**Ph- Adult ALL**

**HALLMARQ* Trial Phase III**

*HALLMARQ: Halting Acute Lymphoblastic Leukemia with MARQibo*

VinCRIStine Sulfate LIPOSOME Injection in Subjects ≥ 60 Years Old With Newly Diagnosed ALL

A Phase 3, multicenter, randomized study to evaluate the substitution of VinCRIStine Sulfate LIPOSOME Injection (VSLI) for standard Vincristine Sulfate Injection (VSI) in the induction, intensification, and maintenance phases of combination chemotherapy in the treatment of subjects ≥ 60 years old with newly diagnosed acute lymphoblastic leukemia (ALL).

### Endpoints:

**Primary Objectives:**
- Overall Survival (OS)

**Secondary Objectives:**
- Complete remission (CR+CRi); best response during study
- Duration of Response (CR+CRi)
- Event Free Survival (EFS)
- Post-induction Therapy MRD Status

### Study Design:

<table>
<thead>
<tr>
<th>Study Design:</th>
<th>Induction Course I</th>
<th>Early Intensification Course II</th>
<th>Early Intensification Course IIB</th>
<th>CNS Prophylaxis and Interim Maintenance Course III</th>
<th>Late Intensification Course IV</th>
<th>Prolonged Maintenance Course V</th>
</tr>
</thead>
<tbody>
<tr>
<td>Arm A</td>
<td>VSI 1.4 mg/m²</td>
<td>VSI 1.4 mg/m²</td>
<td>VSI 1.4 mg/m²</td>
<td>VSI 1.4 mg/m²</td>
<td>VSI 1.4 mg/m²</td>
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</tr>
<tr>
<td>Arm B</td>
<td>VSI 1.4 mg/m²</td>
<td>VSI 1.4 mg/m²</td>
<td>VSI 1.4 mg/m² (no dose cap)</td>
<td>VSI 1.4 mg/m² (no dose cap)</td>
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</tr>
</tbody>
</table>

### Select Inclusion Criteria‡

- Newly diagnosed, histologically proven, untreated Philadelphia chromosome-negative (Ph-) ALL, with ≥ 5% bone marrow blasts
- Eastern Cooperative Oncology Group (ECOG) performance status of 0-2
- Life expectancy ≥ 3 months
- Near normal renal and liver function, prior to study enrollment, unless the abnormality is considered attributable to leukemia

### Select Exclusion Criteria‡

- Prior systemic chemotherapy (for ALL or other malignancy)
- Prior vincristine for any reason
- Burkitt’s lymphoma/leukemia
- Philadelphia chromosome-positive (Ph+) ALL and/or BCR/ABL rearrangements documented by FISH, cytogenetics or PCR
- Active central nervous system (CNS) disease
- Active serious infection not controlled by oral or IV antibiotics or antifungals

### Target Enrollment:

348

### Study Sites:

Up to 100 globally

### Start Date:

Mar 2012

### Est. Completion Date:

Aug 2017

Study ID Numbers: NCT01439347; TTX404

Vincristine sulfate LIPOSOME injection is currently under clinical investigation and has not been approved for use in newly diagnosed acute lymphoblastic leukemia (ALL).

For information about participating in this trial, please contact:
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CURRENTLY ENROLLING