ae01_s Listing of Patients with Adverse Events by Trial Treatment and CRTN/Patient Number
Serious Adverse Events On Treatment
Serious Adverse Events
Protocol(s): BM16549
Analysis: SAFETY Center: ALL CENTERS
Treatment: Ibandronate 100mg monthly; N = 396
2-Year Analysis
Adverse Event Onset between Time of Very First Drug Intake and Study Day 9999, Time 23:59

CRTN/Pt. No. / Adverse Event	Age yr	Sex	Weight kg	Race	Intensity	Day of Onset	Duration in days	Relation to Trial Treatment	Outcome	Treatment given for AE	Discontinued or Dose Adjusted
32336/3014	77	F	71	CAUCASIAN							
APHASIA*					SEVERE	24	29	UNRELATED	RESO - W. SEQUEL	YES	DOSAGE MODIFIED
MENINGIOMA*					SEVERE	24	?	UNRELATED	UNRESOLVED	YES	DOSAGE MODIFIED
DIABETES MELLITUS*					MODERATE	36	?	UNRELATED	UNRESOLVED	YES	DOSAGE MODIFIED
PULMONARY EMBOLISM*					LIFE THREATEN	85	12	UNRELATED	RESO - NO SEQUEL	YES	NONE
32336/3022	70	F	77	CAUCASIAN							
VESTIBULAR NEURONITIS*					SEVERE	294	8	UNRELATED	RESO - NO SEQUEL	YES	DOSAGE MODIFIED
FACIAL PARESIS*					SEVERE	307	8	UNRELATED	RESO - NO SEQUEL	YES	DOSAGE MODIFIED
LOCALISED OSTEOARTHRITIS*					SEVERE	418	195	UNRELATED	RESO - W. SEQUEL	YES	DOSAGE MODIFIED
32337/3072	68	F	49	CAUCASIAN							
HYPERTHYROIDISM*					SEVERE	415	200	UNRELATED	RESO - NO SEQUEL	YES	NONE
32337/3080	60	F	75	CAUCASIAN							
MENISCUS LESION*					SEVERE	215	152	UNRELATED	RESO - W. SEQUEL	YES	DISCONTINUED
32337/3091	59	F	59	CAUCASIAN							
THYROID NEOPLASM*					SEVERE		?	UNRELATED	RESO - NO SEQUEL	YES	DOSAGE MODIFIED
32339/0516	64	F	60	CAUCASIAN							
INTESTINAL OBSTRUCTION*					SEVERE	58	16	UNRELATED	RESO - NO SEQUEL	YES	NONE

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* Serious adverse event
'?' = At least one date is missing or invalid.
Time window for early withdrawal pts up to month 23 is from 1st drug intake up to the maximum of the last daily dose date plus 15 days or the last monthly dose date plus 45 days
AE01 23FEB2005:17:25:15 (18 of 27)

ae01_s Listing of Patients with Adverse Events by Trial Treatment and CRTN/Patient Number
Serious Adverse Events On Treatment
Serious Adverse Events
Protocol(s): BM16549
Analysis: SAFETY Center: ALL CENTERS
Treatment: Ibandronate 100mg monthly; N = 396
2-Year Analysis
Adverse Event Onset between Time of Very First Drug Intake and Study Day 9999, Time 23:59

CRTN/Pt. No. Adverse Event	Age yr	Sex	Weight kg	Race	Intensity	Day of Onset	Duration in days	Relation to Trial Treatment	Outcome	Treatment given for AE	Discontinued or Dose Adjusted
32342/4577 BILE DUCT OBSTRUCTION*	71	F	77	CAUCASIAN	SEVERE	40	4	UNRELATED	RESO - NO SEQUEL	YES	DOSAGE MODIFIED
32348/8516 CONCUSSION*	71	F	72	CAUCASIAN	SEVERE	14	<= 1	UNRELATED	RESO - NO SEQUEL	NO	DOSAGE MODIFIED
32351/1406 VASCULAR GRAFT OCCLUSION*	72	F	44	CAUCASIAN	SEVERE	440	16	UNRELATED	RESO - NO SEQUEL	YES	DISCONTINUED
32355/1215 SCIATICA*	57	F	118	CAUCASIAN	SEVERE	400	47	UNRELATED	RESO - NO SEQUEL	YES	NONE
32356/1605 HYPERPARATHYROIDISM*	70	F	64	CAUCASIAN	MODERATE	394	87	UNRELATED	RESO - NO SEQUEL	YES	DOSAGE MODIFIED
32357/1703 TACHYCARDIA*	59	F	51	CAUCASIAN	MODERATE	355	176	UNRELATED	RESO - NO SEQUEL	YES	DOSAGE MODIFIED
32359/1159 GASTROINTESTINAL HAEMORRHAGE*	74	F	65	CAUCASIAN	SEVERE	69	2	UNRELATED	RESO - NO SEQUEL	YES	DOSAGE MODIFIED
32361/1101 PNEUMONIA*	75	F	56	CAUCASIAN	MODERATE	1	17	UNRELATED	RESO - NO SEQUEL	YES	DISCONTINUED

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Time window for early withdrawal pts up to month 23 is from 1st drug intake up to the maximum of the last daily dose date plus 15 days or the last monthly dose date plus 45 days

ae01_s Listing of Patients with Adverse Events by Trial Treatment and CRTN/Patient Number
Serious Adverse Events On Treatment
Serious Adverse Events
Protocol(s): BM16549
Analysis: SAFETY Center: ALL CENTERS
Treatment: Ibandronate 100mg monthly; N = 396
2-Year Analysis
Adverse Event Onset between Time of Very First Drug Intake and Study Day 9999, Time 23:59

