
Limitations and Caveats

Description	

Adverse Events

Time Frame	up to 22.7 months
Adverse Event Reporting Description	SAF included all participants, who were administered any dose of any study intervention. Participants who were randomized to Placebo + IMRT but who were incorrectly administered any dose of Xevinapant were analyzed in the Xevinapant + IMRT group.
Source Vocabulary for Table Default	MedDRA version 27.0
Collection Approach for Table Default	Non-systematic Assessment

All-Cause Mortality

	Xevinapant + IMRT Participants received 3 cycles of oral solution of Xevinapant at a dose of 200 milligrams per day (mg/day) once daily from Day 1 to 14, per 3-week cycle in combination with 66 Gray (Gy) of intensity modulated radiation therapy (IMRT) in 33 fractions, 2 Gy/fraction, 5 days/week followed by 3 cycles of monotherapy of Xevinapant at a dose of 200 mg/day from Day 1 to 14, per 3-week cycle (Each cycle is of 3 weeks).	**Placebo + IMRT** Participants received 3 cycles of oral solution of placebo matched to Xevinapant once daily from Day 1 to 14 per 3-week cycle in combination with with 66 Gray (Gy) of intensity modulated radiation therapy (IMRT) in 33 fractions, 2 Gy/fraction, 5 days/week followed by 3 cycles of monotherapy of placebo matched to Xevinapant from Day 1 to 14, per 3-week cycle (Each cycle is of 3 weeks).
Total Number Affected	9	14
Total Number At Risk	82	83

Serious Adverse Events

	Xevinapant + IMRT Participants received 3 cycles of oral solution of Xevinapant at a dose of 200 milligrams per day (mg/day) once daily from Day 1 to 14, per 3-week cycle in combination with 66 Gray (Gy) of intensity modulated radiation therapy (IMRT) in 33 fractions, 2 Gy/fraction, 5 days/week followed by 3 cycles of monotherapy of Xevinapant at a dose of 200 mg/day from Day 1 to 14, per 3-week cycle (Each cycle is of 3 weeks).	**Placebo + IMRT** Participants received 3 cycles of oral solution of placebo matched to Xevinapant once daily from Day 1 to 14 per 3-week cycle in combination with with 66 Gray (Gy) of intensity modulated radiation therapy (IMRT) in 33 fractions, 2 Gy/fraction, 5 days/week followed by 3 cycles of monotherapy of placebo matched to Xevinapant from Day 1 to 14, per 3-week cycle (Each cycle is of 3 weeks).
Total # Affected by any Serious Adverse Event	19	15
Total # at Risk by any Serious Adverse Event	82	83

Gastrointestinal disorders

Mesenteric artery thrombosis[1]

MedDRA 27.0, Non-Systematic Assessment

Number of participants affected	0	1
Number of events	0	1
Number of participants at risk [blank=Total]	82 (0%) [82]	83 (1.2%) [83]

Oral pain[1]

MedDRA 27.0, Non-Systematic Assessment

Number of participants affected	1	0
Number of events	1	0
Number of participants at risk [blank=Total]	82 (1.22%) [82]	83 (0%) [83]

Stomatitis[1]

MedDRA 27.0, Non-Systematic Assessment

Number of participants affected	0	1
Number of events	0	1
Number of participants at risk [blank=Total]	82 (0%) [82]	83 (1.2%) [83]

General disorders and administration site conditions

Death[1]

MedDRA 27.0, Non-Systematic Assessment

Number of participants affected	1	0
Number of events	1	0
Number of participants at risk [blank=Total]	82 (1.22%) [82]	83 (0%) [83]

Device related thrombosis[1]

MedDRA 27.0, Non-Systematic Assessment

Number of participants affected	0	1
Number of events	0	1
Number of participants at risk [blank=Total]	82 (0%) [82]	83 (1.2%) [83]

Disease progression[1]

MedDRA 27.0, Non-Systematic Assessment

Number of participants affected	0	1
Number of events	0	1
Number of participants at risk [blank=Total]	82 (0%) [82]	83 (1.2%) [83]

General physical health deterioration[1]

