ValiSeek
Renovating Remedies
Transforming Therapy

VAL401: A NOVEL CANCER THERAPEUTIC

COMPOSITION

VAL401 comprises a novel cancer therapeutic that combines Risperidone with Rumenic Acid as part of a non-toxic lipid formulation in gelatin capsules, administered orally, being developed by ValiSeek Limited

KEY FEATURES

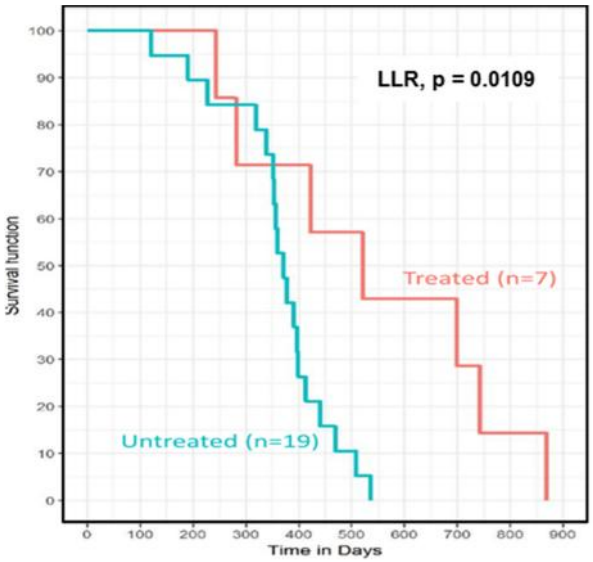
- Risperidone is safe and tolerable
- Simple and low cost manufacturing
- Patent protected formulation

INTELLECTUAL PROPERTY

Issued US patents: US 9072743, US 9375433, US 9585887, US 9585890 and US 9808462; Issued New Zealand patent: NZ 706067; Australian patent: AU 2013322612 with further US and international patent applications pending

PHASE 2 TRIAL HEADLINE RESULTS

- Stage IV Non-Small Cell Lung adenocarcinoma patients recruited, having failed prior chemotherapy with no further treatment options available
- 8 patients received treatment with VAL401 for up to 3 months; of these 7 have been used for the Overall Survival data
- 20 case-matched patients identified who would have been eligible for the trial but did not consent in the same clinic are used for comparison (untreated), 19 of these used for survival calculation. They received palliative treatment only
- Overall Survival improvement statistically significant for treated patients as displayed in the Kaplan-Meier graph below:



Kaplan-Meier Survival Graph showing length of time in days of patient Overall Survival from time of first lung cancer chemotherapy treatment as a proxy for date of diagnosis

PHASE 2 TRIAL OTHER ENDPOINTS

Clinical Pharmacokinetics

- Plasma levels measured of Risperidone and metabolite 9-OH Risperidone after single a 2 mg dose VAL401
- Pharmacokinetics, safety and tolerability in line with expectations from previous medical uses of API, seen as a comparison to J&J monograph data

Safety, Tolerability

- Broadly seen to be comparable to traditional risperidone formulations
- Dose range of active risperidone proposed is within safe, licensed current usage

Patient Quality of Life

- Undergoing analysis

Progression-free Survival (primary endpoint)

- Superseded by Overall Survival

PHASE 3 TRIAL PROPOSED

- Randomised, controlled, multinational trial with comparison to standard of care proposed in approximately 200 patients
- Standard dosage proposed as 2 mg per day with patient dose adjustments after blood level analysis

TARGET PRODUCT PROFILE

- Oral anti-cancer agent with potential to be administered alongside **any other chemo or immunotherapy** to provide anti-cancer activity alongside palliative and side effect mitigating quality of life improvements
- Quality of Life improvements can improve **immunotherapy (I/O)** response due to general health/immune system boost

INITIAL MARKET

- Non Small Cell Lung Cancer accounts for 80% of all lung cancer
- The lung cancer market was projected to USD 7.9 billion in 2020 at a CAGR of 6.6%
- First indication lung cancer, line extensions possible into other adenocarcinomas

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