表 2.7.4.7-20　死亡例の一覧表（PX-171-006）

Study	Treatment Group	Subject ID	Age/ Sex	Death Date	Number of Days from First Dose of Any Study Drug	Number of Days from Last Dose of Any Study Drug	Number of Days from Last Dose of Carfilzomib	Cause of Death Primary (Secondary)	Relationship to Study Treatment by Investigator	Relationship to Study Treatment by Sponsor	Fatal AE Preferred Term (AE Number)
Primary Safety Population: Carfilzomib Lenalidomide Dexamethasone (CRd) Combination and Control (Rd) 20/27 mg/m^2											
PX-171-006	Carfilzomib Lenalidomide Dexamethasone	PX171006-14-27-[redacted]	8[redacted]/ Female	21AUG20[redacted]	271	22	28	Progressive Disease (Adverse Event)	Possible		
		PX171006-14-28-[redacted]	6[redacted]/ Female	06JAN20[redacted]	45	9	9	Progressive Disease (Unknown)	None		疾患進行(11)
		PX171006-14-78-[redacted]	7[redacted]/ Female	27JAN20[redacted]	3	1	1	Other: Natural Causes (Other: Underlying Disease)	None		死亡(1)

AE=Adverse Event; CFZ=carfilzomib; DEX=Dexamethasone ; LEN=lenalidomide; mg/m2=milligram per meter squared.
Notes: MedDRA version 15.1 used for coding.
This listing Includes deaths that occurred less than or equal to 30 days of last dose.
Number of Days from First Dose of Any Study Drug= Death date-first dosing date of any study drug +1.
Number of Days from Last Dose of Any Study Drug /Carfilzomib= Death date- last dosing date of any study drug /Carfilzomib.
In studies PX-171-009, PX-171-011 and 2011-002, Relationship to Study Treatment by Investigator is based on relationship to study drugs of grade 5 TEAEs if primary cause of death is AE. In other studies, it is from death case report form.

出典［総括報告書5.3.5.2-10（PX-171-006），Listing 16.2.7.6］

表 2.7.4.7-21　死亡例の一覧表（PX-171-009）

Study	Treatment Group	Subject ID	Age/ Sex	Death Date	Number of Days from First Dose of Any Study Drug	Number of Days from Last Dose of Any Study Drug	Number of Days from Last Dose of Carfilzomib	Cause of Death Primary (Secondary)	Relationship to Study Treatment by Investigator	Relationship to Study Treatment by Sponsor	Fatal AE Preferred Term (AE Number)
Primary Safety Population: Carfilzomib Lenalidomide Dexamethasone (CRd) Combination and Control (Rd) 20/27 mg/m^2											
PX-171-009	Carfilzomib Lenalidomide Dexamethasone	PX171009-10-388-9[redacted]	6[redacted]/ Male	24JUL20[redacted]	49	1	5	Adverse Event	CFZ: No, DEX: No, LEN: No	CFZ: Yes, DEX: No, LEN: Yes	心筋梗塞(4)
		PX171009-12-858-9[redacted]	7[redacted]/ Male	31DEC20[redacted]	376	9	10	Adverse Event	CFZ: No, DEX: No, LEN: No	CFZ: No, DEX: No, LEN: No	心筋梗塞(33)
		PX171009-14-005-9[redacted]	7[redacted]/ Male	31JUL20[redacted]	352	1	1	Adverse Event	CFZ: Yes, DEX: No, LEN: Yes	CFZ: Yes, DEX: No, LEN: Yes	心停止(15)

AE=Adverse Event; CFZ=carfilzomib; DEX=Dexamethasone ; LEN=lenalidomide; mg/m2=milligram per meter squared.
Notes: MedDRA version 15.1 used for coding.
This listing Includes deaths that occurred less than or equal to 30 days of last dose.
Number of Days from First Dose of Any Study Drug= Death date-first dosing date of any study drug +1.
Number of Days from Last Dose of Any Study Drug /Carfilzomib= Death date- last dosing date of any study drug /Carfilzomib.
In studies PX-171-009, PX-171-011 and 2011-002, Relationship to Study Treatment by Investigator is based on relationship to study drugs of grade 5 TEAEs if primary cause of death is AE. In other studies, it is from death case report form.

表 2.7.4.7-21　死亡例の一覧（PX-171-009）（続き 1）

Study	Treatment Group	Subject ID	Age/ Sex	Death Date	Number of Days from First Dose of Any Study Drug	Number of Days from Last Dose of Any Study Drug	Number of Days from Last Dose of Carfilzomib	Cause of Death Primary (Secondary)	Relationship to Study Treatment by Investigator	Relationship to Study Treatment by Sponsor	Fatal AE Preferred Term (AE Number)
Primary Safety Population: Carfilzomib Lenalidomide Dexamethasone (CRd) Combination and Control (Rd) 20/27 mg/m^2											
PX-171-009	Carfilzomib Lenalidomide Dexamethasone	PX171009-14-027-9[redacted]	7[redacted]/ Male	07JUN20[redacted]	155	20	20	Adverse Event	CFZ: No, DEX: No, LEN: No	CFZ: No, DEX: No, LEN: No	心不全(13)
		PX171009-18-462-9[redacted]	4[redacted]/ Male	25AUG20[redacted]	37	2	7	Progressive Disease		CFZ: No, DEX: No, LEN: No	疾患進行(9)
		PX171009-22-530-9[redacted]	6[redacted]/ Male	06JAN20[redacted]	17	4	8	Adverse Event	CFZ: No, DEX: No, LEN: No	CFZ: No, DEX: No, LEN: No	多臓器不全(1)

AE=Adverse Event; CFZ=carfilzomib; DEX=Dexamethasone ; LEN=lenalidomide; mg/m2=milligram per meter squared.
Notes: MedDRA version 15.1 used for coding.
This listing Includes deaths that occurred less than or equal to 30 days of last dose.
Number of Days from First Dose of Any Study Drug= Death date-first dosing date of any study drug +1.
Number of Days from Last Dose of Any Study Drug /Carfilzomib= Death date- last dosing date of any study drug /Carfilzomib.
In studies PX-171-009, PX-171-011 and 2011-002, Relationship to Study Treatment by Investigator is based on relationship to study drugs of grade 5 TEAEs if primary cause of death is AE. In other studies, it is from death case report form.

表 2.7.4.7-21　死亡例の一覧（PX-171-009）（続き 2）

Study	Treatment Group	Subject ID	Age/ Sex	Death Date	Number of Days from First Dose of Any Study Drug	Number of Days from Last Dose of Any Study Drug	Number of Days from Last Dose of Carfilzomib	Cause of Death Primary (Secondary)	Relationship to Study Treatment by Investigator	Relationship to Study Treatment by Sponsor	Fatal AE Preferred Term (AE Number)
Primary Safety Population: Carfilzomib Lenalidomide Dexamethasone (CRd) Combination and Control (Rd) 20/27 mg/m^2											
PX-171-009	Carfilzomib Lenalidomide Dexamethasone	PX171009-24-716-9[redacted]	6[redacted]/ Male	22OCT20[redacted]	178	1	1	Adverse Event	CFZ: No, DEX: No, LEN: No	CFZ: Yes, DEX: Yes, LEN: Yes	死亡(10)
		PX171009-24-716-9[redacted]	7[redacted]/ Female	16JAN20[redacted]	795	1	288	Adverse Event	CFZ: No, DEX: Yes, LEN: Yes	CFZ: No, DEX: Yes, LEN: Yes	敗血症(26)
		PX171009-24-716-9[redacted]	8[redacted]/ Male	31AUG20[redacted]	551	0	71	Adverse Event	CFZ: No, DEX: No, LEN: No	CFZ: No, DEX: No, LEN: No	死亡(12)

AE=Adverse Event; CFZ=carfilzomib; DEX=Dexamethasone ; LEN=lenalidomide; mg/m2=milligram per meter squared.
Notes: MedDRA version 15.1 used for coding.
This listing Includes deaths that occurred less than or equal to 30 days of last dose.
Number of Days from First Dose of Any Study Drug= Death date-first dosing date of any study drug +1.
Number of Days from Last Dose of Any Study Drug /Carfilzomib= Death date- last dosing date of any study drug /Carfilzomib.
In studies PX-171-009, PX-171-011 and 2011-002, Relationship to Study Treatment by Investigator is based on relationship to study drugs of grade 5 TEAEs if primary cause of death is AE. In other studies, it is from death case report form.

表 2.7.4.7-21　死亡例の一覧（PX-171-009）（続き 3）

Study	Treatment Group	Subject ID	Age/ Sex	Death Date	Number of Days from First Dose of Any Study Drug	Number of Days from Last Dose of Any Study Drug	Number of Days from Last Dose of Carfilzomib	Cause of Death Primary (Secondary)	Relationship to Study Treatment by Investigator	Relationship to Study Treatment by Sponsor	Fatal AE Preferred Term (AE Number)
Primary Safety Population: Carfilzomib Lenalidomide Dexamethasone (CRd) Combination and Control (Rd) 20/27 mg/m^2											
PX-171-009	Carfilzomib Lenalidomide Dexamethasone	PX171009-26-117-9[redacted]	5[redacted]/ Male	30NOV20[redacted]	290	16	22	Other: Cardiac Arrest		CFZ: No, DEX: No, LEN: No	心停止(13)
		PX171009-34-803-9[redacted]	7[redacted]/ Male	07MAR20[redacted]	512	7	13	Adverse Event	CFZ: No, DEX: No, LEN: No	CFZ: No, DEX: No, LEN: No	突然死(12)
		PX171009-38-277-9[redacted]	7[redacted]/ Female	04JUL20[redacted]	697	9	198	Progressive Disease		CFZ: No, DEX: No, LEN: No	肺炎(31)

AE=Adverse Event; CFZ=carfilzomib; DEX=Dexamethasone ; LEN=lenalidomide; mg/m2=milligram per meter squared.
Notes: MedDRA version 15.1 used for coding.
This listing Includes deaths that occurred less than or equal to 30 days of last dose.
Number of Days from First Dose of Any Study Drug= Death date-first dosing date of any study drug +1.
Number of Days from Last Dose of Any Study Drug /Carfilzomib= Death date- last dosing date of any study drug /Carfilzomib.
In studies PX-171-009, PX-171-011 and 2011-002, Relationship to Study Treatment by Investigator is based on relationship to study drugs of grade 5 TEAEs if primary cause of death is AE. In other studies, it is from death case report form.

表 2.7.4.7-21　死亡例の一覧（PX-171-009）（続き 4）

Study	Treatment Group	Subject ID	Age/ Sex	Death Date	Number of Days from First Dose of Any Study Drug	Number of Days from Last Dose of Any Study Drug	Number of Days from Last Dose of Carfilzomib	Cause of Death Primary (Secondary)	Relationship to Study Treatment by Investigator	Relationship to Study Treatment by Sponsor	Fatal AE Preferred Term (AE Number)
Primary Safety Population: Carfilzomib Lenalidomide Dexamethasone (CRd) Combination and Control (Rd) 20/27 mg/m^2											
PX-171-009	Carfilzomib Lenalidomide Dexamethasone	PX171009-38-278-9[redacted]	6[redacted]/ Male	09NOV20[redacted]	140	6	13	Adverse Event	CFZ: No, DEX: No, LEN: No	CFZ: No, DEX: No, LEN: No	心筋梗塞(10)
		PX171009-38-280-9[redacted]	7[redacted]/ Male	27APR20[redacted]	524	26	32	Adverse Event	CFZ: No, DEX: No, LEN: No	CFZ: No, DEX: No, LEN: No	敗血症(27)
		PX171009-38-280-9[redacted]	7[redacted]/ Female	06APR20[redacted]	459	17	23	Adverse Event	CFZ: No, DEX: No, LEN: No	CFZ: No, DEX: No, LEN: No	気管支肺炎(20)

AE=Adverse Event; CFZ=carfilzomib; DEX=Dexamethasone ; LEN=lenalidomide; mg/m2=milligram per meter squared.
Notes: MedDRA version 15.1 used for coding.
This listing Includes deaths that occurred less than or equal to 30 days of last dose.
Number of Days from First Dose of Any Study Drug= Death date-first dosing date of any study drug +1.
Number of Days from Last Dose of Any Study Drug /Carfilzomib= Death date- last dosing date of any study drug /Carfilzomib.
In studies PX-171-009, PX-171-011 and 2011-002, Relationship to Study Treatment by Investigator is based on relationship to study drugs of grade 5 TEAEs if primary cause of death is AE. In other studies, it is from death case report form.

