Supplementary Material 6

Patient Withdrawal, Discontinuation and Death

D.6 Patient Withdrawals, Discontinuations, and Deaths

In total, 35 patients were screened for the BUTEO trial; 12 were subsequently found to be ineligible following screening failures and 23 went on to be recruited to either the dose confirmatory part ($n = 7$) or the Phase II expansion ($n = 16$) of the study. The reasons for screening failures can be found in the CONSORT diagram in section 3.2.

The dose confirmatory cohort accrued seven patients in total.

A further 16 patients were registered for the Phase II cohort, all receiving the confirmed dose of 8mg/kg. From this cohort, one patient was found to be ineligible post-registration and another patient withdrew consent and discontinued treatment, however, all other recruited patients were deemed evaluable for Phase II. The full details on withdrawal and discontinuation are given in tables S2 and S3 respectively. Where discontinuation was attributable to toxicity, further details are given in table S4.

Throughout the trials duration, there were no recorded deaths of trial patients.

Table S2: Patient withdrawal information.

Patient Number	Withdrawal Date	Withdrawal Wish	Withdrawal Reason
2	2015-12-10	Would like to withdraw from trial but willing for data collected at routine visits to be supplied to the Trials Office.	Felt unwell after infusion and would not want any further infusions.
11	2017-07-13	Would like to withdraw from trial treatment but willing to be seen in accordance with trial schedule and for relevant data to be supplied to the Trials Office.	Patient feels tired, has constant mild RUQ pain, and pruritus, he feels that this is worse since starting the trial medication.

Table S3: Patient discontinuation information.

Patient Number	Discontinuation Date	Withdrawn Consent	Toxicity	Other Reasons - specified
2	2015-12-10	Yes		
	Declined further infusions	11	2017-07-13	Yes
		Yes		

Table S4: Patient discontinuation information regarding toxicity.

Patient Number			
	Discontinuation Date	Discontinu Reason	
	11 2017-07-13	Pain	