Recent estimates indicate that there were 11,410 new cases of soft tissue sarcoma. Approximately 400 patients with metastatic, locally advanced, or unresectable soft tissue sarcoma who have relapsed or are refractory to prior non-adjunct chemotherapy, as measured by PFS.

**Objectives**

1. To determine the efficacy of administration of aldoxorubicin compared to investigator’s choice in terms of treatment with metastatic, locally advanced, or unresectable soft tissue sarcoma who have relapsed or are refractory to prior non-adjunct chemotherapy, as measured by PFS.

2. OS of aldoxorubicin compared to investigator’s choice in terms of treatment with metastatic, locally advanced, or unresectable soft tissue sarcoma who have relapsed or are refractory to prior non-adjunct chemotherapy, as measured by PFS.

**Study Design**

Phase 3, randomized, open-label, prospective, multinational study of aldoxorubicin vs investigator’s choice randomized 1:1.

- Subjects with metastatic, locally advanced, or unresectable soft tissue sarcoma who have relapsed or are refractory to aldoxorubicin, and meets compared with doxorubicin and doxorubicin alone (22% vs 17%), this increased response rate has not translated into a survival benefit.

- Further, the toxicity of the regimen, especially in older subjects, has created major safety concerns that reduce the therapeutic options for this age sector.

**Methods**

- Patients with metastatic, locally advanced, or unresectable soft tissue sarcoma (STS) who have relapsed or are refractory to prior non-adjunct chemotherapy, as measured by PFS.

**Phase 2 PFS Results in 1st-Line Soft Tissue Sarcoma**

<table>
<thead>
<tr>
<th>Arm</th>
<th>Days 1+8</th>
<th>Days 1+15</th>
<th>Days 1+21</th>
<th>Days 1+28</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aldoxorubicin</td>
<td>2.0 mg/m²</td>
<td>2.0 mg/m²</td>
<td>2.0 mg/m²</td>
<td>2.0 mg/m²</td>
</tr>
<tr>
<td>Doxorubicin</td>
<td>50 mg/m²</td>
<td>50 mg/m²</td>
<td>50 mg/m²</td>
<td>50 mg/m²</td>
</tr>
</tbody>
</table>

**Conclusion**

Aldoxorubicin is quantitatively and selectively bound to the cysteine-13 residue of the -HY-1 domain to form a covalent adduct which is resistant to degradation and active for up to 12 hours.