表 2.7.4.7-21　死亡例の一覧（PX-171-009）（続き 5）

Study	Treatment Group	Subject ID	Age/ Sex	Death Date	Number of Days from First Dose of Any Study Drug	Number of Days from Last Dose of Any Study Drug	Number of Days from Last Dose of Carfilzomib	Cause of Death Primary (Secondary)	Relationship to Study Treatment by Investigator	Relationship to Study Treatment by Sponsor	Fatal AE Preferred Term (AE Number)
Primary Safety Population: Carfilzomib Lenalidomide Dexamethasone (CRd) Combination and Control (Rd) 20/27 mg/m^2											
PX-171-009	Carfilzomib Lenalidomide Dexamethasone	PX171009-39-477-9[redacted]	5[redacted]/ Female	15JUL20[redacted]	11	3	9	Adverse Event	CFZ: No, DEX: Yes, LEN: No	CFZ: No, DEX: Yes, LEN: No	肺炎(1)
		PX171009-41-252-9[redacted]	7[redacted]/ Male	23MAR20[redacted]	453	11	17	Adverse Event	CFZ: No, DEX: No, LEN: No	CFZ: No, DEX: No, LEN: No	左室機能不全(4)
		PX171009-41-255-9[redacted]	4[redacted]/ Male	07APR20[redacted]	111	26	32	Adverse Event	CFZ: No, DEX: No, LEN: No	CFZ: No, DEX: No, LEN: No	循環虚脱(2)

AE=Adverse Event; CFZ=carfilzomib; DEX=Dexamethasone ; LEN=lenalidomide; mg/m2=milligram per meter squared.

Notes: MedDRA version 15.1 used for coding.
This listing Includes deaths that occurred less than or equal to 30 days of last dose.
Number of Days from First Dose of Any Study Drug= Death date-first dosing date of any study drug +1.
Number of Days from Last Dose of Any Study Drug /Carfilzomib= Death date- last dosing date of any study drug /Carfilzomib.
In studies PX-171-009, PX-171-011 and 2011-002, Relationship to Study Treatment by Investigator is based on relationship to study drugs of grade 5 TEAEs if primary cause of death is AE. In other studies, it is from death case report form.

表 2.7.4.7-21　死亡例の一覧（PX-171-009）（続き 6）

Study	Treatment Group	Subject ID	Age/ Sex	Death Date	Number of Days from First Dose of Any Study Drug	Number of Days from Last Dose of Any Study Drug	Number of Days from Last Dose of Carfilzomib	Cause of Death Primary (Secondary)	Relationship to Study Treatment by Investigator	Relationship to Study Treatment by Sponsor	Fatal AE Preferred Term (AE Number)
Primary Safety Population: Carfilzomib Lenalidomide Dexamethasone (CRd) Combination and Control (Rd) 20/27 mg/m^2											
PX-171-009	Carfilzomib Lenalidomide Dexamethasone	PX171009-46-302-9[redacted]	7[redacted]/ Male	20NOV20[redacted]	631	0	111	Adverse Event	CFZ: No, DEX: No, LEN: No	CFZ: No, DEX: No, LEN: No	心内膜炎(10)
		PX171009-46-302-9[redacted]	5[redacted]/ Female	11MAR20[redacted]	5	1	3	Adverse Event	CFZ: No, DEX: No, LEN: No	CFZ: No, DEX: No, LEN: No	上気道感染(1)
		PX171009-46-303-9[redacted]	5[redacted]/ Male	06APR20[redacted]	980	7	488	Adverse Event	CFZ: No, DEX: No, LEN: No	CFZ: No, DEX: No, LEN: No	急性呼吸窮迫症候群(109)

AE=Adverse Event; CFZ=carfilzomib; DEX=Dexamethasone ; LEN=lenalidomide; mg/m2=milligram per meter squared.

Notes: MedDRA version 15.1 used for coding.

This listing Includes deaths that occurred less than or equal to 30 days of last dose.

Number of Days from First Dose of Any Study Drug= Death date-first dosing date of any study drug +1.

Number of Days from Last Dose of Any Study Drug /Carfilzomib= Death date- last dosing date of any study drug /Carfilzomib.

In studies PX-171-009, PX-171-011 and 2011-002, Relationship to Study Treatment by Investigator is based on relationship to study drugs of grade 5 TEAEs if primary cause of death is AE. In other studies, it is from death case report form.

表 2.7.4.7-21　死亡例の一覧（PX-171-009）（続き 7）

Study	Treatment Group	Subject ID	Age/ Sex	Death Date	Number of Days from First Dose of Any Study Drug	Number of Days from Last Dose of Any Study Drug	Number of Days from Last Dose of Carfilzomib	Cause of Death Primary (Secondary)	Relationship to Study Treatment by Investigator	Relationship to Study Treatment by Sponsor	Fatal AE Preferred Term (AE Number)
Primary Safety Population: Carfilzomib Lenalidomide Dexamethasone (CRd) Combination and Control (Rd) 20/27 mg/m^2											
PX-171-009	Carfilzomib Lenalidomide Dexamethasone	PX171009-46-303-9[redacted]	5[redacted]/ Male	19JAN20[redacted]	85	9	13	Adverse Event	CFZ: No, DEX: No, LEN: No	CFZ: No, DEX: No, LEN: No	急性心不全(4)
		PX171009-46-306-9[redacted]	6[redacted]/ Female	03JAN20[redacted]	279	5	11	Adverse Event	CFZ: No, DEX: No, LEN: No	CFZ: No, DEX: No, LEN: No	自殺既遂(11)
		PX171009-46-306-9[redacted]	7[redacted]/ Female	10OCT20[redacted]	239	7	7	Adverse Event	CFZ: No, DEX: No, LEN: No	CFZ: No, DEX: No, LEN: No	硬膜下血腫(3)

AE=Adverse Event; CFZ=carfilzomib; DEX=Dexamethasone ; LEN=lenalidomide; mg/m2=milligram per meter squared.
Notes: MedDRA version 15.1 used for coding.
This listing Includes deaths that occurred less than or equal to 30 days of last dose.
Number of Days from First Dose of Any Study Drug= Death date-first dosing date of any study drug +1.
Number of Days from Last Dose of Any Study Drug /Carfilzomib= Death date- last dosing date of any study drug /Carfilzomib.
In studies PX-171-009, PX-171-011 and 2011-002, Relationship to Study Treatment by Investigator is based on relationship to study drugs of grade 5 TEAEs if primary cause of death is AE. In other studies, it is from death case report form.

表 2.7.4.7-21　死亡例の一覧（PX-171-009）（続き 8）

Study	Treatment Group	Subject ID	Age/ Sex	Death Date	Number of Days from First Dose of Any Study Drug	Number of Days from Last Dose of Any Study Drug	Number of Days from Last Dose of Carfilzomib	Cause of Death Primary (Secondary)	Relationship to Study Treatment by Investigator	Relationship to Study Treatment by Sponsor	Fatal AE Preferred Term (AE Number)
Primary Safety Population: Carfilzomib Lenalidomide Dexamethasone (CRd) Combination and Control (Rd) 20/27 mg/m^2											
PX-171-009	Carfilzomib Lenalidomide Dexamethasone	PX171009-46-307-9[redacted]	5[redacted]/ Female	02SEP20[redacted]	280	12	18	Adverse Event	CFZ: No, DEX: No, LEN: No	CFZ: No, DEX: No, LEN: No	敗血症(12)
		PX171009-46-308-9[redacted]	8[redacted]/ Female	08DEC20[redacted]	4	1	2	Adverse Event	CFZ: No, DEX: No, LEN: No	CFZ: Yes, DEX: No, LEN: Yes	心肺不全(4)
		PX171009-49-426-9[redacted]	7[redacted]/ Female	02APR20[redacted]	182	6	6	Adverse Event	CFZ: No, DEX: No, LEN: No	CFZ: No, DEX: No, LEN: No	急性呼吸窮迫症候群(25)

AE=Adverse Event; CFZ=carfilzomib; DEX=Dexamethasone ; LEN=lenalidomide; mg/m2=milligram per meter squared.
Notes: MedDRA version 15.1 used for coding.
This listing Includes deaths that occurred less than or equal to 30 days of last dose.
Number of Days from First Dose of Any Study Drug= Death date-first dosing date of any study drug +1.
Number of Days from Last Dose of Any Study Drug /Carfilzomib= Death date- last dosing date of any study drug /Carfilzomib.
In studies PX-171-009, PX-171-011 and 2011-002, Relationship to Study Treatment by Investigator is based on relationship to study drugs of grade 5 TEAEs if primary cause of death is AE. In other studies, it is from death case report form.

表 2.7.4.7-21　死亡例の一覧（PX-171-009）（続き 9）

Study	Treatment Group	Subject ID	Age/ Sex	Death Date	Number of Days from First Dose of Any Study Drug	Number of Days from Last Dose of Any Study Drug	Number of Days from Last Dose of Carfilzomib	Cause of Death Primary (Secondary)	Relationship to Study Treatment by Investigator	Relationship to Study Treatment by Sponsor	Fatal AE Preferred Term (AE Number)
Primary Safety Population: Carfilzomib Lenalidomide Dexamethasone (CRd) Combination and Control (Rd) 20/27 mg/m^2											
PX-171-009	Carfilzomib Lenalidomide Dexamethasone	PX171009-49-426-9[redacted]	8[redacted]/ Male	17JUN20[redacted]	130	18	23	Adverse Event	CFZ: No, DEX: No, LEN: No	CFZ: No, DEX: No, LEN: No	敗血症性ショック(7)
		PX171009-51-658-9[redacted]	5[redacted]/ Female	30JUL20[redacted]	258	1	4	Adverse Event	CFZ: Yes, DEX: No, LEN: Yes	CFZ: Yes, DEX: No, LEN: Yes	頭蓋内出血(5)
		PX171009-82-604-9[redacted]	6[redacted]/ Male	24OCT20[redacted]	19	12	17	Adverse Event	CFZ: No, DEX: No, LEN: No	CFZ: No, DEX: No, LEN: No	気管支肺炎(4)

AE=Adverse Event; CFZ=carfilzomib; DEX=Dexamethasone ; LEN=lenalidomide; mg/m2=milligram per meter squared.
Notes: MedDRA version 15.1 used for coding.
This listing Includes deaths that occurred less than or equal to 30 days of last dose.
Number of Days from First Dose of Any Study Drug= Death date-first dosing date of any study drug +1.
Number of Days from Last Dose of Any Study Drug /Carfilzomib= Death date- last dosing date of any study drug /Carfilzomib.
In studies PX-171-009, PX-171-011 and 2011-002, Relationship to Study Treatment by Investigator is based on relationship to study drugs of grade 5 TEAEs if primary cause of death is AE. In other studies, it is from death case report form.