CRTN/Pt. No. / Adverse Event	Age yr	Sex	Weight kg	Race	Intensity	Day of Onset	Duration in days	Relation to Trial Treatment	Outcome	Treatment given for AE	Discontinued or Dose Adjusted
32361/1106	71	F	55	CAUCASIAN							
PELVIC PROLAPSE*					MODERATE	33	507	UNRELATED	RESO - W. SEQUEL	YES	DOSAGE MODIFIED
TACHYCARDIA*					MODERATE	280	?	UNRELATED	UNRESOLVED	YES	NONE
PULMONARY EMBOLISM*					LIFE THREATEN	548	5	UNRELATED	RESO - NO SEQUEL	YES	DOSAGE MODIFIED
32364/1364	68	F	71	CAUCASIAN							
CEREBROVASCULAR ACCIDENT*					LIFE THREATEN	62	?	UNRELATED	DEATH	YES	DISCONTINUED
32364/1390	66	F	73	CAUCASIAN							
GANGRENE*					SEVERE	258	152	UNRELATED	RESO - W. SEQUEL	YES	DOSAGE MODIFIED
CARDIAC FAILURE CONGESTIVE*					LIFE THREATEN	666	4	UNRELATED	RESO - NO SEQUEL	YES	DOSAGE MODIFIED
32365/6502	56	F	59	CAUCASIAN							
NEPHROLITHIASIS*					SEVERE	586	49	UNRELATED	RESO - W. SEQUEL	YES	DOSAGE MODIFIED
32368/9022	71	F	68	CAUCASIAN							
GASTRITIS HAEMORRHAGIC*					MODERATE	330	8	PROBABLE	RESO - NO SEQUEL	YES	DOSAGE MODIFIED
32368/9076	57	F	76	CAUCASIAN							
HAEMATOMA INFECTION*					MODERATE	262	5	UNRELATED	RESO - NO SEQUEL	YES	NONE
32368/9096	67	F	82	CAUCASIAN							
SUPERINFECTION*					MODERATE	576	50	UNRELATED	RESO - W. SEQUEL	YES	NONE
OSTEITIS*					MODERATE	624	45	UNRELATED	RESO - NO SEQUEL	YES	DOSAGE MODIFIED

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Time window for early withdrawal pts up to month 23 is from 1st drug intake up to the maximum of the last daily dose date plus 15 days or the last monthly dose date plus 45 days

ae01_s Listing of Patients with Adverse Events by Trial Treatment and CRTN/Patient Number
Serious Adverse Events On Treatment
Serious Adverse Events
Protocol(s): BM16549
Analysis: SAFETY Center: ALL CENTERS
Treatment: Ibandronate 100mg monthly; N = 396
2-Year Analysis
Adverse Event Onset between Time of Very First Drug Intake and Study Day 9999, Time 23:59

CRTN/Pt. No. / Adverse Event	Age yr	Sex	Weight kg	Race	Intensity	Day of Onset	Duration in days	Relation to Trial Treatment	Outcome	Treatment given for AE	Discontinued or Dose Adjusted
32368/9342	69	F	63	CAUCASIAN							
URETHRAL SYNDROME*					MODERATE		?	UNRELATED	RESO - NO SEQUEL	YES	DOSAGE MODIFIED
REFLUX GASTRITIS*					SEVERE	638	130	UNRELATED	RESO - W. SEQUEL	YES	DOSAGE MODIFIED
32368/9346	64	F	59	CAUCASIAN							
CERVICAL POLYP*					MILD	625	4	UNRELATED	RESO - NO SEQUEL	YES	NONE
DIARRHOEA*					MODERATE	721	6	UNRELATED	RESO - NO SEQUEL	YES	DOSAGE MODIFIED
32368/9352	67	F	75	CAUCASIAN							
LARYNGOPHARYNGITIS*					MODERATE	553	7	UNRELATED	RESO - NO SEQUEL	YES	NONE
32368/9359	76	F	69	CAUCASIAN							
RECTOSIGMOID CANCER*					SEVERE	315	17	UNRELATED	RESO - NO SEQUEL	YES	DISCONTINUED

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AE01 23FEB2005:17:25:15 (21 of 27)

ae01_s Listing of Patients with Adverse Events by Trial Treatment and CRTN/Patient Number
Serious Adverse Events On Treatment
Serious Adverse Events
Protocol(s): BM16549
Analysis: SAFETY Center: ALL CENTERS
Treatment: Ibandronate 150mg monthly; N = 396
2-Year Analysis
Adverse Event Onset between Time of Very First Drug Intake and Study Day 9999, Time 23:59

CRTN/Pt. No. Adverse Event	Age yr	Sex	Weight kg	Race	Intensity	Day of Onset	Duration in days	Relation to Trial Treatment	Outcome	Treatment given for AE	Discontinued or Dose Adjusted
32304/0167	65	F	45	CAUCASIAN							
AUTOIMMUNE THYROIDITIS*					MODERATE	346	?	UNRELATED	UNRESOLVED	YES	DOSAGE MODIFIED
32306/7605	57	F	59	CAUCASIAN							
BURSITIS*					SEVERE	443	270	UNRELATED	RESO - NO SEQUEL	YES	DOSAGE MODIFIED
32308/7666	77	F	46	CAUCASIAN							
LOWER RESPIRATORY TRACT INFECTION*					MODERATE	426	11	UNRELATED	RESO - NO SEQUEL	YES	DOSAGE MODIFIED
LUNG NEOPLASM MALIGNANT*					LIFE THREATEN	553	?	UNRELATED	UNRESOLVED	NO	DISCONTINUED
32310/2552	59	F	63	HISPANIC							
PAIN TRAUMA ACTIVATED*					MODERATE	702	?	UNRELATED	UNRESOLVED	YES	NONE
32313/6028	67	F	62	CAUCASIAN							
NEUROPATHY PERIPHERAL*					MODERATE	534	?	UNRELATED	UNRESOLVED	NO	NONE
32314/8726	76	F	76	CAUCASIAN							
APPENDICITIS*					SEVERE	18	<= 1	UNRELATED	RESO - NO SEQUEL	YES	NONE
32314/8755	62	F	64	CAUCASIAN							
ERYSIPELAS*					MODERATE	613	13	UNRELATED	RESO - NO SEQUEL	YES	NONE
32314/8761	72	F	50	CAUCASIAN							
MYOCARDIAL ISCHAEMIA*					MODERATE	383	4	UNRELATED	RESO - W. SEQUEL	YES	NONE
32318/8001	61	F	60	CAUCASIAN							
NEPHROLITHIASIS*					MODERATE	264	8	UNRELATED	RESO - NO SEQUEL	YES	NONE

