

**5.3.10.1 Deaths**

(Content from P060021/A011, November 2007 Amendment, Section V, Clinical, Section 5.3, Pages 84-85)

**5.3.10.1 Deaths**

A total of 11 patients died over the course of the Pivotal Study S01-01US, as described in clinical study report S01-01US (seven in OP-1 Putty group, and four in the autograft group). An additional five patients died after S01-01US (four from the OP-1 Putty group and one from the autograft group), and could not therefore be enrolled in extension study 06-UPLF-01. Anecdotal information regarding the causes of death for these 5 patients was collected during attempts to locate and enroll these patients for 06-UPLF-01, and this information has been presented in clinical study report 06-UPLF-01. Deaths that occurred during S01-01US or that were discovered during attempted enrollment for 06-UPLF-01 are presented by study interval in the patient accounting table (Table 6 in section 2), and are summarized in Table 37. No patterns of concern emerged with respect to etiology of death, or the time to occurrence post surgery.

**Table 37: Deaths**

Treatment Group	Patient ID	Cause of Death	Days From Surgery	Relationship to Treatment
OP-1 Putty	1305	Bone and liver cancer secondary to renal cell carcinoma	1016 days*	Not related
	1326	Pulmonary embolism	18 days	Not related
	1706	Cerebral haemorrhage	200 days	Not related
	2506	Myocardial infarction	192 days	Not related
	4120	Small cell lung carcinoma	738 days	Not related
	4207	Cardiac failure	730 days	Not related
	5010	Multiple myeloma	241 days	Not related
	1506**	Cerebrovascular accident	445 days	--
	2307**	Pulmonary fibrosis	499 days	--
	2406**	Brain mass consistent with blastoma	926 days	--
	3107**	Unknown	Unknown	--
Autograft	2519	Lung neoplasm malignant	757 days	Not related
	3010	Endometrial cancer metastatic	257 days	Not related
	4401	Small cell lung cancer	1020 days*	Not related
	5012	Refractory anemia with excess blasts	584 days	Not related
	1102**	Subarachnoid haemorrhage	1808 days	--

\* Death occurred &gt;24 months post-procedure.

\*\* Information about these deaths was obtained after completion of S01-01US during attempts to contact patients for enrollment in 06-UPLF-01. As deaths occurred between studies, no further details were available to the Sponsor.