### BACKGROUND

**Aim:**
- Among the most active class of agents in NHL
- Standard of care: CHOP or IRIS for first-line NHL
- Frequently used in relapse, in sensitive patients, due to cumulative cardiotoxicity
- ≥200 mg/m² dose reduces CHOP
- ≥300 mg/m² dose reduces IRIS
- ≥50% patients develop CHF
- ≥40% patients experience ≥1 toxicity
- ≥500 mg/m² dose induces CHF
- ≥30% patients develop ≥3 line treatment of relapsed aggressive (de novo or transformed) NHL
- Pixantrone: Among the most active class of agents in NHL

Up to six treatment cycles

**Unless stated otherwise, data presented in this poster are for the intent-to-treat (ITT) population.**

### STUDY OBJECTIVES

**Primary**
- Compare efficacy (CR/CRu rate by independent review on an ITT basis) of pixantrone to other commonly used single agents in treatment of relapsed NHL

**Secondary**
- Overall Response Rate (CR+CRu+PR), response lasting ≥4 months, progression-free survival (PFS), overall survival (OS), safety

### METHODS

- **Study Design:** Randomized, controlled, international, multi-center study
- **62 sites of treatment of relapsed aggressive (de novo or transformed) NHL
- 51 prior anthracycline-containing regimens (cumulative doxorubicin or equivalent dose) are allowed to be approved in eligible patients
- Follow-up 18 months after last study treatment

### Key Inclusion/Exclusion Criteria

**Indications:**
- Historically confirmed aggressive NHL (REAL/COI classification)
- Prior therapy with CHOP or equivalent
- Fewer than 2 cycles of prior therapy
- Serologic to the last antecedent chemotherapy
- Chemotherapy, radiotherapy, or other antineoplastic within 2 weeks before treatment
- Patients with serious infections or anemia

### RESULTS

#### Study Population

<table>
<thead>
<tr>
<th>Feature</th>
<th>Pixantrone (N=70)</th>
<th>Comparator (N=70)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, median yrs</td>
<td>68 (23.4%)</td>
<td>18 (25.7%)</td>
<td>0.0074</td>
</tr>
<tr>
<td>ECOG performance status, n (%)</td>
<td>7 (10.0%)</td>
<td>11 (16.4%)</td>
<td>0.2</td>
</tr>
<tr>
<td>Prior SRT, n (%)</td>
<td>10 (14.3%)</td>
<td>12 (17.1%)</td>
<td>0.12</td>
</tr>
<tr>
<td>Relapsed therapy</td>
<td>68 (97.1%)</td>
<td>67 (95.7%)</td>
<td>0.544</td>
</tr>
</tbody>
</table>

**PROGRESSIVE-FREE SURVIVAL**

#### Percentage of All Patients With Responses Lasting 24 Months

<table>
<thead>
<tr>
<th>Response</th>
<th>Pixantrone (N=70)</th>
<th>Comparator (N=70)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>CR/CRu</td>
<td>17 (24.3%)</td>
<td>10 (14.3%)</td>
<td>0.003</td>
</tr>
<tr>
<td>PR</td>
<td>7 (10.0%)</td>
<td>11 (16.4%)</td>
<td>0.2</td>
</tr>
</tbody>
</table>

#### Overall Survival

<table>
<thead>
<tr>
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<th>Comparator (N=70)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Median OS</td>
<td>10.2 months</td>
<td>9.1 months</td>
<td>0.544</td>
</tr>
</tbody>
</table>

**SUPPORTING DATA**

#### Time From Response to Progression of Disease/Death

<table>
<thead>
<tr>
<th>CR/CRu/Responder Analysis</th>
<th>Pixantrone (N=70)</th>
<th>Comparator (N=70)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Median PFS</td>
<td>1.1 months</td>
<td>2.6 months</td>
<td>0.003</td>
</tr>
</tbody>
</table>

### Cardiac Safety Assessment

### SUMMARY AND CONCLUSIONS

This study demonstrated that relapsed/refractory aggressive NHL patients treated with pixantrone, compared with other chemotherapy agents, achieved:

- Significance increase in CR/CRu rate
- Significant improvement in PFS and percentage of all patients with responses lasting ≥4 months

### REFERENCES