VAC-3S, an Immunoprotective HIV Vaccine Directed to the 3 Motif of gp41, in Patients Receiving ART: Safety, Dose Response and Schedule Assessment.

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1 | Introduction and Background

We have developed a novel immunotherapeutic vaccine (VAC-3S) composed of 2009 Sennepin 4 and 2013 Tsong 4 2 investigational antigens derived from the amino acid sequences of the highly conserved 3 motif of HIV-1 gp41, to assess its safety and immunogenicity in healthy volunteers and patients with HIV infection.

2 | Study Methods

A Phase I Study: Prospective, randomised, placebo-controlled, double-blind dose-escalation study designed to assess safety and tolerability, clinical efficacy, immune response, and potential protective effect of 3S antigen in healthy volunteers and patients with HIV infection.

3 | Study Results: Immunogenicity

Table 1: Immunologic endpoints at 24 weeks and safety

<table>
<thead>
<tr>
<th>Group</th>
<th>Dose</th>
<th>Safety</th>
<th>Immunogenicity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Placebo</td>
<td>0.1 µg</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>0.3 µg</td>
<td>1 µg</td>
<td>Not related</td>
<td>None</td>
</tr>
<tr>
<td>10 µg</td>
<td>10 µg</td>
<td>Related</td>
<td>None</td>
</tr>
</tbody>
</table>

4 | Discussion

We have developed a novel immunotherapeutic vaccine (VAC-3S) directed to the 3 motif of gp41. Anti-CD4 antibodies can have a key role in thrill the immune system and rectify the physiology of biomarker control. Anti-CD4 antibodies (VAC-3S) are safe in phase I studies, and further dose escalation to 20 µg is complete. Planning for high dose a comprehensive immunotherapeutic assessment is also completed, prior to move to the clinic program.

5 | Conclusions

The pathophysiology of HIV disease is dominated by the immune system and the reticuloendothelial system. Further work is needed to define the role of anti-CD4 antibodies in HIV disease progression. Further dose escalation to 20 µg is complete. Planning for high dose a comprehensive immunotherapeutic assessment is also completed, prior to move to the clinic program.