First in human Phase I/II study of NUC-1031 in patients with advanced gynaecological cancers

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BACKGROUND
- Resistance to chemotherapy limits patient survival
- Limited treatment options for relapsed gynaecological cancers

ProTides: Novel Tidale Analogues
- A new class of anti-cancer agents
- Innovative phosphorolipidate technology
- Overcomes key cancer resistance pathways

NUC-1031: The First Anti-Cancer ProTide
- Small molecules that target cancer cells
- Easier development and administration
- Potentially less toxic compared to standard treatments

RESULTS
- A small phase I study with encouraging results
- NUC-1031 achieves over 10x higher intracellular hitGTP than gemcitabine

PHARMACOLOGY
- NUC-1031 achieves a half-life that is more favourable than gemcitabine (9.2 hours versus 1.5 hours respectively)

EFFICACY
- No unexpected adverse events (AEs)
- Moderate grade AEs: Grade 1-2 acne, fatigue, transaminases, nausea, asthenia, thrombocytopenia

PHASE I RESULTS
- Dose 3: NUC-1031 at 100 mg/m²/day
- Dose 6: NUC-1031 at 150 mg/m²/day

CONCLUSIONS
- Impressive disease control rates in refractory gynaecological cancers
- Novel and well tolerated with no unexpected AEs
- Generates high intracellular levels of the active agent hitGTP
- Overcomes key cancer resistance pathways
- Ongoing Phase II study in combination with carboplatin
- Phase III global studies planned in ovarian cancer

**Figure 3: Progression Free Survival**