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ae01_s Listing of Patients with Adverse Events by Trial Treatment and CRTN/Patient Number
Serious Adverse Events On Treatment
Serious Adverse Events
Protocol(s): BM16549
Analysis: SAFETY Center: ALL CENTERS
Treatment: Ibandronate 150mg monthly; N = 396
2-Year Analysis
Adverse Event Onset between Time of Very First Drug Intake and Study Day 9999, Time 23:59

CRTN/Pt. No. / Adverse Event	Age yr	Sex	Weight kg	Race	Intensity	Day of Onset	Duration in days	Relation to Trial Treatment	Outcome	Treatment given for AE	Discontinued or Dose Adjusted
32318/8019 CARDIAC FAILURE*	65	F	60	CAUCASIAN	MILD	91	22	UNRELATED	RESO - NO SEQUEL	NO	DOSAGE MODIFIED
32318/8022 BREAST CANCER IN SITU*	57	F	62	CAUCASIAN	SEVERE	294	?	UNRELATED	UNRESOLVED	YES	DOSAGE MODIFIED
32318/8038 PYELONEPHRITIS*	77	F	64	CAUCASIAN	MODERATE	230	11	UNRELATED	RESO - NO SEQUEL	YES	NONE
32320/8107 GASTRIC ULCER HAEMORRHAGE*	74	F	43	CAUCASIAN	SEVERE	425	8	PROBABLE	RESO - NO SEQUEL	YES	DISCONTINUED
32320/8389 HYPERTENSION*	60	F	77	CAUCASIAN	SEVERE	360	4	UNRELATED	RESO - NO SEQUEL	YES	DOSAGE MODIFIED
32323/5101 VERTEBROBASILAR INSUFFICIENCY*	72	F	53	CAUCASIAN	MODERATE	205	9	UNRELATED	RESO - NO SEQUEL	YES	NONE
32323/5145 SALMONELLOSIS*	70	F	61	CAUCASIAN	MODERATE	669	6	UNRELATED	RESO - NO SEQUEL	YES	DOSAGE MODIFIED
32324/4002 RENAL COLIC*	74	F	63	CAUCASIAN	MODERATE	522	6	UNRELATED	RESO - NO SEQUEL	NO	DOSAGE MODIFIED

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AE01 23FEB2005:17:25:15 (23 of 27)

ae01_s Listing of Patients with Adverse Events by Trial Treatment and CRTN/Patient Number
Serious Adverse Events On Treatment
Serious Adverse Events
Protocol(s): BM16549
Analysis: SAFETY Center: ALL CENTERS
Treatment: Ibandronate 150mg monthly; N = 396
2-Year Analysis
Adverse Event Onset between Time of Very First Drug Intake and Study Day 9999, Time 23:59

CRTN/Pt. No. Adverse Event	Age yr	Sex	Weight kg	Race	Intensity	Day of Onset	Duration in days	Relation to Trial Treatment	Outcome	Treatment given for AE	Discontinued or Dose Adjusted
32324/4005 PSEUDARTHROSIS*	60	F	79	CAUCASIAN	MODERATE		?	UNRELATED	RESO - NO SEQUEL	YES	NONE
32324/4036 MELAENA*	63	F	63	CAUCASIAN	MILD	98	<= 1	UNRELATED	RESO - NO SEQUEL	NO	NONE
32326/4510 HEAD INJURY*	73	F	61	CAUCASIAN	SEVERE	529	3	UNRELATED	RESO - NO SEQUEL	NO	NONE
32326/4525 ABDOMINAL PAIN UPPER*	74	F	53	CAUCASIAN	SEVERE	125	10	UNRELATED	RESO - NO SEQUEL	NO	NONE
32331/2020 AORTIC ANEURYSM*	77	F	58	CAUCASIAN	SEVERE	277	?	UNRELATED	UNRESOLVED	YES	NONE
32332/2752 CARDIAC FAILURE*	65	F	59	CAUCASIAN	SEVERE	249	35	UNRELATED	RESO - NO SEQUEL	YES	NONE
32336/3007 GAMMOPATHY*	67	F	78	CAUCASIAN	MODERATE	325	?	UNRELATED	UNRESOLVED	NO	NONE
32336/3018 INTERMITTENT CLAUDICATION*	73	F	68	CAUCASIAN	SEVERE	249	13	UNRELATED	RESO - W. SEQUEL	NO	DOSAGE MODIFIED
32339/0502 CARDIAC FAILURE*	67	F	72	CAUCASIAN	MODERATE	586	4	UNRELATED	RESO - NO SEQUEL	YES	DOSAGE MODIFIED
32340/0554 FEMUR FRACTURE*	59	F	41	CAUCASIAN	SEVERE	297	22	UNRELATED	RESO - NO SEQUEL	YES	DOSAGE MODIFIED

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AE01 23FEB2005:17:25:15 (24 of 27)

ae01_s Listing of Patients with Adverse Events by Trial Treatment and CRTN/Patient Number
Serious Adverse Events On Treatment
Serious Adverse Events
Protocol(s): BM16549
Analysis: SAFETY Center: ALL CENTERS
Treatment: Ibandronate 150mg monthly; N = 396
2-Year Analysis
Adverse Event Onset between Time of Very First Drug Intake and Study Day 9999, Time 23:59