MedDRA 27.0, Non-Systematic Assessment

Number of participants affected	1	0
Number of events	1	0
Number of participants at risk [blank=Total]	82 (1.22%) [82]	83 (0%) [83]

Pain[1]

MedDRA 27.0, Non-Systematic Assessment

Number of participants affected	0	1
Number of events	0	1
Number of participants at risk [blank=Total]	82 (0%) [82]	83 (1.2%) [83]

Infections and infestations

Abscess jaw[1]

MedDRA 27.0, Non-Systematic Assessment

Number of participants affected	0	1
Number of events	0	1
Number of participants at risk [blank=Total]	82 (0%) [82]	83 (1.2%) [83]

Cellulitis[1]

MedDRA 27.0, Non-Systematic Assessment

Number of participants affected	1	0
Number of events	1	0
Number of participants at risk [blank=Total]	82 (1.22%) [82]	83 (0%) [83]

COVID-19[1]

MedDRA 27.0, Non-Systematic Assessment

Number of participants affected	1	0
Number of events	1	0
Number of participants at risk [blank=Total]	82 (1.22%) [82]	83 (0%) [83]

Enteritis infectious[1]

MedDRA 27.0, Non-Systematic Assessment

Number of participants affected	0	1
Number of events	0	1
Number of participants at risk [blank=Total]	82 (0%) [82]	83 (1.2%) [83]

Mucosal infection[1]

MedDRA 27.0, Non-Systematic Assessment

Number of participants affected	0	1
Number of events	0	1
Number of participants at risk [blank=Total]	82 (0%) [82]	83 (1.2%) [83]

Pneumonia[1]

MedDRA 27.0, Non-Systematic Assessment

Number of participants affected	5	3
Number of events	5	3
Number of participants at risk [blank=Total]	82 (6.1%) [82]	83 (3.61%) [83]

Pneumonia aspiration[1]

MedDRA 27.0, Non-Systematic Assessment

Number of participants affected	3	0
Number of events	3	0
Number of participants at risk [blank=Total]	82 (3.66%) [82]	83 (0%) [83]

Sepsis[1]

MedDRA 27.0, Non-Systematic Assessment

Number of participants affected	1	0
Number of events	1	0
Number of participants at risk [blank=Total]	82 (1.22%) [82]	83 (0%) [83]

Urethritis[1]

MedDRA 27.0, Non-Systematic Assessment

Number of participants affected	1	0
Number of events	1	0
Number of participants at risk [blank=Total]	82 (1.22%) [82]	83 (0%) [83]

Vascular device infection[1]

MedDRA 27.0, Non-Systematic Assessment

Number of participants affected	0	1
Number of events	0	1
Number of participants at risk [blank=Total]	82 (0%) [82]	83 (1.2%) [83]

Wound infection[1]

MedDRA 27.0, Non-Systematic Assessment

Number of participants affected	0	1
Number of events	0	2
Number of participants at risk [blank=Total]	82 (0%) [82]	83 (1.2%) [83]

Investigations

Weight decreased[1]

MedDRA 27.0, Non-Systematic Assessment

Number of participants affected	1	0
Number of events	1	0
Number of participants at risk [blank=Total]	82 (1.22%) [82]	83 (0%) [83]

Metabolism and nutrition disorders

Decreased appetite[1]

MedDRA 27.0, Non-Systematic Assessment

Number of participants affected	2	1
Number of events	2	1
Number of participants at risk [blank=Total]	82 (2.44%) [82]	83 (1.2%) [83]

Hypoalbuminaemia[1]

MedDRA 27.0, Non-Systematic Assessment

Number of participants affected	0	1
Number of events	0	1
Number of participants at risk [blank=Total]	82 (0%) [82]	83 (1.2%) [83]

Hypokalaemia[1]

MedDRA 27.0, Non-Systematic Assessment

Number of participants affected	1	0
Number of events	1	0
Number of participants at risk [blank=Total]	82 (1.22%) [82]	83 (0%) [83]

Hyponatraemia[1]

MedDRA 27.0, Non-Systematic Assessment

Number of participants affected	1	0
Number of events	1	0
Number of participants at risk [blank=Total]	82 (1.22%) [82]	83 (0%) [83]