表 2.7.4.7-21　死亡例の一覧（PX-171-009）（続き 10）

Study	Treatment Group	Subject ID	Age/ Sex	Death Date	Number of Days from First Dose of Any Study Drug	Number of Days from Last Dose of Any Study Drug	Number of Days from Last Dose of Carfilzomib	Cause of Death Primary (Secondary)	Relationship to Study Treatment by Investigator	Relationship to Study Treatment by Sponsor	Fatal AE Preferred Term (AE Number)
Primary Safety Population: Carfilzomib Lenalidomide Dexamethasone (CRd) Combination and Control (Rd) PX-171-009 control											
PX-171-009	Lenalidomide Dexamethasone	PX171009-10-381-9[redacted]	7[redacted]/ Male	31JAN20[redacted]	119	19		Adverse Event	DEX: No, LEN: No	DEX: No, LEN: No	疾患進行(11)
		PX171009-10-388-9[redacted]	5[redacted]/ Male	07OCT20[redacted]	99	29		Progressive Disease		DEX: No, LEN: No	疾患進行(9), 脳出血(11)
		PX171009-14-120-9[redacted]	7[redacted]/ Male	17SEP20[redacted]	66	10		Progressive Disease		DEX: No, LEN: No	疾患進行(19)

AE=Adverse Event; CFZ=carfilzomib; DEX=Dexamethasone ; LEN=lenalidomide; mg/m2=milligram per meter squared.
Notes: MedDRA version 15.1 used for coding.
This listing Includes deaths that occurred less than or equal to 30 days of last dose.
Number of Days from First Dose of Any Study Drug= Death date-first dosing date of any study drug +1.
Number of Days from Last Dose of Any Study Drug /Carfilzomib= Death date- last dosing date of any study drug /Carfilzomib.
In studies PX-171-009, PX-171-011 and 2011-002, Relationship to Study Treatment by Investigator is based on relationship to study drugs of grade 5 TEAEs if primary cause of death is AE. In other studies, it is from death case report form.

表 2.7.4.7-21　死亡例の一覧（PX-171-009）（続き 11）

Study	Treatment Group	Subject ID	Age/ Sex	Death Date	Number of Days from First Dose of Any Study Drug	Number of Days from Last Dose of Any Study Drug	Number of Days from Last Dose of Carfilzomib	Cause of Death Primary (Secondary)	Relationship to Study Treatment by Investigator	Relationship to Study Treatment by Sponsor	Fatal AE Preferred Term (AE Number)
Primary Safety Population: Carfilzomib Lenalidomide Dexamethasone (CRd) Combination and Control (Rd) PX-171-009 control											
PX-171-009	Lenalidomide Dexamethasone	PX171009-18-451-9[redacted]	6[redacted]/ Female	26JUN20[redacted]	82	4		Adverse Event	DEX: No, LEN: No	DEX: No, LEN: No	死亡(1)
		PX171009-18-451-9[redacted]	6[redacted]/ Female	22JAN20[redacted]	46	9		Adverse Event	DEX: No, LEN: No	DEX: No, LEN: No	肺炎(3)
		PX171009-24-717-9[redacted]	6[redacted]/ Male	24JUL20[redacted]	61	19		Adverse Event	DEX: Yes, LEN: No	DEX: Yes, LEN: No	敗血症性ショック(1)

AE=Adverse Event; CFZ=carfilzomib; DEX=Dexamethasone ; LEN=lenalidomide; mg/m2=milligram per meter squared.
Notes: MedDRA version 15.1 used for coding.
This listing Includes deaths that occurred less than or equal to 30 days of last dose.
Number of Days from First Dose of Any Study Drug= Death date-first dosing date of any study drug +1.
Number of Days from Last Dose of Any Study Drug /Carfilzomib= Death date- last dosing date of any study drug /Carfilzomib.
In studies PX-171-009, PX-171-011 and 2011-002, Relationship to Study Treatment by Investigator is based on relationship to study drugs of grade 5 TEAEs if primary cause of death is AE. In other studies, it is from death case report form.

表 2.7.4.7-21　死亡例の一覧（PX-171-009）（続き 12）

Study	Treatment Group	Subject ID	Age/ Sex	Death Date	Number of Days from First Dose of Any Study Drug	Number of Days from Last Dose of Any Study Drug	Number of Days from Last Dose of Carfilzomib	Cause of Death Primary (Secondary)	Relationship to Study Treatment by Investigator	Relationship to Study Treatment by Sponsor	Fatal AE Preferred Term (AE Number)
Primary Safety Population: Carfilzomib Lenalidomide Dexamethasone (CRd) Combination and Control (Rd) PX-171-009 control											
PX-171-009	Lenalidomide Dexamethasone	PX171009-24-719-9[redacted]	8[redacted]/ Male	29OCT20[redacted]	312	5		Adverse Event	DEX: No, LEN: No	DEX: No, LEN: No	敗血症性ショック(2)
		PX171009-24-721-9[redacted]	7[redacted]/ Male	27MAY20[redacted]	152	1		Adverse Event	DEX: No, LEN: No	DEX: No, LEN: No	不整脈(29)
		PX171009-26-008-9[redacted]	6[redacted]/ Male	07JUL20[redacted]	788	30		Adverse Event	DEX: Yes, LEN: Yes	DEX: Yes, LEN: Yes	肝感染(45)

AE=Adverse Event; CFZ=carfilzomib; DEX=Dexamethasone ; LEN=lenalidomide; mg/m2=milligram per meter squared.
Notes: MedDRA version 15.1 used for coding.
This listing Includes deaths that occurred less than or equal to 30 days of last dose.
Number of Days from First Dose of Any Study Drug= Death date-first dosing date of any study drug +1.
Number of Days from Last Dose of Any Study Drug /Carfilzomib= Death date- last dosing date of any study drug /Carfilzomib.
In studies PX-171-009, PX-171-011 and 2011-002, Relationship to Study Treatment by Investigator is based on relationship to study drugs of grade 5 TEAEs if primary cause of death is AE. In other studies, it is from death case report form.

表 2.7.4.7-21　死亡例の一覧（PX-171-009）（続き 13）

Study	Treatment Group	Subject ID	Age/ Sex	Death Date	Number of Days from First Dose of Any Study Drug	Number of Days from Last Dose of Any Study Drug	Number of Days from Last Dose of Carfilzomib	Cause of Death Primary (Secondary)	Relationship to Study Treatment by Investigator	Relationship to Study Treatment by Sponsor	Fatal AE Preferred Term (AE Number)
Primary Safety Population: Carfilzomib Lenalidomide Dexamethasone (CRd) Combination and Control (Rd) PX-171-009 control											
PX-171-009	Lenalidomide Dexamethasone	PX171009-26-013-9[redacted]	5[redacted]/ Male	27AUG20[redacted]	330	18		Adverse Event	DEX: No, LEN: No	DEX: No, LEN: No	多臓器不全(21)
		PX171009-26-055-9[redacted]	7[redacted]/ Female	01NOV20[redacted]	480	10		Adverse Event	DEX: No, LEN: No	DEX: No, LEN: No	尿路性敗血症(36)
		PX171009-28-234-9[redacted]	7[redacted]/ Male	01MAR20[redacted]	95	0		Adverse Event	DEX: No, LEN: No	DEX: No, LEN: No	肺炎(1)

AE=Adverse Event; CFZ=carfilzomib; DEX=Dexamethasone ; LEN=lenalidomide; mg/m2=milligram per meter squared.
Notes: MedDRA version 15.1 used for coding.
This listing Includes deaths that occurred less than or equal to 30 days of last dose.
Number of Days from First Dose of Any Study Drug= Death date-first dosing date of any study drug +1.
Number of Days from Last Dose of Any Study Drug /Carfilzomib= Death date- last dosing date of any study drug /Carfilzomib.
In studies PX-171-009, PX-171-011 and 2011-002, Relationship to Study Treatment by Investigator is based on relationship to study drugs of grade 5 TEAEs if primary cause of death is AE. In other studies, it is from death case report form.

表 2.7.4.7-21　死亡例の一覧（PX-171-009）（続き 14）

Study	Treatment Group	Subject ID	Age/ Sex	Death Date	Number of Days from First Dose of Any Study Drug	Number of Days from Last Dose of Any Study Drug	Number of Days from Last Dose of Carfilzomib	Cause of Death Primary (Secondary)	Relationship to Study Treatment by Investigator	Relationship to Study Treatment by Sponsor	Fatal AE Preferred Term (AE Number)
Primary Safety Population: Carfilzomib Lenalidomide Dexamethasone (CRd) Combination and Control (Rd) PX-171-009 control											
PX-171-009	Lenalidomide Dexamethasone	PX171009-38-277-9[redacted]	5[redacted]/ Male	14JAN20[redacted]	554	13		Adverse Event	DEX: No, LEN: No	DEX: No, LEN: No	ウイルス性肺炎(16)
		PX171009-38-277-9[redacted]	6[redacted]/ Female	26FEB20[redacted]	203	27		Adverse Event	DEX: No, LEN: No	DEX: No, LEN: No	気管支肺炎(36)
		PX171009-38-278-9[redacted]	7[redacted]/ Female	24JUL20[redacted]	98	13		Adverse Event	DEX: No, LEN: No	DEX: No, LEN: No	心不全(7)

AE=Adverse Event; CFZ=carfilzomib; DEX=Dexamethasone ; LEN=lenalidomide; mg/m2=milligram per meter squared.

Notes: MedDRA version 15.1 used for coding.

This listing Includes deaths that occurred less than or equal to 30 days of last dose.

Number of Days from First Dose of Any Study Drug= Death date-first dosing date of any study drug +1.

Number of Days from Last Dose of Any Study Drug /Carfilzomib= Death date- last dosing date of any study drug /Carfilzomib.

In studies PX-171-009, PX-171-011 and 2011-002, Relationship to Study Treatment by Investigator is based on relationship to study drugs of grade 5 TEAEs if primary cause of death is AE. In other studies, it is from death case report form.

表 2.7.4.7-21　死亡例の一覧（PX-171-009）（続き 15）

Study	Treatment Group	Subject ID	Age/ Sex	Death Date	Number of Days from First Dose of Any Study Drug	Number of Days from Last Dose of Any Study Drug	Number of Days from Last Dose of Carfilzomib	Cause of Death Primary (Secondary)	Relationship to Study Treatment by Investigator	Relationship to Study Treatment by Sponsor	Fatal AE Preferred Term (AE Number)
Primary Safety Population: Carfilzomib Lenalidomide Dexamethasone (CRd) Combination and Control (Rd) PX-171-009 control											
PX-171-009	Lenalidomide Dexamethasone	PX171009-38-278-9[redacted]	6[redacted]/ Female	04DEC20[redacted]	12	0		Adverse Event	DEX: No, LEN: No	DEX: No, LEN: No	突然死(2)
		PX171009-39-478-9[redacted]	7[redacted]/ Male	10JUL20[redacted]	241	15		Progressive Disease		DEX: No, LEN: No	疾患進行(10)
		PX171009-39-482-9[redacted]	7[redacted]/ Male	11FEB20[redacted]	102	1		Adverse Event	DEX: No, LEN: Yes	DEX: No, LEN: Yes	肺塞栓症(1)

AE=Adverse Event; CFZ=carfilzomib; DEX=Dexamethasone ; LEN=lenalidomide; mg/m2=milligram per meter squared.
Notes: MedDRA version 15.1 used for coding.
This listing Includes deaths that occurred less than or equal to 30 days of last dose.
Number of Days from First Dose of Any Study Drug= Death date-first dosing date of any study drug +1.
Number of Days from Last Dose of Any Study Drug /Carfilzomib= Death date- last dosing date of any study drug /Carfilzomib.
In studies PX-171-009, PX-171-011 and 2011-002, Relationship to Study Treatment by Investigator is based on relationship to study drugs of grade 5 TEAEs if primary cause of death is AE. In other studies, it is from death case report form.

