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
- Manufacturing of VAL401 is simple and low cost
- Patents protect VAL401 formulation and anti-cancer use
- Length & Quality of Life improved in end-stage cancer patients

INTELLECTUAL PROPERTY

PHASE 2 TRIAL HEADLINE RESULTS
- Stage IV Non-Small Cell Lung cancer patients recruited, having failed prior chemotherapy with no further treatment options
- 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:

<table>
<thead>
<tr>
<th>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</th>
</tr>
</thead>
</table>

- To characterize the responders, the time between initiation and death was studied as a measure of Overall Survival, with responders showing greater than the mean and median survival
- Per protocol population excludes two patients receiving ≤ 10 days treatment; intention to treat includes all treated patients
- Overall Response Rate: 60% of per protocol population
- Progression-free and Overall Survival times stated in the table below, where Day Zero is the first day of VAL401 and “PFS” is defined as the time until the patient was removed from trial.

<table>
<thead>
<tr>
<th>Responders (n=3)</th>
<th>PFS mean (range)</th>
<th>OS mean (range)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>8.7 weeks (7.1 - 11.6)</td>
<td>12.8 weeks (11.6 - 15.3)</td>
</tr>
<tr>
<td>Non-responders, intention to treat population (n=4)</td>
<td>2.5 weeks (0.4 - 4.7)</td>
<td>3.9 weeks (0.4 - 7.4)</td>
</tr>
<tr>
<td>Non-responders, per protocol population (n=2)</td>
<td>4.3 weeks (4.0 - 4.7)</td>
<td>7.1 weeks (6.8 - 7.4)</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Analyte: Risperidone, 9-OH Risperidone Combined</th>
<th>Single Dose 2 mg VAL401</th>
<th>Median</th>
</tr>
</thead>
<tbody>
<tr>
<td>AUC to infinity (ng.h/ml)</td>
<td>433.21</td>
<td></td>
</tr>
<tr>
<td>Clearance (L/min)</td>
<td>7.69E-02</td>
<td></td>
</tr>
<tr>
<td>Cmax (ng/ml)</td>
<td>22.5</td>
<td></td>
</tr>
<tr>
<td>Cmin (ng/ml)</td>
<td>14.5</td>
<td></td>
</tr>
<tr>
<td>Mean residence time (h)</td>
<td>12.96</td>
<td></td>
</tr>
<tr>
<td>t1/2 (h)</td>
<td>8.98</td>
<td></td>
</tr>
</tbody>
</table>

Safety, Tolerability
- Broadly comparable to other risperidone formulations
- Dose range of active risperidone proposed in VAL401 treatment is within safe, licensed current usage

Patient Quality of Life
- 19 out of 28 measures showed improvement between treatment initiation and removal from trial
- Improvement in pain linked to high drug exposure
- Improvement in fatigue seen with lower exposures
- Responders and non-responders equally reported improvements in Quality of Life measures suggesting palliative effects are in addition to survival benefit.

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
- Also applicable to end-stage palliative treatment

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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