Trial in progress: A phase 2 study of BPM 31510 with vitamin K and standard chemoradiation in newly diagnosed glioblastoma

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Rationale

- BPM 31510 is oxidized CoQ10 (ubidecarenone) with a lipid nanodispersion that significantly increases bioavailability
- While CoQ10 is classically an antioxidant, supraphysiologic concentrations have a paradoxical *pro-oxidant* effect with specificity for tumor cells
- Glioblastoma (GBM) is reliant on mechanisms of redox homeostasis and may be susceptible to perturbations in this system. Radiotherapy is a known producer of reactive oxygen species and showed synergy with BPM 31510 in vivo
- BPM 31510 has a favorable safety profile with primarily hepatotoxicity and coagulopathy (mitigated by Vit K)

Sun et al. (2020) *Scientific Reports*
Bi et al. (2020) *Nature Reviews Cancer*

Design

- Phase 2 multi-center single-arm trial
- Begins with dose-confirmation phase, starting at 110 mg/kg weekly administered as continuous infusion over 96h
- BPM 31510 (with Vit K) given in combination with standard chemoradiation
- Planned enrollment: 50 patients

Key inclusion criteria

- Newly diagnosed GBM with no prior treatment
- KPS ≥ 60
- INR ≤ 1.5 x ULN

Key exclusion criteria

- Tumor-associated hemorrhage
- Severe coagulopathy or bleeding
- Anticoagulation or Avastin

Outcomes

Primary outcome
- 6-month progression-free survival (PFS6) by RANO

Secondary outcomes
- Overall survival
- Safety

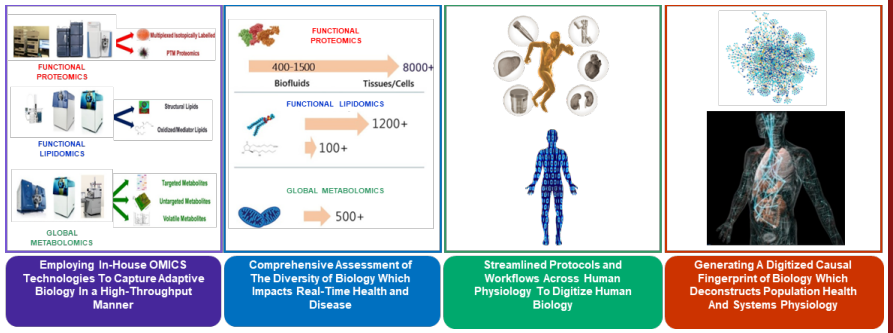
Exploratory outcomes
- PK/PD
- Change in FDG-PET SUV

Trial update:

- Trial ongoing with 1 site open
- Planning to open 11 sites in the USA and 4 sites in the UK
- 4 patients have enrolled: 2 patients completed treatment, 1 discontinued due to disease progression non-related to BPM 31510 IV, and 1 ongoing treatment
- 2 patients have not progressed with >6 months of follow up

Clinical Biomarker Discovery and Development

- Using multiomics analysis of multiple sample types from BPM 31510 treated patients along with Bayesian AI (NAi Interrogative Biology®) approach, will allow for causal association of biomarker discovery



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