Marasmus[1]

MedDRA 27.0, Non-Systematic Assessment

Number of participants affected	0	1
Number of events	0	1
Number of participants at risk [blank=Total]	82 (0%) [82]	83 (1.2%) [83]

Neoplasms benign, malignant and unspecified (incl cysts and polyps)

Tumour haemorrhage[1]

MedDRA 27.0, Non-Systematic Assessment

Number of participants affected	0	1
Number of events	0	1
Number of participants at risk [blank=Total]	82 (0%) [82]	83 (1.2%) [83]

Nervous system disorders

Cerebrovascular accident[1]

MedDRA 27.0, Non-Systematic Assessment

Number of participants affected	1	1
Number of events	1	1
Number of participants at risk [blank=Total]	82 (1.22%) [82]	83 (1.2%) [83]

Cognitive disorder[1]

MedDRA 27.0, Non-Systematic Assessment

Number of participants affected	1	0
Number of events	1	0

Number of participants at risk [blank=Total]	82 (1.22%) [82]	83 (0%) [83]

Facial paralysis[1]

MedDRA 27.0, Non-Systematic Assessment

Number of participants affected	1	0
Number of events	1	0
Number of participants at risk [blank=Total]	82 (1.22%) [82]	83 (0%) [83]

Product issues

Device dislocation[1]

MedDRA 27.0, Non-Systematic Assessment

Number of participants affected	0	2
Number of events	0	2
Number of participants at risk [blank=Total]	82 (0%) [82]	83 (2.41%) [83]

Psychiatric disorders

Completed suicide[1]

MedDRA 27.0, Non-Systematic Assessment

Number of participants affected	1	0
Number of events	1	0
Number of participants at risk [blank=Total]	82 (1.22%) [82]	83 (0%) [83]

Renal and urinary disorders

Acute kidney injury[1]

MedDRA 27.0, Non-Systematic Assessment

Number of participants affected	1	0
Number of events	1	0
Number of participants at risk [blank=Total]	82 (1.22%) [82]	83 (0%) [83]

Renal failure[1]

MedDRA 27.0, Non-Systematic Assessment

Number of participants affected	1	0
Number of events	1	0
Number of participants at risk [blank=Total]	82 (1.22%) [82]	83 (0%) [83]

Respiratory, thoracic and mediastinal disorders

Asphyxia[1]

MedDRA 27.0, Non-Systematic Assessment

Number of participants affected	0	1
Number of events	0	1
Number of participants at risk [blank=Total]	82 (0%) [82]	83 (1.2%) [83]

Cough[1]

MedDRA 27.0, Non-Systematic Assessment

Number of participants affected	0	1
Number of events	0	1
Number of participants at risk [blank=Total]	82 (0%) [82]	83 (1.2%) [83]

Dyspnoea[1]

MedDRA 27.0, Non-Systematic Assessment

Number of participants affected	0	1
Number of events	0	1
Number of participants at risk [blank=Total]	82 (0%) [82]	83 (1.2%) [83]

Interstitial lung disease[1]

MedDRA 27.0, Non-Systematic Assessment

Number of participants affected	1	0
Number of events	1	0
Number of participants at risk [blank=Total]	82 (1.22%) [82]	83 (0%) [83]

Vascular disorders

Hypovolaemic shock[1]

MedDRA 27.0, Non-Systematic Assessment

Number of participants affected	0	1
Number of events	0	1
Number of participants at risk [blank=Total]	82 (0%) [82]	83 (1.2%) [83]

†	Events were collected by systematic assessment
1	Term from vocabulary, MedDRA 27.0
2	Term from vocabulary, MedDRA version 27.0

