Continuous administration of AAT as salvage therapy for steroid resistant gut GVHD is feasible.

In summary, Preliminary results are encouraging, and further exploration of AAT therapy in extended phase II

Methods: Seven patients (5 female, 4 male) with hematologic malignancies have so far been enrolled in the first and second cohort. Patients were 35-59 (median 50-56) years old and were given transplants from HLA-matched siblings (n=5) or received cord blood (n=2) following high intensity (myeloablative) or reduced intensity conditioning with cyclophosphamide + TBI (n=2). All patients received cyclophosphamide and MMF for GVHD prophylaxis. Acute GVHD of grades II-IV developed at 49 to 72 (median of 48) days, and treatment with systemic methylprednisolone, 2 mg/kg/day was instituted. Patients showing no clinically satisfactory response after 5 days were given AAT (GlaxoSmithKline) at 50 mg/kg/on day 1, followed by 10 mg/kg (first cohort) or 60 mg/kg (second cohort) every other day for a total of 8 doses (15 days).

Table 1: Clinical Parameters in AAT-Treated Subjects

<table>
<thead>
<tr>
<th>Patient #</th>
<th>Diagnosis</th>
<th>Age</th>
<th>Donor Type</th>
<th>Conditioning Regimen</th>
<th>GVHD Prophylaxis</th>
<th>GVHD Onset</th>
<th>Follow-up</th>
<th>Remission</th>
</tr>
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<tbody>
<tr>
<td>XX001</td>
<td>AML</td>
<td>35</td>
<td>MMUCB</td>
<td>Flu/Cy/TBI</td>
<td>CSA/MMF</td>
<td>III</td>
<td>90-27</td>
<td>CR (ARDS)</td>
</tr>
<tr>
<td>XX002</td>
<td>AML</td>
<td>32</td>
<td>MMUCB</td>
<td>Flu/Cy/TBI</td>
<td>CSA/MMF</td>
<td>IV</td>
<td>30-27</td>
<td>CR (ARDS)</td>
</tr>
<tr>
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<td>MM</td>
<td>32</td>
<td>MMUCB</td>
<td>Flu/Cy/TBI</td>
<td>CSA/MMF</td>
<td>II</td>
<td>60-27</td>
<td>PR</td>
</tr>
<tr>
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<td>MM</td>
<td>32</td>
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<td>Flu/Cy/TBI</td>
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<td>III</td>
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<td>CSA/MMF</td>
<td>III</td>
<td>90-27</td>
<td>CR (ARDS)</td>
</tr>
</tbody>
</table>

- AAT Plasma Levels (N=7)

- AAT Stool Levels (N=7)

- AAT Clearance (N=7)

- Summary and Conclusion

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