CRTN/Pt. No. Adverse Event	Age yr	Sex	Weight kg	Race	Intensity	Day of Onset	Duration in days	Relation to Trial Treatment	Outcome	Treatment given for AE	Discontinued or Dose Adjusted
32340/0562 PNEUMONIA*	61	F	64	CAUCASIAN	MODERATE	303	7	UNRELATED	RESO - NO SEQUEL	YES	DOSAGE MODIFIED
32340/0572 HYPERPARATHYROIDISM PRIMARY*	66	F	81	CAUCASIAN	MODERATE	190	72	UNRELATED	RESO - W. SEQUEL	YES	DOSAGE MODIFIED
32342/4569 PNEUMONIA*	60	F	76	CAUCASIAN	SEVERE	547	14	UNRELATED	RESO - NO SEQUEL	YES	DOSAGE MODIFIED
32348/8523 MACULAR HOLE*	67	F	65	CAUCASIAN	MODERATE	132	2	UNRELATED	RESO - W. SEQUEL	YES	DOSAGE MODIFIED
32348/8577 CHEST PAIN*	72	F	75	CAUCASIAN	MODERATE	204	2	UNRELATED	RESO - NO SEQUEL	NO	NONE
32356/1604 INTESTINAL OBSTRUCTION*	63	F	53	CAUCASIAN	MODERATE	200	12	UNRELATED	RESO - NO SEQUEL	YES	DISCONTINUED
32357/1712 EAR INFECTION*	58	F	63	CAUCASIAN	MILD	663	6	UNRELATED	RESO - NO SEQUEL	YES	NONE
32361/1110 GASTRIC ULCER*	71	F	37	ASIAN	MODERATE	45	154	UNRELATED	RESO - NO SEQUEL	YES	NONE
32361/1123 LOCALISED OSTEOARTHRITIS*	80	F	78	CAUCASIAN	SEVERE	46	29	UNRELATED	RESO - W. SEQUEL	YES	DOSAGE MODIFIED

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Time window for early withdrawal pts up to month 23 is from 1st drug intake up to the maximum of the last daily dose date plus 15 days or the last monthly dose date plus 45 days
AE01 23FEB2005:17:25:15 (25 of 27)

ae01_s Listing of Patients with Adverse Events by Trial Treatment and CRTN/Patient Number
Serious Adverse Events On Treatment
Serious Adverse Events
Protocol(s): BM16549
Analysis: SAFETY Center: ALL CENTERS
Treatment: Ibandronate 150mg monthly; N = 396
2-Year Analysis
Adverse Event Onset between Time of Very First Drug Intake and Study Day 9999, Time 23:59

CRTN/Pt. No. / Adverse Event	Age yr	Sex	Weight kg	Race	Intensity	Day of Onset	Duration in days	Relation to Trial Treatment	Outcome	Treatment given for AE	Discontinued or Dose Adjusted
32364/1362	60	F	83	CAUCASIAN							
INTERVERTEBRAL DISC PROTRUSION*					SEVERE	109	3	UNRELATED	RESO - NO SEQUEL	YES	DOSAGE MODIFIED
32364/1379	66	F	57	CAUCASIAN							
ANGINA PECTORIS*					MODERATE	631	2	UNRELATED	RESO - NO SEQUEL	YES	NONE
32368/9023	64	F	82	CAUCASIAN							
ABDOMINAL PAIN*					MODERATE	163	13	UNRELATED	RESO - NO SEQUEL	YES	DISCONTINUED
32368/9089	69	F	59	CAUCASIAN							
MAJOR DEPRESSION*					SEVERE	137	99	UNRELATED	RESO - W. SEQUEL	YES	DISCONTINUED
32368/9091	56	F	60	CAUCASIAN							
CHEST PAIN*					MODERATE	462	3	UNRELATED	RESO - NO SEQUEL	YES	NONE
32368/9311	62	F	73	CAUCASIAN							
LOWER LIMB FRACTURE*					SEVERE	44	21	UNRELATED	RESO - NO SEQUEL	YES	DOSAGE MODIFIED
32368/9316	79	F	60	CAUCASIAN							
CONSTIPATION*					SEVERE	210	7	UNRELATED	RESO - NO SEQUEL	YES	DOSAGE MODIFIED
MYOCARDIAL ISCHAEMIA*					MILD	210	7	UNRELATED	RESO - NO SEQUEL	YES	DOSAGE MODIFIED
HAEMORRHAGIC CEREBRAL INFARCTION*					LIFE THREATEN	285	?	UNRELATED	DEATH	NO	DISCONTINUED
32369/1890	70	F	46	CAUCASIAN							
EMPHYSEMA*					MILD	256	?	UNRELATED	UNRESOLVED	YES	DOSAGE MODIFIED

CRTN = Clinical Research Task Number (center no.)
For processing, missing TT end date and time are replaced by TT start date and time.
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'?' = At least one date is missing or invalid.
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AE01 23FEB2005:17:25:15 (26 of 27)

ae01_s Listing of Patients with Adverse Events by Trial Treatment and CRTN/Patient Number
Serious Adverse Events On Treatment
Serious Adverse Events
Protocol(s): BM16549
Analysis: SAFETY Center: ALL CENTERS
Treatment: Ibandronate 150mg monthly; N = 396
2-Year Analysis
Adverse Event Onset between Time of Very First Drug Intake and Study Day 9999, Time 23:59

CRTN/Pt. No. / Adverse Event	Age yr	Sex	Weight kg	Race	Intensity	Day of Onset	Duration in days	Relation to Trial Treatment	Outcome	Treatment given for AE	Discontinued or Dose Adjusted
32373/9156	66	F	55	HISPANIC							
GASTROINTESTINAL HAEMORRHAGE*					LIFE THREATEN	8	4	UNRELATED	RESO - NO SEQUEL	YES	DOSAGE MODIFIED
LOCALISED OSTEOARTHRITIS*					SEVERE	561	107	UNRELATED	RESO - NO SEQUEL	YES	DOSAGE MODIFIED

CRTN = Clinical Research Task Number (center no.)
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Time window for early withdrawal pts up to month 23 is from 1st drug intake up to the maximum of the last daily dose date plus 15 days or the last monthly dose date plus 45 days
AE01 23FEB2005:17:25:15 (27 of 27)

（5.3.5.1-4 Supporting Data Presentations ae01_s を再掲）

表 2.7.4.7-6　海外第Ⅲb 相臨床試験における重篤な有害事象の一覧（MA17903）

ae01_s Listing of Patients with Serious Adverse Events On Treatment by Trial Treatment and CRTN/Patient Number
Serious Adverse Events
Protocol(s): MA17903
Analysis: SAFETY Center: ALL CENTERS
Treatment: Ibandronate 100 mg monthly; N = 358
Adverse Event Onset between Time of Very First Drug Intake and Study Day 9999, Time 23:59