Other Adverse Events

Frequency Threshold for reporting Other Adverse Events: 5

	Xevinapant + IMRT Participants received 3 cycles of oral solution of Xevinapant at a dose of 200 milligrams per day (mg/day) once daily from Day 1 to 14, per 3-week cycle in combination with 66 Gray (Gy) of intensity modulated radiation therapy (IMRT) in 33 fractions, 2 Gy/fraction, 5 days/week followed by 3 cycles of monotherapy of Xevinapant at a dose of 200 mg/day from Day 1 to 14, per 3-week cycle (Each cycle is of 3 weeks).	**Placebo + IMRT** Participants received 3 cycles of oral solution of placebo matched to Xevinapant once daily from Day 1 to 14 per 3-week cycle in combination with with 66 Gray (Gy) of intensity modulated radiation therapy (IMRT) in 33 fractions, 2 Gy/fraction, 5 days/week followed by 3 cycles of monotherapy of placebo matched to Xevinapant from Day 1 to 14, per 3-week cycle (Each cycle is of 3 weeks).
Total # Affected by any Other Adverse Event	81	81
Total # at Risk by any Other Adverse Event	82	83

Blood and lymphatic system disorders

Anaemia[1]

MedDRA 27.0, Non-Systematic Assessment

Number of participants affected	20	8
Number of events	24	8
Number of participants at risk [blank=Total]	82 (24.39%) [82]	83 (9.64%) [83]

Lymphopenia[1]

MedDRA 27.0, Non-Systematic Assessment

Number of participants affected	13	11
Number of events	17	11
Number of participants at risk [blank=Total]	82 (15.85%) [82]	83 (13.25%) [83]

Gastrointestinal disorders

Constipation[1]

MedDRA 27.0, Non-Systematic Assessment

Number of participants affected	11	17
Number of events	13	22
Number of participants at risk [blank=Total]	82 (13.41%) [82]	83 (20.48%) [83]

Dry mouth[1]

MedDRA 27.0, Non-Systematic Assessment

Number of participants affected	23	27
Number of events	23	30
Number of participants at risk [blank=Total]	82 (28.05%) [82]	83 (32.53%) [83]

Dysphagia[1]

MedDRA 27.0, Non-Systematic Assessment

Number of participants affected	17	10
Number of events	18	11
Number of participants at risk [blank=Total]	82 (20.73%) [82]	83 (12.05%) [83]

Nausea[1]

MedDRA 27.0, Non-Systematic Assessment

Number of participants affected	14	9
Number of events	15	9
Number of participants at risk [blank=Total]	82 (17.07%) [82]	83 (10.84%) [83]

Odynophagia[1]

MedDRA 27.0, Non-Systematic Assessment

Number of participants affected	6	7
Number of events	8	7
Number of participants at risk [blank=Total]	82 (7.32%) [82]	83 (8.43%) [83]

Stomatitis[1]

MedDRA 27.0, Non-Systematic Assessment

Number of participants affected	20	18
Number of events	29	19
Number of participants at risk [blank=Total]	82 (24.39%) [82]	83 (21.69%) [83]

Vomiting[1]

MedDRA 27.0, Non-Systematic Assessment

Number of participants affected	6	7
Number of events	7	7
Number of participants at risk [blank=Total]	82 (7.32%) [82]	83 (8.43%) [83]

General disorders and administration site conditions

Asthenia[1]

MedDRA 27.0, Non-Systematic Assessment

Number of participants affected	11	7
Number of events	13	9
Number of participants at risk [blank=Total]	82 (13.41%) [82]	83 (8.43%) [83]

Localised oedema[1]

MedDRA 27.0, Non-Systematic Assessment

Number of participants affected	4	6
Number of events	5	6
Number of participants at risk [blank=Total]	82 (4.88%) [82]	83 (7.23%) [83]

Mucosal inflammation[1]

MedDRA 27.0, Non-Systematic Assessment

Number of participants affected	10	11
Number of events	12	12
Number of participants at risk [blank=Total]	82 (12.2%) [82]	83 (13.25%) [83]

Infections and infestations

Pneumonia[1]

MedDRA 27.0, Non-Systematic Assessment

Number of participants affected	4	7
Number of events	4	7
Number of participants at risk [blank=Total]	82 (4.88%) [82]	83 (8.43%) [83]

Injury, poisoning and procedural complications

Radiation mucositis[1]

MedDRA 27.0, Non-Systematic Assessment

Number of participants affected	18	17
Number of events	18	17

Number of participants at risk [blank=Total]	82 (21.95%) [82]	83 (20.48%) [83]