表 2.7.4.7-21　死亡例の一覧（PX-171-009）（続き 16）

Study	Treatment Group	Subject ID	Age/ Sex	Death Date	Number of Days from First Dose of Any Study Drug	Number of Days from Last Dose of Any Study Drug	Number of Days from Last Dose of Carfilzomib	Cause of Death Primary (Secondary)	Relationship to Study Treatment by Investigator	Relationship to Study Treatment by Sponsor	Fatal AE Preferred Term (AE Number)
Primary Safety Population: Carfilzomib Lenalidomide Dexamethasone (CRd) Combination and Control (Rd) PX-171-009 control											
PX-171-009	Lenalidomide Dexamethasone	PX171009-41-252-9[redacted]	6[redacted]/ Male	26JUL20[redacted]	659	1		Adverse Event	DEX: No, LEN: No	DEX: No, LEN: No	死亡(9)
		PX171009-41-253-9[redacted]	7[redacted]/ Male	28OCT20[redacted]	532	17		Progressive Disease		DEX: No, LEN: No	多発性骨髄腫(17)
		PX171009-41-253-9[redacted]	7[redacted]/ Female	06JUL20[redacted]	313	11		Adverse Event	DEX: No, LEN: Yes	DEX: No, LEN: Yes	急性腎不全(9)

AE=Adverse Event; CFZ=carfilzomib; DEX=Dexamethasone ; LEN=lenalidomide; mg/m2=milligram per meter squared.
Notes: MedDRA version 15.1 used for coding.
This listing Includes deaths that occurred less than or equal to 30 days of last dose.
Number of Days from First Dose of Any Study Drug= Death date-first dosing date of any study drug +1.
Number of Days from Last Dose of Any Study Drug /Carfilzomib= Death date- last dosing date of any study drug /Carfilzomib.
In studies PX-171-009, PX-171-011 and 2011-002, Relationship to Study Treatment by Investigator is based on relationship to study drugs of grade 5 TEAEs if primary cause of death is AE. In other studies, it is from death case report form.

表 2.7.4.7-21　死亡例の一覧（PX-171-009）（続き 17）

Study	Treatment Group	Subject ID	Age/ Sex	Death Date	Number of Days from First Dose of Any Study Drug	Number of Days from Last Dose of Any Study Drug	Number of Days from Last Dose of Carfilzomib	Cause of Death Primary (Secondary)	Relationship to Study Treatment by Investigator	Relationship to Study Treatment by Sponsor	Fatal AE Preferred Term (AE Number)
Primary Safety Population: Carfilzomib Lenalidomide Dexamethasone (CRd) Combination and Control (Rd) PX-171-009 control											
PX-171-009	Lenalidomide Dexamethasone	PX171009-41-254-9[redacted]	7[redacted]/ Male	30JAN20[redacted]	668	21		Adverse Event	DEX: No, LEN: Yes	DEX: No, LEN: Yes	骨髄異形成症候群(5)
		PX171009-41-254-9[redacted]	6[redacted]/ Female	08MAY20[redacted]	323	3		Adverse Event	DEX: No, LEN: No	DEX: No, LEN: No	昏睡(3)
		PX171009-41-256-9[redacted]	6[redacted]/ Male	15AUG20[redacted]	195	13		Progressive Disease		DEX: No, LEN: No	疾患進行(3)

AE=Adverse Event; CFZ=carfilzomib; DEX=Dexamethasone ; LEN=lenalidomide; mg/m2=milligram per meter squared.
Notes: MedDRA version 15.1 used for coding.
This listing Includes deaths that occurred less than or equal to 30 days of last dose.
Number of Days from First Dose of Any Study Drug= Death date-first dosing date of any study drug +1.
Number of Days from Last Dose of Any Study Drug /Carfilzomib= Death date- last dosing date of any study drug /Carfilzomib.
In studies PX-171-009, PX-171-011 and 2011-002, Relationship to Study Treatment by Investigator is based on relationship to study drugs of grade 5 TEAEs if primary cause of death is AE. In other studies, it is from death case report form.

表 2.7.4.7-21　死亡例の一覧（PX-171-009）（続き 18）

Study	Treatment Group	Subject ID	Age/ Sex	Death Date	Number of Days from First Dose of Any Study Drug	Number of Days from Last Dose of Any Study Drug	Number of Days from Last Dose of Carfilzomib	Cause of Death Primary (Secondary)	Relationship to Study Treatment by Investigator	Relationship to Study Treatment by Sponsor	Fatal AE Preferred Term (AE Number)
Primary Safety Population: Carfilzomib Lenalidomide Dexamethasone (CRd) Combination and Control (Rd) PX-171-009 control											
PX-171-009	Lenalidomide Dexamethasone	PX171009-46-302-9[redacted]	6[redacted]/ Female	12NOV20[redacted]	55	5		Adverse Event	DEX: No, LEN: No	DEX: No, LEN: No	心不全(1)
		PX171009-46-303-9[redacted]	7[redacted]/ Female	13NOV20[redacted]	102	5		Adverse Event	DEX: Yes, LEN: Yes	DEX: Yes, LEN: Yes	敗血症(3)
		PX171009-46-306-9[redacted]	6[redacted]/ Female	19MAR20[redacted]	390	5		Adverse Event	DEX: Yes, LEN: No	DEX: Yes, LEN: No	呼吸不全(9)

AE=Adverse Event; CFZ=carfilzomib; DEX=Dexamethasone ; LEN=lenalidomide; mg/m2=milligram per meter squared.
Notes: MedDRA version 15.1 used for coding.
This listing Includes deaths that occurred less than or equal to 30 days of last dose.
Number of Days from First Dose of Any Study Drug= Death date-first dosing date of any study drug +1.
Number of Days from Last Dose of Any Study Drug /Carfilzomib= Death date- last dosing date of any study drug /Carfilzomib.
In studies PX-171-009, PX-171-011 and 2011-002, Relationship to Study Treatment by Investigator is based on relationship to study drugs of grade 5 TEAEs if primary cause of death is AE. In other studies, it is from death case report form.

表 2.7.4.7-21　死亡例の一覧（PX-171-009）（続き 19）

Study	Treatment Group	Subject ID	Age/ Sex	Death Date	Number of Days from First Dose of Any Study Drug	Number of Days from Last Dose of Any Study Drug	Number of Days from Last Dose of Carfilzomib	Cause of Death Primary (Secondary)	Relationship to Study Treatment by Investigator	Relationship to Study Treatment by Sponsor	Fatal AE Preferred Term (AE Number)
Primary Safety Population: Carfilzomib Lenalidomide Dexamethasone (CRd) Combination and Control (Rd) PX-171-009 control											
PX-171-009	Lenalidomide Dexamethasone	PX171009-46-309-9[redacted]	6[redacted]/ Male	25MAR20[redacted]	46	24		Adverse Event	DEX: No, LEN: No	DEX: No, LEN: No	敗血症(3)
		PX171009-51-651-9[redacted]	5[redacted]/ Male	11FEB20[redacted]	376	22		Other: Acute Pneumonia,cardiopulmonary Decompensation		DEX: No, LEN: No	心不全(5), 肺障害(6)
		PX171009-51-653-9[redacted]	5[redacted]/ Male	20SEP20[redacted]	43	7		Adverse Event	DEX: No, LEN: No	DEX: No, LEN: No	心筋梗塞(1)

AE=Adverse Event; CFZ=carfilzomib; DEX=Dexamethasone ; LEN=lenalidomide; mg/m2=milligram per meter squared.
Notes: MedDRA version 15.1 used for coding.
This listing Includes deaths that occurred less than or equal to 30 days of last dose.
Number of Days from First Dose of Any Study Drug= Death date-first dosing date of any study drug +1.
Number of Days from Last Dose of Any Study Drug /Carfilzomib= Death date- last dosing date of any study drug /Carfilzomib.
In studies PX-171-009, PX-171-011 and 2011-002, Relationship to Study Treatment by Investigator is based on relationship to study drugs of grade 5 TEAEs if primary cause of death is AE. In other studies, it is from death case report form.

表 2.7.4.7-21　死亡例の一覧（PX-171-009）（続き 20）

Study	Treatment Group	Subject ID	Age/ Sex	Death Date	Number of Days from First Dose of Any Study Drug	Number of Days from Last Dose of Any Study Drug	Number of Days from Last Dose of Carfilzomib	Cause of Death Primary (Secondary)	Relationship to Study Treatment by Investigator	Relationship to Study Treatment by Sponsor	Fatal AE Preferred Term (AE Number)
Primary Safety Population: Carfilzomib Lenalidomide Dexamethasone (CRd) Combination and Control (Rd) PX-171-009 control											
PX-171-009	Lenalidomide Dexamethasone	PX171009-51-658-9[redacted]	6[redacted]/ Male	24JUL20[redacted]	317	14		Adverse Event	DEX: No, LEN: Yes	DEX: No, LEN: Yes	急性冠動脈症候群(1)
		PX171009-51-659-9[redacted]	6[redacted]/ Male	27FEB20[redacted]	71	21		Adverse Event	DEX: No, LEN: No	DEX: No, LEN: No	骨髄異形成症候群(3)
		PX171009-89-630-9[redacted]	4[redacted]/ Female	22DEC20[redacted]	86	8		Adverse Event	DEX: No, LEN: No	DEX: No, LEN: No	心肺不全(4)

AE=Adverse Event; CFZ=carfilzomib; DEX=Dexamethasone ; LEN=lenalidomide; mg/m2=milligram per meter squared.
Notes: MedDRA version 15.1 used for coding.
This listing Includes deaths that occurred less than or equal to 30 days of last dose.
Number of Days from First Dose of Any Study Drug= Death date-first dosing date of any study drug +1.
Number of Days from Last Dose of Any Study Drug /Carfilzomib= Death date- last dosing date of any study drug /Carfilzomib.
In studies PX-171-009, PX-171-011 and 2011-002, Relationship to Study Treatment by Investigator is based on relationship to study drugs of grade 5 TEAEs if primary cause of death is AE. In other studies, it is from death case report form.

出典［総括報告書5.3.5.1-1（PX-171-009），Listing 16.2.22］

表 2.7.4.7-22　死亡例の一覧表（PX-171-003 part 1（A0））

Study	Treatment Group	Subject ID	Age/ Sex	Death Date	Number of Days from First Dose of Any Study Drug	Number of Days from Last Dose of Any Study Drug	Number of Days from Last Dose of Carfilzomib	Cause of Death Primary (Secondary)	Relationship to Study Treatment by Investigator	Relationship to Study Treatment by Sponsor	Fatal AE Preferred Term (AE Number)
Safety Population: Carfilzomib monotherapy and Control <20/27 mg/m^2											
PX-171-003 A0	Carfilzomib	PX171003-1 4-15-[redacted]	6[redacted]/ Female	31JAN20[redacted]	74	29	29	Progressive Disease (Progressive Disease)	Unlikely		疾患進行(18)
		PX171003-2 6-06-[redacted]	4[redacted]/ Female	06FEB20[redacted]	115	13	13	Progressive Disease (Organ Failure)	None		疾患進行(50)
		PX171003-2 6-08-[redacted]	5[redacted]/ Male	22DEC20[redacted]	31	29	29	Progressive Disease (Progressive Disease)	Unlikely		疾患進行(20)

AE=Adverse Event; CFZ=carfilzomib; DEX=Dexamethasone ; LEN=lenalidomide; mg/m2=milligram per meter squared.
Notes: MedDRA version 15.1 used for coding.
This listing Includes deaths that occurred less than or equal to 30 days of last dose.
Number of Days from First Dose of Any Study Drug= Death date-first dosing date of any study drug +1.
Number of Days from Last Dose of Any Study Drug /Carfilzomib= Death date- last dosing date of any study drug /Carfilzomib.
In studies PX-171-009, PX-171-011 and 2011-002, Relationship to Study Treatment by Investigator is based on relationship to study drugs of grade 5 TEAEs if primary cause of death is AE. In other studies, it is from death case report form.