MA17903 CRTN/Pt. No. / Adverse Event	BM16549 CRTN/Pt. No.	Age yr	Sex	Weight kg	Race / Intensity	Day of Onset	Duration in days	Relation to Trial Treatment	Outcome	Trt given for AE	Discontinued or Dose Adjusted
43083/1512	32336/3017	77	F	90	CAUCASIAN						
AORTIC VALVE STENOSIS*					SEVERE	102	760	UNRELATED	RESO - NO SEQUEL	YES	DOSAGE MODIFIED
43083/1514	32336/3022	72	F	70	CAUCASIAN						
OSTEOARTHRITIS*					SEVERE	145	52	UNRELATED	RESO - NO SEQUEL	YES	NONE
43084/1537	32337/3072	70	F	50	CAUCASIAN						
HYPERTHYROIDISM*					SEVERE	210	112	UNRELATED	RESO - NO SEQUEL	YES	NONE
LARYNGEAL NEOPLASM*					SEVERE	264	3	UNRELATED	RESO - NO SEQUEL	YES	NONE
43084/1552	32337/3060	57	F	59	CAUCASIAN						
OSTEOARTHRITIS*					MODERATE	1067	8	UNRELATED	RESO - NO SEQUEL	YES	NONE
43090/3006	32325/4107	72	F	70	CAUCASIAN						
DIVERTICULITIS*					SEVERE	969	12	UNRELATED	RESO - NO SEQUEL	YES	NONE
43090/3008	32325/4111	68	F	84	CAUCASIAN						
AORTIC ANEURYSM*					SEVERE	927	2	UNRELATED	RESO - NO SEQUEL	YES	NONE
43090/3010	32325/4201	77	F	59	CAUCASIAN						
TENDON RUPTURE*					SEVERE	934	81	UNRELATED	RESO - NO SEQUEL	YES	NONE
43091/3015	32324/4018	69	F	50	CAUCASIAN						
BLADDER CANCER*					SEVERE	161	?	UNRELATED	UNRESOLVED	YES	NONE
ABDOMINAL PAIN*					SEVERE	820	?	UNRELATED	UNRESOLVED	YES	NONE
INTESTINAL OBSTRUCTION*					SEVERE	843	?	UNRELATED	DEATH	NO	DISCONTINUED
43091/3022	32324/4011	62	F	74	CAUCASIAN						
FACIAL PARESIS*					MILD	899	28	UNRELATED	RESO - NO SEQUEL	NO	NONE
HEMIPARESIS*					MILD	899	28	UNRELATED	RESO - NO SEQUEL	NO	NONE
43091/3023	32324/4008	73	F	52	CAUCASIAN						
WRIST FRACTURE*					MILD	853	43	UNRELATED	RESO - NO SEQUEL	YES	NONE

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Time window for on treatment adverse events is from 1st drug intake up to the last monthly dose date plus 45 days
AE08/AE01 05MAR2008:18:35:40

ae01_s Listing of Patients with Serious Adverse Events On Treatment by Trial Treatment and CRTN/Patient Number
Serious Adverse Events
Protocol(s): MA17903
Analysis: SAFETY Center: ALL CENTERS
Treatment: Ibandronate 100 mg monthly; N = 358
Adverse Event Onset between Time of Very First Drug Intake and Study Day 9999, Time 23:59

MA17903 CRTN/Pt. No. Adverse Event	BM16549 CRTN/Pt. No.	Age yr	Sex	Weight kg	Race Intensity	Day of Onset	Duration in days	Relation to Trial Treatment	Outcome	Trt given for AE	Discontinued or Dose Adjusted
43091/3030	32324/4029	78	F	48	CAUCASIAN						
ADENOCARCINOMA PANCREAS*					SEVERE	100	?	UNRELATED	DEATH	YES	DISCONTINUED
43091/3034	32324/4030	75	F	64	CAUCASIAN						
BACK PAIN*					MILD	158	?	UNRELATED	RESO - NO SEQUEL	YES	NONE
THORACIC VERTEBRAL FRACTURE*					MODERATE	649	< 1	UNRELATED	RESO - NO SEQUEL	YES	NONE
43093/6514	32323/5136	78	F	81	CAUCASIAN						
ANKLE FRACTURE*					MODERATE	168	7	UNRELATED	RESO - NO SEQUEL	YES	NONE
THROMBOPHLEBITIS*					MILD	223	?	UNRELATED	UNRESOLVED	YES	NONE
BACK PAIN*					MODERATE	527	?	UNRELATED	UNRESOLVED	YES	NONE
URETERITIS*					MODERATE	581	15	UNRELATED	RESO - NO SEQUEL	YES	NONE
43093/6522	32323/5141	67	F	52	CAUCASIAN						
FEMUR FRACTURE*					MODERATE	826	?	UNRELATED	UNRESOLVED	YES	NONE
PNEUMONIA*					MILD	945	?	UNRELATED	UNRESOLVED	YES	NONE
43093/6524	32323/5138	77	F	60	CAUCASIAN						
INFECTED SKIN ULCER*					MILD	534	?	UNRELATED	UNRESOLVED	YES	NONE
PULMONARY EMBOLISM*					LIFE THREATE	688	2	UNRELATED	DEATH	NO	DISCONTINUED
43093/6529	32323/5122	75	F	47	CAUCASIAN						
UTERINE PROLAPSE*					MILD	641	7	UNRELATED	RESO - NO SEQUEL	YES	NONE
GASTROINTESTINAL NEOPLASM*					LIFE THREATE	939	?	UNRELATED	DEATH	YES	NONE
43093/6534	32323/5132	67	F	67	CAUCASIAN						
SUPRAVENTRICULAR TACHYCARDIA*					MODERATE	62	?	UNRELATED	UNRESOLVED	YES	NONE
ATRIAL FIBRILLATION*					MILD	370	?	UNRELATED	UNRESOLVED	NO	NONE
POST PROCEDURAL HAEMORRHAGE*					MILD	617	6	UNRELATED	RESO - NO SEQUEL	NO	NONE
43094/8040	32341/4540	77	F	44	CAUCASIAN						
CHRONIC OBSTRUCTIVE PULMONARY DISEASE*					SEVERE	164	?	UNRELATED	UNRESOLVED	YES	DISCONTINUED
43095/8058	32342/4579	58	F	45	CAUCASIAN						
BREAST CANCER*					MODERATE	515	340	UNRELATED	RESO - NO SEQUEL	YES	NONE

