ISRCTN basic results report – MUK eleven ISRCTN14749537

The MUK eleven trial closed early; basic results are reported below.

1. Participant Flow

This information is provided in a narrative form rather than a flow diagram due to the small number of patients. Four patients were consented and registered to the study. Patient 4 was found to be ineligible due to lack of evidence of disease progression and so did not go on to receive treatment. All three remaining patients were allocated to receive Lenalidomide. Patients 1 and 2, the first cohort of 2, were allocated to dose level 1, and as neither experienced a dose-limiting toxicity (DLT), the dose level was increased to dose level 2 for patient 3.

Patients allocated	Dose level	Description of dose level
Patients 1 and 2	1	Reolysin® $1x10^{10}$ $TCID_{50}$ and Lenalidomide 10mg or the maximum previously tolerated dose if lower
Patient 3	2	Reolysin® $1x10^{10}$ $TCID_{50}$ and Lenalidomide maximum previously tolerated dose

Only patient 1 attended off treatment follow-ups at 6 and 12 weeks post end of treatment. All three treated patients are included in the Data Summaries report.

2. Baseline Characteristics

All three treated patients were male and between the ages of 58-71 at the time of registration. At baseline, two patients had an ECOG performance status of 0, and one patient had a status of 1. All three patients had stage I multiple myeloma as classified by the International Staging System (ISS) at baseline. Two patients had a normal ECG baseline result, and one was abnormal.

3. Outcome Measures

As the MUK eleven trial closed early with only a small number of participants, a full final analysis was not undertaken, and data are instead presented as summaries in the subsections below.

3.1. DLTs

All three patients were evaluable for DLTs, but no DLTs were reported during the DLT reporting period.

3.2. Treatment received and reasons for stopping treatment

Two patients commenced two cycles of treatment, and one patient commenced all six cycles of treatment. Treatment discontinuation was due to an adverse event for one patient, and due to disease progression for the other two patients.

3.3. Withdrawals

There were no withdrawals.

3.4. Response to treatment and timing of assessment (from baseline)

Response assessments were carried out on day 1 of each of the 6 cycles, at the end of treatment and, if applicable, at off-treatment follow-ups.

Patient number	Response assessment time point	Response
1	Cycle 2 day 1	Stable disease or no change
	End of treatment	Stable disease or no change
	Off-treatment follow-up (6 weeks post end of treatment)	Progressive disease
	Off-treatment follow-up (12 weeks post end of treatment)	Progressive disease
2	Cycle 2 day 1	Progressive disease
	End of treatment	Progressive disease
3	Cycle 2 day 1	Stable disease or no change
	Cycle 3 day 1	Stable disease or no change
	Cycle 4 day 1	Stable disease or no change
	Cycle 5 day 1	Progressive disease
	Cycle 6 day 1	Progressive disease
	End of treatment	Progressive disease

3.5. Disease progressions

Disease progression is defined as serological or clinical evidence of progression compared to baseline assessment, according to IMWG criteria. All 3 patients progressed, at between 47 and 153 days post trial registration

3.6. Deaths

No deaths were reported.

4. Adverse events

4.1. SAEs, SARs and SUSARs

One SAE occurred which was classified as expected for Reolysin and Lenalidomide, definitely related to Reolysin and unlikely to be related to Lenalidomide. The patient recovered from this SAE.

MedDRA System Organ Class	Main diagnosis or symptom	CTCAE grade	Associated symptom	Seriousness criteria
Immune system disorders	Pyrexia	2	Flu Like Symptoms	Required / prolonged hospitalisation

No SUSARs were reported.

4.2. Adverse events

Grade refers to CTCAE grade in the table below. The number of occurrences of each adverse event is summarised below. Neutropenia was the only adverse event occurring more than once at multiple grades. All other adverse events were single occurrences.

Adverse event	Frequency*
Neutropenia	
Grade 2	1
Grade 3	2

Grade 4	1
Other AEs at grade 1	
Atelectasis	1
Back pain	1
Dizziness	1
Headache	1
Hypocalcaemia	1
Hypokalemia	1
Vomiting	1
Other AEs at grade 2	
Fever	1
Flu like symptoms	1
Nausea	1
Hypophosphatemia	1

**Patients can experience the same event more than once.*