表 2.7.4.7-22　死亡例の一覧表（PX-171-003 part 1（A0））（続き）

Study	Treatment Group	Subject ID	Age/ Sex	Death Date	Number of Days from First Dose of Any Study Drug	Number of Days from Last Dose of Any Study Drug	Number of Days from Last Dose of Carfilzomib	Cause of Death Primary (Secondary)	Relationship to Study Treatment by Investigator	Relationship to Study Treatment by Sponsor	Fatal AE Preferred Term (AE Number)
Safety Population: Carfilzomib monotherapy and Control <20/27 mg/m^2											
PX-171-003 A0	Carfilzomib	PX171003-2 6-13-[redacted]	5[redacted]/ Male	11JAN20[redacted]	37	21	21	Progressive Disease (Unknown)	None		形質細胞腫 (28)

AE=Adverse Event; CFZ=carfilzomib; DEX=Dexamethasone ; LEN=lenalidomide; mg/m2=milligram per meter squared.
Notes: MedDRA version 15.1 used for coding.
This listing Includes deaths that occurred less than or equal to 30 days of last dose.
Number of Days from First Dose of Any Study Drug= Death date-first dosing date of any study drug +1.
Number of Days from Last Dose of Any Study Drug /Carfilzomib= Death date- last dosing date of any study drug /Carfilzomib.
In studies PX-171-009, PX-171-011 and 2011-002, Relationship to Study Treatment by Investigator is based on relationship to study drugs of grade 5 TEAEs if primary cause of death is AE. In other studies, it is from death case report form.

出典［総括報告書5.3.5.2-5（PX-171-003 part 1（A0）），Listing 16.2.7.5］

表 2.7.4.7-23　死亡例の一覧表（PX-171-004 part 2）

Study	Treatment Group	Subject ID	Age/ Sex	Death Date	Number of Days from First Dose of Any Study Drug	Number of Days from Last Dose of Any Study Drug	Number of Days from Last Dose of Carfilzomib	Cause of Death Primary (Secondary)	Relationship to Study Treatment by Investigator	Relationship to Study Treatment by Sponsor	Fatal AE Preferred Term (AE Number)
Safety Population: Carfilzomib monotherapy and Control <20/27 mg/m^2											
PX-171-004 Part 2	Carfilzomib	PX171004-2 6-06-[redacted]	5[redacted]/ Male	25JAN20[redacted]	4	2	2	Adverse Event (Other: Tumour Lysis Cannot Be Ruled Out)	Probable		多臓器不全 (9)
Safety Population: Carfilzomib monotherapy and Control 20/27 mg/m^2											
PX-171-004 Part 2	Carfilzomib	PX171004-1 4-15-[redacted]	7[redacted]/ Male	31MAR20[redacted]	93	21	21	Progressive Disease	None		疾患進行 (17)
Safety Population: Carfilzomib monotherapy and Control 20/27 mg/m^2											
PX-171-004 Part 2	Carfilzomib	PX171004-2 6-06-[redacted]	5[redacted]/ Male	05JUN20[redacted]	4	2	2	Adverse Event (Unknown)	Possible		痙攣(8)
		PX171004-2 6-08-[redacted]	5[redacted]/ Female	30OCT20[redacted]	10	8	8	Adverse Event (Progressive Disease)	Unlikely		急性腎不全(2)

出典［総括報告書5.3.5.2-8（PX-171-004 part 2），Listing 16.2.7.5］

表 2.7.4.7-24　死亡例の一覧表（PX-171-005）

Study	Treatment Group	Subject ID	Age/ Sex	Death Date	Number of Days from First Dose of Any Study Drug	Number of Days from Last Dose of Any Study Drug	Number of Days from Last Dose of Carfilzomib	Cause of Death Primary (Secondary)	Relationship to Study Treatment by Investigator	Relationship to Study Treatment by Sponsor	Fatal AE Preferred Term (AE Number)
Safety Population: Carfilzomib monotherapy and Control <20/27 mg/m^2											
PX-171-005	Carfilzomib	PX171005-14-18-[redacted]	5[redacted]/ Female	26NOV20[redacted]	38	22	22	Progressive Disease	None		疾患進行 (12)
Safety Population: Carfilzomib monotherapy and Control <20/27 mg/m^2											
PX-171-005	Carfilzomib	PX171005-14-18-[redacted]	4[redacted]/ Male	19JAN20[redacted]	14	5	5	Progressive Disease (Other: Sepsis)	None		疾患進行(1)
		PX171005-14-28-[redacted]	5[redacted]/ Female	05JUL20[redacted]	273	25	25	Progressive Disease	None		脊髄圧迫(11)
		PX171005-14-33-[redacted]	6[redacted]/ Female	05JUN20[redacted]	54	16	16	Progressive Disease	None		多発性骨髄腫 (22)

AE=Adverse Event; CFZ=carfilzomib; DEX=Dexamethasone ; LEN=lenalidomide; mg/m2=milligram per meter squared.
Notes: MedDRA version 15.1 used for coding.
This listing Includes deaths that occurred less than or equal to 30 days of last dose.
Number of Days from First Dose of Any Study Drug= Death date-first dosing date of any study drug +1.
Number of Days from Last Dose of Any Study Drug /Carfilzomib= Death date- last dosing date of any study drug /Carfilzomib.
In studies PX-171-009, PX-171-011 and 2011-002, Relationship to Study Treatment by Investigator is based on relationship to study drugs of grade 5 TEAEs if primary cause of death is AE. In other studies, it is from death case report form.

表 2.7.4.7-24　死亡例の一覧表（PX-171-005）（続き）

Study	Treatment Group	Subject ID	Age/ Sex	Death Date	Number of Days from First Dose of Any Study Drug	Number of Days from Last Dose of Any Study Drug	Number of Days from Last Dose of Carfilzomib	Cause of Death Primary (Secondary)	Relationship to Study Treatment by Investigator	Relationship to Study Treatment by Sponsor	Fatal AE Preferred Term (AE Number)
Safety Population: Carfilzomib monotherapy and Control <20/27 mg/m^2											
PX-171-005	Carfilzomib	PX171005-14-33-[redacted]	6[redacted]/ Male	30DEC20[redacted]	156	29	29	Progressive Disease	None		疾患進行(35)
		PX171005-14-33-[redacted]	7[redacted]/ Male	28AUG20[redacted]	33	17	17	Progressive Disease (Progressive Disease)	None		疾患進行(5)
		PX171005-14-33-[redacted]	5[redacted]/ Male	04JAN20[redacted]	365	27	27	Adverse Event (Unknown)	None		細菌性肺炎(29)

AE=Adverse Event; CFZ=carfilzomib; DEX=Dexamethasone ; LEN=lenalidomide; mg/m2=milligram per meter squared.
Notes: MedDRA version 15.1 used for coding.
This listing Includes deaths that occurred less than or equal to 30 days of last dose.
Number of Days from First Dose of Any Study Drug= Death date-first dosing date of any study drug +1.
Number of Days from Last Dose of Any Study Drug /Carfilzomib= Death date- last dosing date of any study drug /Carfilzomib.
In studies PX-171-009, PX-171-011 and 2011-002, Relationship to Study Treatment by Investigator is based on relationship to study drugs of grade 5 TEAEs if primary cause of death is AE. In other studies, it is from death case report form.

出典［総括報告書5.3.5.2-9（PX-171-005），Listing 16.2.7.5］

表 2.7.4.7-25　死亡例の一覧表（PX-171-007）

Phase: 2							
			Cause of Death				
Subject Number	Cohort	Date of Death (Study Day)	Primary Cause (Fatal AE Preferred Term)	Contributing/ Secondary Cause	Relationship to Study Drug	Was Autopsy Performed?	Circumstances of Subject's Death
7-21-[redacted]	20/36 mg/m²	29JAN20[redacted] (80)	DISEASE PROGRESSION (疾患進行)		NONE	No	PATIENT DIED FROM DISEASE PROGRESSION OF SMALL CELL CARCINOMA
7-24-[redacted]	20/36 mg/m²	14MAY20[redacted] (16)	DISEASE PROGRESSION (疾患進行)	UNKNOWN	UNLIKELY	No	PT ENROLLED INTO HOSPICE PROGRAM AFTER FAILING ON TREATMENTS. SUBSEQ. DIED DUE TO DISEASE PROGRESSION
7-29-[redacted]	20/36 mg/m²	06NOV20[redacted] (17)	DISEASE PROGRESSION (肝腎不全)	ADVERSE EVENT: 15	UNLIKELY	No	HEPATORENAL FAILURE DUE TO PROGRESSIVE SMALL CELL LUNG CANCER
7-30-[redacted]	20/36 mg/m²	03APR20[redacted] (59)	DISEASE PROGRESSION (疾患進行)	OTHER: NONE	NONE	No	PATIENT DIED AT HOME IN HIS SLEEP

出典［総括報告書5.3.5.2-11（PX-171-007），Listing 16.2.1.30，Listing 16.2.1.31］

表 2.7.4.7-26　死亡例の一覧表（PX-171-011）

Study	Treatment Group	Subject ID	Age/ Sex	Death Date	Number of Days from First Dose of Any Study Drug	Number of Days from Last Dose of Any Study Drug	Number of Days from Last Dose of Carfilzomib	Cause of Death Primary (Secondary)	Relationship to Study Treatment by Investigator	Relationship to Study Treatment by Sponsor	Fatal AE Preferred Term (AE Number)
Safety Population: Carfilzomib monotherapy and Control 20/27 mg/m^2											
PX-171-011	Carfilzomib	PX171011-16-329-1[redacted]	5[redacted]/ Male	11OCT20[redacted]	50	15	15	Progressive Disease		CFZ: No	疾患進行 (2)

AE=Adverse Event; CFZ=carfilzomib; DEX=Dexamethasone ; LEN=lenalidomide; mg/m2=milligram per meter squared.
Notes: MedDRA version 15.1 used for coding.
This listing Includes deaths that occurred less than or equal to 30 days of last dose.
Number of Days from First Dose of Any Study Drug= Death date-first dosing date of any study drug +1.
Number of Days from Last Dose of Any Study Drug /Carfilzomib= Death date- last dosing date of any study drug /Carfilzomib.
In studies PX-171-009, PX-171-011 and 2011-002, Relationship to Study Treatment by Investigator is based on relationship to study drugs of grade 5 TEAEs if primary cause of death is AE. In other studies, it is from death case report form.

表 2.7.4.7-26　死亡例の一覧表（PX-171-011）（続き 1）

Study	Treatment Group	Subject ID	Age/ Sex	Death Date	Number of Days from First Dose of Any Study Drug	Number of Days from Last Dose of Any Study Drug	Number of Days from Last Dose of Carfilzomib	Cause of Death Primary (Secondary)	Relationship to Study Treatment by Investigator	Relationship to Study Treatment by Sponsor	Fatal AE Preferred Term (AE Number)
Safety Population: Carfilzomib monotherapy and Control 20/27 mg/m^2											
PX-171-011	Carfilzomib	PX171011-18-455-1[redacted]	5[redacted]/ Male	22APR20[redacted]	29	20	20	Adverse Event	CFZ: No	CFZ: No	心停止(3)
		PX171011-18-455-1[redacted]	5[redacted]/ Female	26FEB20[redacted]	167	18	18	Progressive Disease		CFZ: No	多発性骨髄腫(17)
		PX171011-22-526-1[redacted]	4[redacted]/ Female	03DEC20[redacted]	80	25	25	Progressive Disease		CFZ: No	疾患進行(27)

AE=Adverse Event; CFZ=carfilzomib; DEX=Dexamethasone ; LEN=lenalidomide; mg/m2=milligram per meter squared.
Notes: MedDRA version 15.1 used for coding.
This listing Includes deaths that occurred less than or equal to 30 days of last dose.
Number of Days from First Dose of Any Study Drug= Death date-first dosing date of any study drug +1.
Number of Days from Last Dose of Any Study Drug /Carfilzomib= Death date- last dosing date of any study drug /Carfilzomib.
In studies PX-171-009, PX-171-011 and 2011-002, Relationship to Study Treatment by Investigator is based on relationship to study drugs of grade 5 TEAEs if primary cause of death is AE. In other studies, it is from death case report form.

