Combination of reovirus (Pelareorep) and granulocyte-macrophage colony-stimulating factor (GM-CSF) alongside standard chemoradiotherapy and adjuvant chemotherapy (temozolomide) for patients with glioblastoma multiforme (GBM): Long term follow up results of the ReoGlio phase Ib trial

Professor Susan Short

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ctru
Leeds Institute of Clinical Trials Research

ReoGlio

UNIVERSITY OF LEEDS

Disclosures

I have the following relevant financial relationships to disclose:

Consultant for Blue Earth Diagnostics
Speaker's Bureau for Bayer pharmaceuticals
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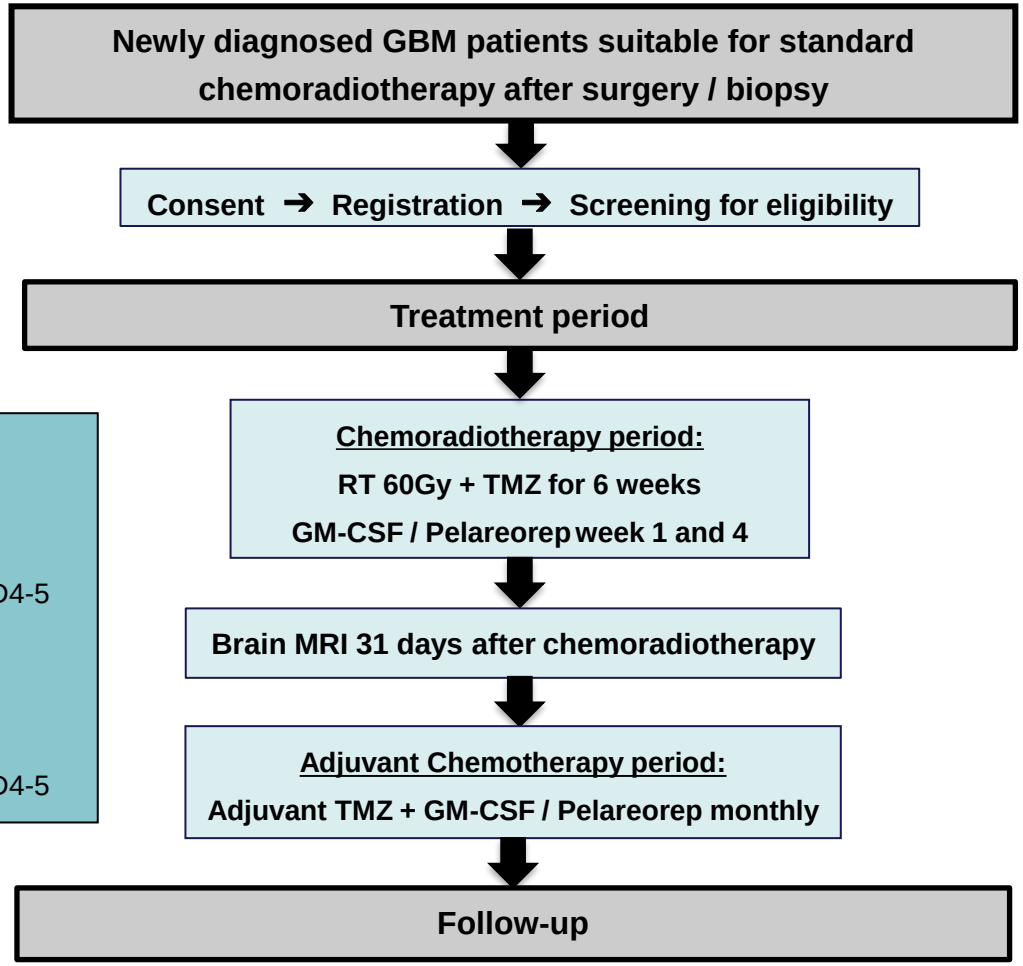
ReoGlio trial: flow diagram



Dose levels:

- **Level 1 (DL1)**:
GM-CSF 50µg/day D1-3,
Pelareorep: $1x10^{10}$ $TCID_{50}$ D4-5

- **Level 2 (DL2)**:
GM-CSF: 50µg/day D1-3,
Pelareorep: $3x10^{10}$ $TCID_{50}$ D4-5

ReoGlio trial: study population

- First patient Oct 2017, completed data collection Feb 2020
- Recruitment across 4 centres in UK
- 17 patients included, 15 treated (7 DL1, 8 DL2)
- Median Age 53y
- M:F = 9:6
- Debulking surgery in all cases
- ECOG performance status = 0 in 10 patients, 1 in 5 patients

Primary endpoint – Dose limiting toxicities (DLTs)

Assessed between day 1 chemoradiotherapy, up to day 1 of planned adjuvant chemotherapy.

Table 1: DLT evaluability by dose level

DLT evaluability	DL1 (n=7)	DL2 (n=8)
Evaluable	6 (85.7%)	6 (75.0%)
Not evaluable*	1 (14.3%)	2 (25.0%)

*and were replaced at the current dose level

Table 2: Summary of all DLTs experienced

Dose level	DLT type	Description	Treatment received
DL2	Non-haematological toxicity	Hypotension (grade 3)	Received 1 cycle of chemoradiotherapy

87% of patients completed treatment as planned

Secondary endpoint – PFS & OS

Calculated as time from registration to progression event /death or date last known to be alive and progression-free. Analysed using Kaplan-Meier method. Replaced patients excluded from this analysis.

Extended follow up to June 2021 agreed via substantial amendment

- Median OS dose level 1 = 12.6 Mo
- Median OS dose level 2 = 16.1 Mo

All patient median OS = 13.1 Mo

- 24 month OS dose level 1 = 16.7%
- 24 month OS dose level 2 = 50%

One patient alive at 42 months

Conclusion

- First clinical data using Pelareorep with GM-CSF alongside standard chemoradiotherapy in patients with newly diagnosed GBM
- Safety Review Committee (including 2 independent clinicians) reviewed safety data throughout trial and determined that the combination is safe and tolerable
- Overall the treatment was well tolerated alongside standard chemoradiotherapy. DL2 recommended for future studies
- Long term survival analysis suggests this is an active combination in a subset of GBM patients

Investigational Medicinal Product for this trial was provided by Oncolytics Biotech Inc.