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ae01_s Listing of Patients with Serious Adverse Events On Treatment by Trial Treatment and CRTN/Patient Number
Serious Adverse Events
Protocol(s): MA17903
Analysis: SAFETY Center: ALL CENTERS
Treatment: Ibandronate 100 mg monthly; N = 358
Adverse Event Onset between Time of Very First Drug Intake and Study Day 9999, Time 23:59

MA17903 CRTN/Pt. No. Adverse Event	BM16549 CRTN/Pt. No.	Age yr	Sex	Weight kg	Race Intensity	Day of Onset	Duration in days	Relation to Trial Treatment	Outcome	Trt given for AE	Discontinued or Dose Adjusted
43096/2001	32320/8139	68	F	71	CAUCASIAN						
CHOLELITHIASIS*					SEVERE	662	< 1	UNRELATED	RESO - NO SEQUEL	NO	NONE
AORTIC VALVE STENOSIS*					MODERATE	714	< 1	UNRELATED	RESO - NO SEQUEL	NO	NONE
43096/2008	32320/8102	81	F	65	CAUCASIAN						
WRIST FRACTURE*					MODERATE	163	37	UNRELATED	RESO - NO SEQUEL	YES	NONE
BACK PAIN*					MODERATE	719	10	UNRELATED	RESO - NO SEQUEL	YES	NONE
43096/2019	32320/8119	73	F	76	CAUCASIAN						
MYOCARDIAL INFARCTION*					SEVERE	555	18	UNRELATED	RESO - W. SEQUEL	YES	DOSAGE MODIFIED
43096/2021	32320/8120	66	F	47	CAUCASIAN						
WEIGHT DECREASED*					MODERATE	55	27	UNRELATED	RESO - NO SEQUEL	NO	NONE
43096/2025	32320/8123	67	F	72	CAUCASIAN						
CATARACT*					MODERATE	578	54	UNRELATED	RESO - NO SEQUEL	YES	NONE
CATARACT*					MODERATE	630	71	UNRELATED	RESO - NO SEQUEL	YES	NONE
43096/2028	32320/8132	77	F	63	CAUCASIAN						
MYOCARDIAL ISCHAEMIA*					MODERATE	229	18	UNRELATED	RESO - NO SEQUEL	YES	NONE
43096/2037	32320/8392	60	F	76	CAUCASIAN						
VERTEBROBASILAR INSUFFICIENCY*					MODERATE	37	9	UNRELATED	RESO - NO SEQUEL	YES	NONE
43097/2057	32318/8008	58	F	56	CAUCASIAN						
MYOCARDIAL INFARCTION*					SEVERE	127	8	UNRELATED	RESO - NO SEQUEL	YES	NONE
43097/2071	32318/8025	77	F	65	CAUCASIAN						
ACUTE MYOCARDIAL INFARCTION*					SEVERE	342	29	UNRELATED	RESO - NO SEQUEL	YES	DOSAGE MODIFIED
43098/2112	32319/8220	60	F	74	CAUCASIAN						
HYPERTENSION*					MILD	709	47	UNRELATED	RESO - NO SEQUEL	YES	NONE
ABDOMINAL PAIN UPPER*					MILD	747	4	UNRELATED	RESO - NO SEQUEL	NO	NONE

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ae01_s Listing of Patients with Serious Adverse Events On Treatment by Trial Treatment and CRTN/Patient Number
Serious Adverse Events
Protocol(s): MA17903
Analysis: SAFETY Center: ALL CENTERS
Treatment: Ibandronate 100 mg monthly; N = 358
Adverse Event Onset between Time of Very First Drug Intake and Study Day 9999, Time 23:59

MA17903 CRTN/Pt. No. Adverse Event	BM16549 CRTN/Pt. No.	Age yr	Sex	Weight kg	Race Intensity	Day of Onset	Duration in days	Relation to Trial Treatment	Outcome	Trt given for AE	Discontinued or Dose Adjusted
43098/2113	32319/8153	78	F	54	CAUCASIAN						
RIB FRACTURE*					MILD	644	7	UNRELATED	RESO - NO SEQUEL	NO	NONE
RECTAL NEOPLASM*					MODERATE	755	55	UNRELATED	RESO - NO SEQUEL	YES	DISCONTINUED
43098/2119	32319/8150	66	F	63	CAUCASIAN						
GOITRE*					MILD	544	9	UNRELATED	RESO - NO SEQUEL	YES	NONE
BRAIN NEOPLASM BENIGN*					MODERATE	876	16	UNRELATED	RESO - NO SEQUEL	YES	NONE
DEEP VEIN THROMBOSIS*					MILD	973	18	UNRELATED	RESO - NO SEQUEL	YES	NONE
43098/2127	32319/8164	64	F	64	CAUCASIAN						
NEPHROLITHIASIS*					MODERATE	120	15	UNRELATED	RESO - NO SEQUEL	YES	NONE
43100/2175	32343/8263	62	F	58	CAUCASIAN						
VERTEBROBASILAR INSUFFICIENCY*					MODERATE	361	8	UNRELATED	RESO - NO SEQUEL	YES	NONE
43100/2178	32343/8277	72	F	60	CAUCASIAN						
SIGNET-RING CELL CARCINOMA*					MODERATE	476	12	UNRELATED	RESO - NO SEQUEL	YES	NONE
43101/9013	32348/8534	73	F	71	CAUCASIAN						
WOUND INFECTION*					MODERATE	168	11	UNRELATED	RESO - NO SEQUEL	YES	NONE
43101/9015	32348/8526	69	F	65	CAUCASIAN						
PELVIC FRACTURE*					MODERATE	289	< 1	UNRELATED	RESO - NO SEQUEL	YES	NONE
43101/9016	32348/8525	75	F	52	CAUCASIAN						
CONFUSIONAL STATE*					SEVERE	1054	?	UNRELATED	UNRESOLVED	NO	DOSAGE MODIFIED
43101/9022	32348/8522	75	F	66	CAUCASIAN						
ATRIAL FLUTTER*					MODERATE	252	3	UNRELATED	RESO - NO SEQUEL	NO	NONE
43101/9026	32348/8543	79	F	71	CAUCASIAN						
COLON CANCER*					MILD	998	75	UNRELATED	RESO - NO SEQUEL	YES	NONE