表 2.7.4.7-26　死亡例の一覧表（PX-171-011）（続き 2）

Study	Treatment Group	Subject ID	Age/ Sex	Death Date	Number of Days from First Dose of Any Study Drug	Number of Days from Last Dose of Any Study Drug	Number of Days from Last Dose of Carfilzomib	Cause of Death Primary (Secondary)	Relationship to Study Treatment by Investigator	Relationship to Study Treatment by Sponsor	Fatal AE Preferred Term (AE Number)
Safety Population: Carfilzomib monotherapy and Control 20/27 mg/m^2											
PX-171-011	Carfilzomib	PX171011-22-532-1[redacted]	4[redacted]/ Female	14NOV20[redacted]	15	12	12	Adverse Event	CFZ: No	CFZ: No	多臓器不全(2)
		PX171011-22-539-1[redacted]	7[redacted]/ Male	14APR20[redacted]	46	30	30	Progressive Disease		CFZ: No	疾患進行(11)
		PX171011-22-539-1[redacted]	6[redacted]/ Male	12JUL20[redacted]	36	23	23	Progressive Disease		CFZ: No	疾患進行(3)

AE=Adverse Event; CFZ=carfilzomib; DEX=Dexamethasone ; LEN=lenalidomide; mg/m2=milligram per meter squared.
Notes: MedDRA version 15.1 used for coding.
This listing Includes deaths that occurred less than or equal to 30 days of last dose.
Number of Days from First Dose of Any Study Drug= Death date-first dosing date of any study drug +1.
Number of Days from Last Dose of Any Study Drug /Carfilzomib= Death date- last dosing date of any study drug /Carfilzomib.
In studies PX-171-009, PX-171-011 and 2011-002, Relationship to Study Treatment by Investigator is based on relationship to study drugs of grade 5 TEAEs if primary cause of death is AE. In other studies, it is from death case report form.

表 2.7.4.7-26　死亡例の一覧表（PX-171-011）（続き 3）

Study	Treatment Group	Subject ID	Age/ Sex	Death Date	Number of Days from First Dose of Any Study Drug	Number of Days from Last Dose of Any Study Drug	Number of Days from Last Dose of Carfilzomib	Cause of Death Primary (Secondary)	Relationship to Study Treatment by Investigator	Relationship to Study Treatment by Sponsor	Fatal AE Preferred Term (AE Number)
Safety Population: Carfilzomib monotherapy and Control 20/27 mg/m^2											
PX-171-011	Carfilzomib	PX171011-24-717-1[redacted]	7[redacted]/ Male	02FEB20[redacted]	104	10	10	Adverse Event	CFZ: No	CFZ: No	心肺停止(6)
		PX171011-24-719-1[redacted]	5[redacted]/ Male	07DEC20[redacted]	313	21	21	Progressive Disease		CFZ: No	疾患進行(16)
		PX171011-24-719-1[redacted]	8[redacted]/ Female	20JAN20[redacted]	208	6	6	Adverse Event	CFZ: No	CFZ: No	ブドウ球菌性敗血症(6)

AE=Adverse Event; CFZ=carfilzomib; DEX=Dexamethasone ; LEN=lenalidomide; mg/m2=milligram per meter squared.
Notes: MedDRA version 15.1 used for coding.
This listing Includes deaths that occurred less than or equal to 30 days of last dose.
Number of Days from First Dose of Any Study Drug= Death date-first dosing date of any study drug +1.
Number of Days from Last Dose of Any Study Drug /Carfilzomib= Death date- last dosing date of any study drug /Carfilzomib.
In studies PX-171-009, PX-171-011 and 2011-002, Relationship to Study Treatment by Investigator is based on relationship to study drugs of grade 5 TEAEs if primary cause of death is AE. In other studies, it is from death case report form.

表 2.7.4.7-26　死亡例の一覧表（PX-171-011）（続き 4）

Study	Treatment Group	Subject ID	Age/ Sex	Death Date	Number of Days from First Dose of Any Study Drug	Number of Days from Last Dose of Any Study Drug	Number of Days from Last Dose of Carfilzomib	Cause of Death Primary (Secondary)	Relationship to Study Treatment by Investigator	Relationship to Study Treatment by Sponsor	Fatal AE Preferred Term (AE Number)
Safety Population: Carfilzomib monotherapy and Control 20/27 mg/m^2											
PX-171-011	Carfilzomib	PX171011-24-721-1[redacted]	7[redacted]/ Female	06SEP20[redacted]	184	28	28	Progressive Disease		CFZ: No	疾患進行(6)
		PX171011-24-722-1[redacted]	6[redacted]/ Female	22SEP20[redacted]	100	0	0	Adverse Event	CFZ: No	CFZ: No	心停止(5)
		PX171011-38-276-1[redacted]	7[redacted]/ Female	08FEB20[redacted]	143	22	22	Adverse Event	CFZ: No	CFZ: No	腎感染(1)

AE=Adverse Event; CFZ=carfilzomib; DEX=Dexamethasone ; LEN=lenalidomide; mg/m2=milligram per meter squared.
Notes: MedDRA version 15.1 used for coding.
This listing Includes deaths that occurred less than or equal to 30 days of last dose.
Number of Days from First Dose of Any Study Drug= Death date-first dosing date of any study drug +1.
Number of Days from Last Dose of Any Study Drug /Carfilzomib= Death date- last dosing date of any study drug /Carfilzomib.
In studies PX-171-009, PX-171-011 and 2011-002, Relationship to Study Treatment by Investigator is based on relationship to study drugs of grade 5 TEAEs if primary cause of death is AE. In other studies, it is from death case report form.

表 2.7.4.7-26　死亡例の一覧表（PX-171-011）（続き 5）

Study	Treatment Group	Subject ID	Age/ Sex	Death Date	Number of Days from First Dose of Any Study Drug	Number of Days from Last Dose of Any Study Drug	Number of Days from Last Dose of Carfilzomib	Cause of Death Primary (Secondary)	Relationship to Study Treatment by Investigator	Relationship to Study Treatment by Sponsor	Fatal AE Preferred Term (AE Number)
Safety Population: Carfilzomib monotherapy and Control 20/27 mg/m^2											
PX-171-011	Carfilzomib	PX171011-3 8-278-1[redacted]	7[redacted]/ Male	21FEB20[redacted]	30	14	14	Progressive Disease		CFZ: No	疾患進行(10)
		PX171011-3 8-278-1[redacted]	7[redacted]/ Male	18JUN20[redacted]	124	24	24	Adverse Event	CFZ: No	CFZ: No	気管支肺炎(17)
		PX171011-3 8-279-1[redacted]	5[redacted]/ Male	17FEB20[redacted]	108	16	16	Adverse Event	CFZ: No	CFZ: No	肺炎(6)

AE=Adverse Event; CFZ=carfilzomib; DEX=Dexamethasone ; LEN=lenalidomide; mg/m2=milligram per meter squared.
Notes: MedDRA version 15.1 used for coding.
This listing Includes deaths that occurred less than or equal to 30 days of last dose.
Number of Days from First Dose of Any Study Drug= Death date-first dosing date of any study drug +1.
Number of Days from Last Dose of Any Study Drug /Carfilzomib= Death date- last dosing date of any study drug /Carfilzomib.
In studies PX-171-009, PX-171-011 and 2011-002, Relationship to Study Treatment by Investigator is based on relationship to study drugs of grade 5 TEAEs if primary cause of death is AE. In other studies, it is from death case report form.

表 2.7.4.7-26　死亡例の一覧表（PX-171-011）（続き 6）

Study	Treatment Group	Subject ID	Age/ Sex	Death Date	Number of Days from First Dose of Any Study Drug	Number of Days from Last Dose of Any Study Drug	Number of Days from Last Dose of Carfilzomib	Cause of Death Primary (Secondary)	Relationship to Study Treatment by Investigator	Relationship to Study Treatment by Sponsor	Fatal AE Preferred Term (AE Number)
Safety Population: Carfilzomib monotherapy and Control 20/27 mg/m^2											
PX-171-011	Carfilzomib	PX171011-3	6[redacted]/	26AUG20[redacted]	26	10	10	Adverse Event	CFZ: No	CFZ: No	上部消化管出血 (1)
		PX171011-40-909-1[redacted]	6[redacted]/ Male	19OCT20[redacted]	22	7	7	Adverse Event	CFZ: No	CFZ: No	急性腎不全(2)
		PX171011-44-201-1[redacted]	4[redacted]/ Male	17APR20[redacted]	28	26	26	Adverse Event	CFZ: No	CFZ: No	急性腎不全(1)

AE=Adverse Event; CFZ=carfilzomib; DEX=Dexamethasone ; LEN=lenalidomide; mg/m2=milligram per meter squared.
Notes: MedDRA version 15.1 used for coding.
This listing Includes deaths that occurred less than or equal to 30 days of last dose.
Number of Days from First Dose of Any Study Drug= Death date-first dosing date of any study drug +1.
Number of Days from Last Dose of Any Study Drug /Carfilzomib= Death date- last dosing date of any study drug /Carfilzomib.
In studies PX-171-009, PX-171-011 and 2011-002, Relationship to Study Treatment by Investigator is based on relationship to study drugs of grade 5 TEAEs if primary cause of death is AE. In other studies, it is from death case report form.

表 2.7.4.7-26　死亡例の一覧表（PX-171-011）（続き 7）

Study	Treatment Group	Subject ID	Age/ Sex	Death Date	Number of Days from First Dose of Any Study Drug	Number of Days from Last Dose of Any Study Drug	Number of Days from Last Dose of Carfilzomib	Cause of Death Primary (Secondary)	Relationship to Study Treatment by Investigator	Relationship to Study Treatment by Sponsor	Fatal AE Preferred Term (AE Number)
Safety Population: Carfilzomib monotherapy and Control 20/27 mg/m^2											
PX-171-011	Carfilzomib	PX171011-4-201-1[redacted]	4[redacted]/ Male	11JUN20[redacted]	55	26	26	Progressive Disease		CFZ: No	疾患進行(1)
		PX171011-4-202-1[redacted]	6[redacted]/ Male	14NOV20[redacted]	51	29	29	Progressive Disease		CFZ: No	疾患進行(8)
		PX171011-4-203-1[redacted]	7[redacted]/ Female	12DEC20[redacted]	4	2	2	Adverse Event	CFZ: Yes	CFZ: Yes	心血管不全(1)

AE=Adverse Event; CFZ=carfilzomib; DEX=Dexamethasone ; LEN=lenalidomide; mg/m2=milligram per meter squared.
Notes: MedDRA version 15.1 used for coding.
This listing Includes deaths that occurred less than or equal to 30 days of last dose.
Number of Days from First Dose of Any Study Drug= Death date-first dosing date of any study drug +1.
Number of Days from Last Dose of Any Study Drug /Carfilzomib= Death date- last dosing date of any study drug /Carfilzomib.
In studies PX-171-009, PX-171-011 and 2011-002, Relationship to Study Treatment by Investigator is based on relationship to study drugs of grade 5 TEAEs if primary cause of death is AE. In other studies, it is from death case report form.

表 2.7.4.7-26　死亡例の一覧表（PX-171-011）（続き 8）

Study	Treatment Group	Subject ID	Age/ Sex	Death Date	Number of Days from First Dose of Any Study Drug	Number of Days from Last Dose of Any Study Drug	Number of Days from Last Dose of Carfilzomib	Cause of Death Primary (Secondary)	Relationship to Study Treatment by Investigator	Relationship to Study Treatment by Sponsor	Fatal AE Preferred Term (AE Number)
Safety Population: Carfilzomib monotherapy and Control 20/27 mg/m^2											
PX-171-011	Carfilzomib	PX171011-4 6-301-1[redacted]	7[redacted]/ Female	30OCT20[redacted]	539	5	5	Adverse Event	CFZ: No	CFZ: No	急性心不全(27)
		PX171011-4 6-303-1[redacted]	6[redacted]/ Male	27OCT20[redacted]	17	15	15	Adverse Event	CFZ: No	CFZ: No	敗血症(2)
		PX171011-4 6-303-1[redacted]	5[redacted]/ Male	16JUL20[redacted]	274	13	13	Progressive Disease		CFZ: No	疾患進行(20)

AE=Adverse Event; CFZ=carfilzomib; DEX=Dexamethasone ; LEN=lenalidomide; mg/m2=milligram per meter squared.
Notes: MedDRA version 15.1 used for coding.
This listing Includes deaths that occurred less than or equal to 30 days of last dose.
Number of Days from First Dose of Any Study Drug= Death date-first dosing date of any study drug +1.
Number of Days from Last Dose of Any Study Drug /Carfilzomib= Death date- last dosing date of any study drug /Carfilzomib.
In studies PX-171-009, PX-171-011 and 2011-002, Relationship to Study Treatment by Investigator is based on relationship to study drugs of grade 5 TEAEs if primary cause of death is AE. In other studies, it is from death case report form.

