creatinine Clearance	2022-11-29 (-43)	10:40	Screening	Baseline	87.6	mL/min	85 - 125	Yes	G2
		2023-01-11 (1)	11:35	Day 1	Baseline	103.0	mL/min	85 - 125	Yes	G0
		2023-02-09 (30)	10:10	Week 4	Week 4	80.6 (L)	mL/min	85 - 125	Yes	G2 ^
		2023-04-06 (86)	15:50	Week 12	Week 12	87.6	mL/min	85 - 125	Yes	G2 ^
		2023-06-29 (170)	15:10	Week 24	Week 24	71.4 (L)	mL/min	85 - 125	Yes	G3 *^#
Participant ID = 25207-10043 Treatment = BIC 75 mg plus LEN 50 mg Age/Sex/Race/Ethnicity = 72/M/WH/NP First Dose = 2022-11-03 Last Dose (Study Day) = Ongoing										
Urinalysis	Urine Glucose	2022-10-31 (-3)	11:00	Screening	Baseline	Trace (H)		NA	Yes	G1
		2022-11-03 (1)	10:25	Day 1	Baseline	Normal		NA	Yes	G0
		2022-12-01 (29)	10:30	Week 4	Week 4	+4 (H)		NA	No	G3 *^#
		2023-01-26 (85)	7:00	Week 12	Week 12	+4 (H)		NA	Yes	G3 *^#
		2023-04-21 (170)	8:45	Week 24	Week 24	+4 (H)		NA	Yes	G3 *^#
		2023-07-17 (257)	11:00	Week 36	Week 36	+4 (H)		NA	Yes	G3 *^#
Participant ID = 25207-10105 Treatment = BIC 75 mg plus LEN 50 mg Age/Sex/Race/Ethnicity = 62/M/WH/NH First Dose = 2023-01-09 Last Dose (Study Day) = 2023-05-02 (114)										
Urinalysis	Urine Glucose	2022-12-08 (-32)	13:20	Screening	Baseline	+3 (H)		NA	Yes	G3

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Lab Type	Test Name	Date of Collection (Study Day)	Time (hh:mm)	Visit	Analysis Visit	Lab Result	Unit	Normal Range	Fasting Status	Toxi-city Flag
Urinalysis	Urine Glucose	2023-01-09 (1)	8:30	Day 1	Baseline	Normal		NA	Yes	G0
		2023-02-07 (30)	9:45	Week 4	Week 4	+3 (H)		NA	Yes	G3 *^#
		2023-04-04 (86)	10:15	Week 12	Week 12	+2 (H)		NA	Yes	G2 ^
		2023-05-04 (116)	9:15	ESDD	Week 12	+4 (H)		NA	Yes	G3 *^#
Participant ID = 25508-10083 Treatment = BIC 75 mg plus LEN 25 mg Age/Sex/Race/Ethnicity = 53/F/WH/NH										
First Dose = 2022-12-14 Last Dose (Study Day) = Ongoing										
Chemistry	Serum Glucose (Nonfasting)	2023-01-11 (29)	10:31	Week 4	Week 4	275 (H)	mg/dL	70 - 100	No	G3 *^#
		2023-03-07 (84)	10:15	Week 12	Week 12	160 (H)	mg/dL	70 - 100	No	G1 ^

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