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AE08/AE01 05MAR2008:18:35:40 (4 of 14)

ae01_s Listing of Patients with Serious Adverse Events On Treatment by Trial Treatment and CRTN/Patient Number
Serious Adverse Events
Protocol(s): MA17903
Analysis: SAFETY Center: ALL CENTERS
Treatment: Ibandronate 100 mg monthly; N = 358
Adverse Event Onset between Time of Very First Drug Intake and Study Day 9999, Time 23:59

MA17903 CRTN/Pt. No. Adverse Event	BM16549 CRTN/Pt. No.	Age yr	Sex	Weight kg	Race Intensity	Day of Onset	Duration in days	Relation to Trial Treatment	Outcome	Trt given for AE	Discontinued or Dose Adjusted
43101/9037	32348/8508	79	F	73	CAUCASIAN						
FIBROUS DYSPLASIA OF BONE*					MODERATE	505	?	UNRELATED	UNRESOLVED	NO	NONE
HAEMANGIOMA OF LIVER*					MILD	535	?	UNRELATED	UNRESOLVED	NO	NONE
43101/9048	32348/8561	76	F	58	CAUCASIAN						
INGUINAL HERNIA*					MODERATE	819	4	UNRELATED	RESO - NO SEQUEL	YES	NONE
43102/9094	32314/8769	74	F	66	CAUCASIAN						
ATRIOVENTRICULAR BLOCK SECOND DEGREE*					MODERATE	444	2	UNRELATED	RESO - NO SEQUEL	YES	NONE
43102/9099	32314/8705	80	F	49	CAUCASIAN						
MYOCARDIAL INFARCTION*					LIFE THREATE	439	3	UNRELATED	DEATH	YES	NONE
43102/9100	32314/8758	65	F	63	CAUCASIAN						
BREAST CANCER*					MILD	440	115	UNRELATED	RESO - NO SEQUEL	YES	DOSAGE MODIFIED
43102/9106	32314/8762	77	F	49	CAUCASIAN						
OSTEOARTHRITIS*					MODERATE	648	192	UNRELATED	RESO - W. SEQUEL	YES	NONE
43102/9113	32314/8727	79	F	56	CAUCASIAN						
CERVIX DISORDER*					MILD	86	152	UNRELATED	RESO - NO SEQUEL	YES	NONE
43102/9117	32314/8728	67	F	89	CAUCASIAN						
METASTATIC GASTRIC CANCER*					MILD	1050	?	UNRELATED	UNRESOLVED	YES	NONE
43102/9119	32314/8763	78	F	48	CAUCASIAN						
ABDOMINAL PAIN*					MODERATE	330	7	UNRELATED	RESO - NO SEQUEL	NO	NONE
43102/9122	32314/8771	71	F	71	CAUCASIAN						
PATELLA FRACTURE*					MODERATE	73	62	UNRELATED	RESO - NO SEQUEL	YES	NONE
DEEP VEIN THROMBOSIS*					MODERATE	130	6	UNRELATED	RESO - NO SEQUEL	YES	NONE
OSTEOARTHRITIS*					MODERATE	362	122	UNRELATED	RESO - NO SEQUEL	YES	NONE
OSTEOARTHRITIS*					MODERATE	452	?	UNRELATED	UNRESOLVED	YES	NONE

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ae01_s Listing of Patients with Serious Adverse Events On Treatment by Trial Treatment and CRTN/Patient Number
Serious Adverse Events
Protocol(s): MA17903
Analysis: SAFETY Center: ALL CENTERS
Treatment: Ibandronate 100 mg monthly; N = 358
Adverse Event Onset between Time of Very First Drug Intake and Study Day 9999, Time 23:59

MA17903 CRTN/Pt. No. Adverse Event	BM16549 CRTN/Pt. No.	Age yr	Sex	Weight kg	Race Intensity	Day of Onset	Duration in days	Relation to Trial Treatment	Outcome	Trt given for AE	Discontinued or Dose Adjusted
43102/9123	32314/8772	68	F	70	CAUCASIAN						
VAGINAL DISORDER*					MODERATE	224	244	UNRELATED	RESO - NO SEQUEL	YES	NONE
43103/6029	32316/5532	60	F	61	CAUCASIAN						
CHOLELITHIASIS*					MODERATE	82	53	UNRELATED	RESO - NO SEQUEL	YES	NONE
APPENDICITIS*					SEVERE	364	11	UNRELATED	RESO - NO SEQUEL	YES	NONE
43103/6031	32316/5534	60	F	66	CAUCASIAN						
MYOCARDIAL ISCHAEMIA*					MODERATE	477	4	UNRELATED	RESO - NO SEQUEL	YES	NONE
43103/6043	32316/5554	71	F	66	CAUCASIAN						
CATARACT*					MODERATE	36	?	UNRELATED	RESO - NO SEQUEL	YES	NONE
43103/6047	32316/5556	61	F	68	CAUCASIAN						
MYOCARDIAL INFARCTION*					MODERATE	718	4	UNRELATED	RESO - NO SEQUEL	YES	NONE
43104/8021	32326/4530	73	F	64	CAUCASIAN						
MALIGNANT MELANOMA*					MODERATE	126	299	UNRELATED	RESO - NO SEQUEL	YES	NONE
RECTAL CANCER*					SEVERE	642	426	UNRELATED	RESO - NO SEQUEL	YES	NONE
43104/8022	32326/4122	69	F	40	CAUCASIAN						
CACHEXIA*					LIFE THREATE	445	< 1	UNRELATED	DEATH	NO	DISCONTINUED
43104/8026	32326/4128	77	F	60	CAUCASIAN						
SUBDURAL HAEMATOMA*					MODERATE	335	33	UNRELATED	RESO - NO SEQUEL	YES	NONE
43105/4002	32352/1803	61	F	91	CAUCASIAN						
URETERIC OBSTRUCTION*					SEVERE	612	4	UNRELATED	RESO - NO SEQUEL	YES	NONE
43106/4021	32355/1214	75	F	69	CAUCASIAN						
HYPONATRAEMIA*					SEVERE	957	12	UNRELATED	RESO - NO SEQUEL	YES	NONE