表 2.7.4.7-26　死亡例の一覧表（PX-171-011）（続き 9）

Study	Treatment Group	Subject ID	Age/ Sex	Death Date	Number of Days from First Dose of Any Study Drug	Number of Days from Last Dose of Any Study Drug	Number of Days from Last Dose of Carfilzomib	Cause of Death Primary (Secondary)	Relationship to Study Treatment by Investigator	Relationship to Study Treatment by Sponsor	Fatal AE Preferred Term (AE Number)
Safety Population: Carfilzomib monotherapy and Control 20/27 mg/m^2											
PX-171-011	Carfilzomib	PX171011-46-303-1[redacted]	5[redacted]/ Male	29JAN20[redacted]	68	4	4	Progressive Disease		CFZ: No	疾患進行(56)
		PX171011-46-307-1[redacted]	7[redacted]/ Female	06FEB20[redacted]	126	12	12	Adverse Event	CFZ: No	CFZ: No	肺水腫(29)
		PX171011-49-426-1[redacted]	5[redacted]/ Male	08JAN20[redacted]	139	18	18	Progressive Disease		CFZ: No	疾患進行(14)

AE=Adverse Event; CFZ=carfilzomib; DEX=Dexamethasone ; LEN=lenalidomide; mg/m2=milligram per meter squared.
Notes: MedDRA version 15.1 used for coding.
This listing Includes deaths that occurred less than or equal to 30 days of last dose.
Number of Days from First Dose of Any Study Drug= Death date-first dosing date of any study drug +1.
Number of Days from Last Dose of Any Study Drug /Carfilzomib= Death date- last dosing date of any study drug /Carfilzomib.
In studies PX-171-009, PX-171-011 and 2011-002, Relationship to Study Treatment by Investigator is based on relationship to study drugs of grade 5 TEAEs if primary cause of death is AE. In other studies, it is from death case report form.

表 2.7.4.7-26　死亡例の一覧表（PX-171-011）（続き 10）

Study	Treatment Group	Subject ID	Age/ Sex	Death Date	Number of Days from First Dose of Any Study Drug	Number of Days from Last Dose of Any Study Drug	Number of Days from Last Dose of Carfilzomib	Cause of Death Primary (Secondary)	Relationship to Study Treatment by Investigator	Relationship to Study Treatment by Sponsor	Fatal AE Preferred Term (AE Number)
Safety Population: Carfilzomib monotherapy and Control 20/27 mg/m^2											
PX-171-011	Carfilzomib	PX171011-49-428-1[redacted]	5[redacted]/ Female	04MAY20[redacted]	26	9	9	Adverse Event	CFZ: No	CFZ: No	状態悪化(6), 多臓器不全(11)
Safety Population: Carfilzomib monotherapy and Control PX-171-011 control											
PX-171-011	Corticosteroid + optional Cyclophosphamide	PX171011-10-378-1[redacted]	6[redacted]/ Female	07MAR20[redacted]	162	8		Adverse Event	Yes	Yes	肺炎(3)
		PX171011-12-860-1[redacted]	5[redacted]/ Female	29AUG20[redacted]	50	14		Adverse Event	No	No	肺炎(10)

AE=Adverse Event; CFZ=carfilzomib; DEX=Dexamethasone ; LEN=lenalidomide; mg/m2=milligram per meter squared.
Notes: MedDRA version 15.1 used for coding.
This listing Includes deaths that occurred less than or equal to 30 days of last dose.
Number of Days from First Dose of Any Study Drug= Death date-first dosing date of any study drug +1.
Number of Days from Last Dose of Any Study Drug /Carfilzomib= Death date- last dosing date of any study drug /Carfilzomib.
In studies PX-171-009, PX-171-011 and 2011-002, Relationship to Study Treatment by Investigator is based on relationship to study drugs of grade 5 TEAEs if primary cause of death is AE. In other studies, it is from death case report form.

表 2.7.4.7-26　死亡例の一覧表（PX-171-011）（続き 11）

Study	Treatment Group	Subject ID	Age/ Sex	Death Date	Number of Days from First Dose of Any Study Drug	Number of Days from Last Dose of Any Study Drug	Number of Days from Last Dose of Carfilzomib	Cause of Death Primary (Secondary)	Relationship to Study Treatment by Investigator	Relationship to Study Treatment by Sponsor	Fatal AE Preferred Term (AE Number)
Safety Population: Carfilzomib monotherapy and Control PX-171-011 control											
PX-171-011	Corticosteroid + optional Cyclophosphamide	PX171011-12-865-1[redacted]	7[redacted]/ Male	19OCT20[redacted]	65	3		Adverse Event	No	No	好中球減少性敗血症(6)
		PX171011-12-865-1[redacted]	6[redacted]/ Male	29SEP20[redacted]	51	5		Adverse Event	No	No	肺炎(9)
		PX171011-16-329-1[redacted]	7[redacted]/ Male	06MAY20[redacted]	216	17		Progressive Disease		No	疾患進行(11)

AE=Adverse Event; CFZ=carfilzomib; DEX=Dexamethasone ; LEN=lenalidomide; mg/m2=milligram per meter squared.
Notes: MedDRA version 15.1 used for coding.
This listing Includes deaths that occurred less than or equal to 30 days of last dose.
Number of Days from First Dose of Any Study Drug= Death date-first dosing date of any study drug +1.
Number of Days from Last Dose of Any Study Drug /Carfilzomib= Death date- last dosing date of any study drug /Carfilzomib.
In studies PX-171-009, PX-171-011 and 2011-002, Relationship to Study Treatment by Investigator is based on relationship to study drugs of grade 5 TEAEs if primary cause of death is AE. In other studies, it is from death case report form.

表 2.7.4.7-26　死亡例の一覧表（PX-171-011）（続き 12）

Study	Treatment Group	Subject ID	Age/ Sex	Death Date	Number of Days from First Dose of Any Study Drug	Number of Days from Last Dose of Any Study Drug	Number of Days from Last Dose of Carfilzomib	Cause of Death Primary (Secondary)	Relationship to Study Treatment by Investigator	Relationship to Study Treatment by Sponsor	Fatal AE Preferred Term (AE Number)
Safety Population: Carfilzomib monotherapy and Control PX-171-011 control											
PX-171-011	Corticosteroid + optional Cyclophosphamide	PX171011-16-342-1[redacted]	6[redacted]/ Female	26NOV20[redacted]	68	27		Progressive Disease		No	疾患進行(1)
		PX171011-16-342-1[redacted]	6[redacted]/ Male	08NOV20[redacted]	46	18		Progressive Disease		No	疾患進行(1)
		PX171011-18-451-1[redacted]	5[redacted]/ Male	20JUN20[redacted]	38	5		Adverse Event	No	No	肺炎(1)

AE=Adverse Event; CFZ=carfilzomib; DEX=Dexamethasone ; LEN=lenalidomide; mg/m2=milligram per meter squared.
Notes: MedDRA version 15.1 used for coding.
This listing Includes deaths that occurred less than or equal to 30 days of last dose.
Number of Days from First Dose of Any Study Drug= Death date-first dosing date of any study drug +1.
Number of Days from Last Dose of Any Study Drug /Carfilzomib= Death date- last dosing date of any study drug /Carfilzomib.
In studies PX-171-009, PX-171-011 and 2011-002, Relationship to Study Treatment by Investigator is based on relationship to study drugs of grade 5 TEAEs if primary cause of death is AE. In other studies, it is from death case report form.

表 2.7.4.7-26　死亡例の一覧表（PX-171-011）（続き 13）

Study	Treatment Group	Subject ID	Age/ Sex	Death Date	Number of Days from First Dose of Any Study Drug	Number of Days from Last Dose of Any Study Drug	Number of Days from Last Dose of Carfilzomib	Cause of Death Primary (Secondary)	Relationship to Study Treatment by Investigator	Relationship to Study Treatment by Sponsor	Fatal AE Preferred Term (AE Number)
Safety Population: Carfilzomib monotherapy and Control PX-171-011 control											
PX-171-011	Corticosteroid + optional Cyclophosphamide	PX171011-22-526-1[redacted]	6[redacted]/ Male	28MAY20[redacted]	81	11		Progressive Disease		No	疾患進行(6)
		PX171011-22-532-1[redacted]	7[redacted]/ Female	29JUN20[redacted]	727	3		Other: Suspected Pneumonia		No	死亡(17)
		PX171011-24-721-1[redacted]	5[redacted]/ Male	05JAN20[redacted]	7	1		Adverse Event	No	No	急性肺水腫(1)

AE=Adverse Event; CFZ=carfilzomib; DEX=Dexamethasone ; LEN=lenalidomide; mg/m2=milligram per meter squared.
Notes: MedDRA version 15.1 used for coding.
This listing Includes deaths that occurred less than or equal to 30 days of last dose.
Number of Days from First Dose of Any Study Drug= Death date-first dosing date of any study drug +1.
Number of Days from Last Dose of Any Study Drug /Carfilzomib= Death date- last dosing date of any study drug /Carfilzomib.
In studies PX-171-009, PX-171-011 and 2011-002, Relationship to Study Treatment by Investigator is based on relationship to study drugs of grade 5 TEAEs if primary cause of death is AE. In other studies, it is from death case report form.

表 2.7.4.7-26　死亡例の一覧表（PX-171-011）（続き 14）

Study	Treatment Group	Subject ID	Age/ Sex	Death Date	Number of Days from First Dose of Any Study Drug	Number of Days from Last Dose of Any Study Drug	Number of Days from Last Dose of Carfilzomib	Cause of Death Primary (Secondary)	Relationship to Study Treatment by Investigator	Relationship to Study Treatment by Sponsor	Fatal AE Preferred Term (AE Number)
Safety Population: Carfilzomib monotherapy and Control PX-171-011 control											
PX-171-011	Corticosteroid + optional Cyclophosphamide	PX171011-24-721-1[redacted]	6[redacted]/ Male	15MAY20[redacted]	14	0		Progressive Disease		No	疾患進行(1)
		PX171011-24-724-1[redacted]	6[redacted]/ Female	06MAY20[redacted]	47	18		Progressive Disease		No	疾患進行(13)
		PX171011-24-724-1[redacted]	6[redacted]/ Male	19JUN20[redacted]	79	29		Adverse Event	No	No	肺出血(2)

AE=Adverse Event; CFZ=carfilzomib; DEX=Dexamethasone ; LEN=lenalidomide; mg/m2=milligram per meter squared.
Notes: MedDRA version 15.1 used for coding.
This listing Includes deaths that occurred less than or equal to 30 days of last dose.
Number of Days from First Dose of Any Study Drug= Death date-first dosing date of any study drug +1.
Number of Days from Last Dose of Any Study Drug /Carfilzomib= Death date- last dosing date of any study drug /Carfilzomib.
In studies PX-171-009, PX-171-011 and 2011-002, Relationship to Study Treatment by Investigator is based on relationship to study drugs of grade 5 TEAEs if primary cause of death is AE. In other studies, it is from death case report form.