Radiation skin injury[1]

MedDRA 27.0, Non-Systematic Assessment

Number of participants affected	49	39
Number of events	55	39
Number of participants at risk [blank=Total]	82 (59.76%) [82]	83 (46.99%) [83]

Investigations

Alanine aminotransferase increased[1]

MedDRA 27.0, Non-Systematic Assessment

Number of participants affected	13	1
Number of events	16	1
Number of participants at risk [blank=Total]	82 (15.85%) [82]	83 (1.2%) [83]

Amylase increased[1]

MedDRA 27.0, Non-Systematic Assessment

Number of participants affected	19	10
Number of events	25	10
Number of participants at risk [blank=Total]	82 (23.17%) [82]	83 (12.05%) [83]

Aspartate aminotransferase increased[1]

MedDRA 27.0, Non-Systematic Assessment

Number of participants affected	10	1
Number of events	16	1
Number of participants at risk [blank=Total]	82 (12.2%) [82]	83 (1.2%) [83]

Lipase increased[1]

MedDRA 27.0, Non-Systematic Assessment

Number of participants affected	15	2
Number of events	20	2
Number of participants at risk [blank=Total]	82 (18.29%) [82]	83 (2.41%) [83]

Lymphocyte count decreased[1]

MedDRA 27.0, Non-Systematic Assessment

Number of participants affected	23	13
Number of events	25	14
Number of participants at risk [blank=Total]	82 (28.05%) [82]	83 (15.66%) [83]

Weight decreased[1]

MedDRA 27.0, Non-Systematic Assessment

Number of participants affected	19	12
Number of events	20	15
Number of participants at risk [blank=Total]	82 (23.17%) [82]	83 (14.46%) [83]

White blood cell count decreased[1]

MedDRA 27.0, Non-Systematic Assessment

Number of participants affected	9	8
Number of events	14	9
Number of participants at risk [blank=Total]	82 (10.98%) [82]	83 (9.64%) [83]

Metabolism and nutrition disorders

Decreased appetite[1]

MedDRA 27.0, Non-Systematic Assessment

Number of participants affected	16	17
Number of events	16	17
Number of participants at risk [blank=Total]	82 (19.51%) [82]	83 (20.48%) [83]

Hyponatraemia[1]

MedDRA 27.0, Non-Systematic Assessment

Number of participants affected	7	4
Number of events	7	4
Number of participants at risk [blank=Total]	82 (8.54%) [82]	83 (4.82%) [83]

Nervous system disorders

Dysgeusia[1]

MedDRA 27.0, Non-Systematic Assessment

Number of participants affected	12	12
Number of events	13	12
Number of participants at risk [blank=Total]	82 (14.63%) [82]	83 (14.46%) [83]

Headache[1]

MedDRA 27.0, Non-Systematic Assessment

Number of participants affected	7	2
Number of events	7	3
Number of participants at risk [blank=Total]	82 (8.54%) [82]	83 (2.41%) [83]

Psychiatric disorders

Insomnia[1]

MedDRA 27.0, Non-Systematic Assessment

Number of participants affected	5	4
Number of events	5	5
Number of participants at risk [blank=Total]	82 (6.1%) [82]	83 (4.82%) [83]

Respiratory, thoracic and mediastinal disorders

Cough[1]

MedDRA 27.0, Non-Systematic Assessment

Number of participants affected	4	6

Number of events	5	6
Number of participants at risk [blank=Total]	82 (4.88%) [82]	83 (7.23%) [83]

Oropharyngeal pain[1]

MedDRA 27.0, Non-Systematic Assessment

Number of participants affected	5	8
Number of events	6	8
Number of participants at risk [blank=Total]	82 (6.1%) [82]	83 (9.64%) [83]

Skin and subcutaneous tissue disorders

Rash[1]

MedDRA 27.0, Non-Systematic Assessment

Number of participants affected	11	6
Number of events	14	6
Number of participants at risk [blank=Total]	82 (13.41%) [82]	83 (7.23%) [83]

†	Events were collected by systematic assessment
1	Term from vocabulary, MedDRA 27.0
2	Term from vocabulary, MedDRA version 27.0