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Serious Adverse Events
Protocol(s): MA17903
Analysis: SAFETY Center: ALL CENTERS
Treatment: Ibandronate 100 mg monthly; N = 358
Adverse Event Onset between Time of Very First Drug Intake and Study Day 9999, Time 23:59

MA17903 CRTN/Pt. No. Adverse Event	BM16549 CRTN/Pt. No.	Age yr	Sex	Weight kg	Race Intensity	Day of Onset	Duration in days	Relation to Trial Treatment	Outcome	Trt given for AE	Discontinued or Dose Adjusted
43107/4037	32357/1707	65	F	118	CAUCASIAN						
CONTUSION*					SEVERE	284	440	UNRELATED	RESO - NO SEQUEL	YES	DOSAGE MODIFIED
PLEURAL EFFUSION*					MODERATE	284	440	UNRELATED	RESO - NO SEQUEL	NO	NONE
RIB FRACTURE*					SEVERE	284	440	UNRELATED	RESO - NO SEQUEL	YES	DOSAGE MODIFIED
METASTATIC RENAL CELL CARCINOMA*					LIFE THREATE	939	?	UNRELATED	UNRESOLVED	YES	NONE
43111/1013	32313/6021	76	F	51	CAUCASIAN						
CATARACT*					MODERATE	19	?	UNRELATED	UNRESOLVED	YES	NONE
43111/1014	32313/6023	76	F	47	CAUCASIAN						
WRIST FRACTURE*					MODERATE	254	77	UNRELATED	RESO - NO SEQUEL	YES	DOSAGE MODIFIED
43111/1017	32313/6024	69	F	60	CAUCASIAN						
HUMERUS FRACTURE*					MODERATE	115	41	UNRELATED	RESO - W. SEQUEL	YES	NONE
43111/1020	32313/6027	73	F	61	CAUCASIAN						
RETINAL DETACHMENT*					SEVERE	131	55	UNRELATED	RESO - W. SEQUEL	YES	DOSAGE MODIFIED
43112/7012	32333/2822	68	F	62	CAUCASIAN						
FEMUR FRACTURE*					SEVERE	668	10	UNRELATED	RESO - NO SEQUEL	YES	NONE
FEMUR FRACTURE*					SEVERE	1012	?	UNRELATED	UNRESOLVED	YES	NONE
43113/7512	32311/2512	72	F	55	HISPANIC						
MYOCARDIAL INFARCTION*					SEVERE	519	2	UNRELATED	RESO - W. SEQUEL	YES	NONE
43113/7516	32311/2516	73	F	64	HISPANIC						
HIP FRACTURE*					LIFE THREATE	1008	13	UNRELATED	RESO - W. SEQUEL	YES	NONE
CARDIAC ARREST*					LIFE THREATE	1052	?	UNRELATED	DEATH	NO	DISCONTINUED
43114/7536	32310/2564	83	F	77	HISPANIC						
HIP FRACTURE*					SEVERE	778	3	UNRELATED	RESO - W. SEQUEL	YES	NONE

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ae01_s Listing of Patients with Serious Adverse Events On Treatment by Trial Treatment and CRTN/Patient Number
Serious Adverse Events
Protocol(s): MA17903
Analysis: SAFETY Center: ALL CENTERS
Treatment: Ibandronate 150 mg monthly; N = 361
Adverse Event Onset between Time of Very First Drug Intake and Study Day 9999, Time 23:59

MA17903 CRTN/Pt. No. Adverse Event	BM16549 CRTN/Pt. No.	Age yr	Sex	Weight kg	Race Intensity	Day of Onset	Duration in days	Relation to Trial Treatment	Outcome	Trt given for AE	Discontinued or Dose Adjusted
43083/1501	32336/3005	75	F	102	CAUCASIAN						
ATRIAL FIBRILLATION*					SEVERE	924	?	UNRELATED	UNRESOLVED	YES	NONE
ANGINA PECTORIS*					SEVERE	943	5	UNRELATED	RESO - NO SEQUEL	NO	NONE
MELAENA*					SEVERE	1023	4	UNRELATED	RESO - NO SEQUEL	YES	NONE
43083/1503	32336/3002	76	F	88	CAUCASIAN						
CATARACT*					SEVERE	221	96	UNRELATED	RESO - NO SEQUEL	YES	NONE
43083/1513	32336/3018	75	F	68	CAUCASIAN						
INTERMITTENT CLAUDICATION*					SEVERE	209	109	UNRELATED	RESO - NO SEQUEL	YES	NONE
43083/1515	32336/3019	70	F	72	CAUCASIAN						
MENISCUS LESION*					SEVERE	86	93	UNRELATED	RESO - NO SEQUEL	YES	NONE
OSTEOARTHRITIS*					SEVERE	421	110	UNRELATED	RESO - NO SEQUEL	YES	NONE
43083/1518	32336/3025	74	F	77	CAUCASIAN						
PERITONEAL CARCINOMA*					LIFE THREATE	694	46	UNRELATED	RESO - NO SEQUEL	YES	DISCONTINUED
43084/1535	32337/3074	63	F	75	CAUCASIAN						
SUDDEN HEARING LOSS*					SEVERE	298	14	UNRELATED	RESO - NO SEQUEL	YES	NONE
SINUSITIS*					SEVERE	344	70	UNRELATED	RESO - NO SEQUEL	YES	NONE
43084/1546	32337/3065	72	F	50	CAUCASIAN						
RADIUS FRACTURE*					SEVERE	558	7	UNRELATED	RESO - NO SEQUEL	YES	NONE
43091/3017	32324/4009	81	F	57	CAUCASIAN						
ARRHYTHMIA*					SEVERE	686	?	UNRELATED	RESO - NO SEQUEL	YES	NONE
43091/3019	32324/4016	58	F	84	CAUCASIAN						
CENTRAL OBESITY*					MILD	77	4	UNRELATED	RESO - NO SEQUEL	YES	NONE
DIVERTICULAR PERFORATION*					MILD	255	114	UNRELATED	RESO - NO SEQUEL	YES	NONE
HERNIAL EVENTRATION*					MILD	722	68	UNRELATED	RESO - NO SEQUEL	YES	NONE

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