表 2.7.4.7-26　死亡例の一覧表（PX-171-011）（続き 15）

Study	Treatment Group	Subject ID	Age/ Sex	Death Date	Number of Days from First Dose of Any Study Drug	Number of Days from Last Dose of Any Study Drug	Number of Days from Last Dose of Carfilzomib	Cause of Death Primary (Secondary)	Relationship to Study Treatment by Investigator	Relationship to Study Treatment by Sponsor	Fatal AE Preferred Term (AE Number)
Safety Population: Carfilzomib monotherapy and Control PX-171-011 control											
PX-171-011	Corticosteroid + optional Cyclophosphamide	PX171011-24-726-1[redacted]	6[redacted]/ Female	11AUG20[redacted]	81	0		Progressive Disease		No	疾患進行(4)
		PX171011-28-227-1[redacted]	7[redacted]/ Female	17OCT20[redacted]	51	6		Progressive Disease		No	疾患進行(1)
		PX171011-28-231-1[redacted]	6[redacted]/ Female	13AUG20[redacted]	54	4		Progressive Disease		No	多発性骨髄腫(12)

AE=Adverse Event; CFZ=carfilzomib; DEX=Dexamethasone ; LEN=lenalidomide; mg/m2=milligram per meter squared.
Notes: MedDRA version 15.1 used for coding.
This listing Includes deaths that occurred less than or equal to 30 days of last dose.
Number of Days from First Dose of Any Study Drug= Death date-first dosing date of any study drug +1.
Number of Days from Last Dose of Any Study Drug /Carfilzomib= Death date- last dosing date of any study drug /Carfilzomib.
In studies PX-171-009, PX-171-011 and 2011-002, Relationship to Study Treatment by Investigator is based on relationship to study drugs of grade 5 TEAEs if primary cause of death is AE. In other studies, it is from death case report form.

表 2.7.4.7-26　死亡例の一覧表（PX-171-011）（続き 16）

Study	Treatment Group	Subject ID	Age/ Sex	Death Date	Number of Days from First Dose of Any Study Drug	Number of Days from Last Dose of Any Study Drug	Number of Days from Last Dose of Carfilzomib	Cause of Death Primary (Secondary)	Relationship to Study Treatment by Investigator	Relationship to Study Treatment by Sponsor	Fatal AE Preferred Term (AE Number)
Safety Population: Carfilzomib monotherapy and Control PX-171-011 control											
PX-171-011	Corticosteroid + optional Cyclophosphamide	PX171011-38-276-1[redacted]	5[redacted]/ Male	20MAY20[redacted]	350	2		Adverse Event	No	No	敗血症性ショック(7)
		PX171011-38-276-1[redacted]	7[redacted]/ Male	06FEB20[redacted]	49	7		Adverse Event	No	No	気管支肺炎(10)
		PX171011-38-277-1[redacted]	7[redacted]/ Female	26JUN20[redacted]	65	5		Progressive Disease		No	疾患進行(6)

AE=Adverse Event; CFZ=carfilzomib; DEX=Dexamethasone ; LEN=lenalidomide; mg/m2=milligram per meter squared.
Notes: MedDRA version 15.1 used for coding.
This listing Includes deaths that occurred less than or equal to 30 days of last dose.
Number of Days from First Dose of Any Study Drug= Death date-first dosing date of any study drug +1.
Number of Days from Last Dose of Any Study Drug /Carfilzomib= Death date- last dosing date of any study drug /Carfilzomib.
In studies PX-171-009, PX-171-011 and 2011-002, Relationship to Study Treatment by Investigator is based on relationship to study drugs of grade 5 TEAEs if primary cause of death is AE. In other studies, it is from death case report form.

表 2.7.4.7-26　死亡例の一覧表（PX-171-011）（続き 17）

Study	Treatment Group	Subject ID	Age/ Sex	Death Date	Number of Days from First Dose of Any Study Drug	Number of Days from Last Dose of Any Study Drug	Number of Days from Last Dose of Carfilzomib	Cause of Death Primary (Secondary)	Relationship to Study Treatment by Investigator	Relationship to Study Treatment by Sponsor	Fatal AE Preferred Term (AE Number)
Safety Population: Carfilzomib monotherapy and Control PX-171-011 control											
PX-171-011	Corticosteroid + optional Cyclophosphamide	PX171011-38-277-1[redacted]	6[redacted]/ Male	11JUL20[redacted]	24	13		Progressive Disease		No	疾患進行(4)
		PX171011-38-278-1[redacted]	6[redacted]/ Male	25DEC20[redacted]	34	9		Progressive Disease		No	疾患進行(3)
		PX171011-38-279-1[redacted]	7[redacted]/ Male	03JAN20[redacted]	109	1		Progressive Disease		No	疾患進行(7)

AE=Adverse Event; CFZ=carfilzomib; DEX=Dexamethasone ; LEN=lenalidomide; mg/m2=milligram per meter squared.
Notes: MedDRA version 15.1 used for coding.
This listing Includes deaths that occurred less than or equal to 30 days of last dose.
Number of Days from First Dose of Any Study Drug= Death date-first dosing date of any study drug +1.
Number of Days from Last Dose of Any Study Drug /Carfilzomib= Death date- last dosing date of any study drug /Carfilzomib.
In studies PX-171-009, PX-171-011 and 2011-002, Relationship to Study Treatment by Investigator is based on relationship to study drugs of grade 5 TEAEs if primary cause of death is AE. In other studies, it is from death case report form.

表 2.7.4.7-26　死亡例の一覧表（PX-171-011）（続き 18）

Study	Treatment Group	Subject ID	Age/ Sex	Death Date	Number of Days from First Dose of Any Study Drug	Number of Days from Last Dose of Any Study Drug	Number of Days from Last Dose of Carfilzomib	Cause of Death Primary (Secondary)	Relationship to Study Treatment by Investigator	Relationship to Study Treatment by Sponsor	Fatal AE Preferred Term (AE Number)
Safety Population: Carfilzomib monotherapy and Control PX-171-011 control											
PX-171-011	Corticosteroid + optional Cyclophosphamide	PX171011-39-477-1[redacted]	6[redacted]/ Female	14OCT20[redacted]	55	1		Adverse Event	Yes	Yes	敗血症性ショック (2)
		PX171011-44-206-1[redacted]	7[redacted]/ Female	02JUL20[redacted]	527	24		Adverse Event	No	No	全身健康状態低下(31)
		PX171011-46-301-1[redacted]	7[redacted]/ Male	16FEB20[redacted]	58	2		Adverse Event	No	No	呼吸不全(4)

AE=Adverse Event; CFZ=carfilzomib; DEX=Dexamethasone ; LEN=lenalidomide; mg/m2=milligram per meter squared.
Notes: MedDRA version 15.1 used for coding.
This listing Includes deaths that occurred less than or equal to 30 days of last dose.
Number of Days from First Dose of Any Study Drug= Death date-first dosing date of any study drug +1.
Number of Days from Last Dose of Any Study Drug /Carfilzomib= Death date- last dosing date of any study drug /Carfilzomib.
In studies PX-171-009, PX-171-011 and 2011-002, Relationship to Study Treatment by Investigator is based on relationship to study drugs of grade 5 TEAEs if primary cause of death is AE. In other studies, it is from death case report form.

表 2.7.4.7-26　死亡例の一覧表（PX-171-011）（続き 19）

Study	Treatment Group	Subject ID	Age/ Sex	Death Date	Number of Days from First Dose of Any Study Drug	Number of Days from Last Dose of Any Study Drug	Number of Days from Last Dose of Carfilzomib	Cause of Death Primary (Secondary)	Relationship to Study Treatment by Investigator	Relationship to Study Treatment by Sponsor	Fatal AE Preferred Term (AE Number)
Safety Population: Carfilzomib monotherapy and Control PX-171-011 control											
PX-171-011	Corticosteroid + optional Cyclophosphamide	PX171011-4 6-303-1[redacted]	7[redacted]/ Female	23FEB20[redacted]	267	28		Progressive Disease		No	多発性骨髄腫(9)
		PX171011-4 6-303-1[redacted]	6[redacted]/ Male	27AUG20[redacted]	91	0		Adverse Event	No	No	肺炎(1)
		PX171011-4 6-303-1[redacted]	6[redacted]/ Female	29AUG20[redacted]	37	15		Adverse Event	No	No	敗血症(7)

AE=Adverse Event; CFZ=carfilzomib; DEX=Dexamethasone ; LEN=lenalidomide; mg/m2=milligram per meter squared.
Notes: MedDRA version 15.1 used for coding.
This listing Includes deaths that occurred less than or equal to 30 days of last dose.
Number of Days from First Dose of Any Study Drug= Death date-first dosing date of any study drug +1.
Number of Days from Last Dose of Any Study Drug /Carfilzomib= Death date- last dosing date of any study drug /Carfilzomib.
In studies PX-171-009, PX-171-011 and 2011-002, Relationship to Study Treatment by Investigator is based on relationship to study drugs of grade 5 TEAEs if primary cause of death is AE. In other studies, it is from death case report form.

表 2.7.4.7-26　死亡例の一覧表（PX-171-011）（続き 20）

Study	Treatment Group	Subject ID	Age/ Sex	Death Date	Number of Days from First Dose of Any Study Drug	Number of Days from Last Dose of Any Study Drug	Number of Days from Last Dose of Carfilzomib	Cause of Death Primary (Secondary)	Relationship to Study Treatment by Investigator	Relationship to Study Treatment by Sponsor	Fatal AE Preferred Term (AE Number)
Safety Population: Carfilzomib monotherapy and Control PX-171-011 control											
PX-171-011	Corticosteroid + optional Cyclophosphamide	PX171011-46-304-1[redacted]	6[redacted]/ Male	12JUL20[redacted]	90	0		Adverse Event	No	No	心不全(2)
		PX171011-46-307-1[redacted]	7[redacted]/ Male	31JAN20[redacted]	96	28		Adverse Event	No	No	肺炎(14)
		PX171011-49-428-1[redacted]	7[redacted]/ Female	01OCT20[redacted]	88	1		Adverse Event	No	No	心停止(3)

AE=Adverse Event; CFZ=carfilzomib; DEX=Dexamethasone ; LEN=lenalidomide; mg/m2=milligram per meter squared.
Notes: MedDRA version 15.1 used for coding.
This listing Includes deaths that occurred less than or equal to 30 days of last dose.
Number of Days from First Dose of Any Study Drug= Death date-first dosing date of any study drug +1.
Number of Days from Last Dose of Any Study Drug /Carfilzomib= Death date- last dosing date of any study drug /Carfilzomib.
In studies PX-171-009, PX-171-011 and 2011-002, Relationship to Study Treatment by Investigator is based on relationship to study drugs of grade 5 TEAEs if primary cause of death is AE. In other studies, it is from death case report form.

表 2.7.4.7-26　死亡例の一覧表（PX-171-011）（続き 21）

Study	Treatment Group	Subject ID	Age/ Sex	Death Date	Number of Days from First Dose of Any Study Drug	Number of Days from Last Dose of Any Study Drug	Number of Days from Last Dose of Carfilzomib	Cause of Death Primary (Secondary)	Relationship to Study Treatment by Investigator	Relationship to Study Treatment by Sponsor	Fatal AE Preferred Term (AE Number)
Safety Population: Carfilzomib monotherapy and Control PX-171-011 control											
PX-171-011	Corticosteroid + optional Cyclophosphamide	PX171011-56-930-1[redacted]	6[redacted]/ Male	03NOV20[redacted]	67	3		Adverse Event	Yes	Yes	肺炎(6)
		PX171011-89-629-1[redacted]	5[redacted]/ Female	16FEB20[redacted]	149	10		Adverse Event	No	No	急性骨髄性白血病(8)

AE=Adverse Event; CFZ=carfilzomib; DEX=Dexamethasone ; LEN=lenalidomide; mg/m2=milligram per meter squared.
Notes: MedDRA version 15.1 used for coding.
This listing Includes deaths that occurred less than or equal to 30 days of last dose.
Number of Days from First Dose of Any Study Drug= Death date-first dosing date of any study drug +1.
Number of Days from Last Dose of Any Study Drug /Carfilzomib= Death date- last dosing date of any study drug /Carfilzomib.
In studies PX-171-009, PX-171-011 and 2011-002, Relationship to Study Treatment by Investigator is based on relationship to study drugs of grade 5 TEAEs if primary cause of death is AE. In other studies, it is from death case report form.

出典［総括報告書5.3.5.1-2（PX-171-011），Listing 16.2.7.3］