**PROGEM1: Phase I first-in-human study of the novel nucleotide analogue NUC-1031 in adult patients with advanced solid tumours**

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**Background**

**Purpose**
- Primary: Delineate EPID
d - Endpoints: toxicity, safety profile, and preliminary antitumour activity

**Methods**
- A multi-centre, open-label, single-ascending cohort (2–3 design) with NUC-1031 administered as a 5-minute IV bolus injection;
- Schedule A: NUC-1031 administered on days 1, 8, 15 of a 4-week cycle for up to 6 cycles.
- Schedule B: NUC-1031 administered on days 1, 8, 15, 19 of a 4-week cycle for up to 6 cycles.

**Patient Population**
- PsA aged 18 years with relapsed/refractory advanced solid tumours to standard treatment.

**Table 1. Characteristics & Status**

**Pharmacokinetics**
- NUC-1031 is detected in plasma up to 24 hours CI:
- % of NUC-1031 is corrected in plasma to

**Table 3. SAFs of any severity observed in patients (n=11)**

**Conclusions**
- NUC-1031 was safe in a wide range of solid tumours and has achieved or exceeded the primary objectives of this study.
- Further clinical studies are being planned to evaluate the potential of NUC-1031 in a range of solid tumours.

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**Figure 1.** Graph showing the key molecular targets associated with genotoxicity.

**Figure 2.** Graph illustrating the distribution of genotoxicity in different tumour types.

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**Table 2. Schedule of Adverse Events**

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**Table 3. SAFs of any severity observed in patients (n=11)**

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**Figure 3.** Graph comparing the expression levels of different tumour markers in patients with and without NUC-1031 treatment.

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**Figure 4.** Graph showing the efficacy of NUC-1031 in a range of solid tumours.

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**Figure 5.** Graph illustrating the relationship between NUC-1031 dosing and tumour response.

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**Figure 6.** Graph comparing the efficacy of NUC-1031 in a range of solid tumours.