The EXTEND-IA trial was conducted to test the hypothesis that anterior circulation ischemic stroke patients, selected with a “dual target” of vessel occlusion and evidence of salvageable tissue on perfusion imaging within 4.5h of onset, would have improved reperfusion and early neurological improvement when treated with endovascular thrombectomy using the Solitaire™ FR stent thrombectomy device after intravenous (IV) alteplase, compared to alteplase alone.

An investigator-initiated, multi-center, prospective, randomized, open-label, blinded-endpoint (PROBE) study in ischemic stroke patients receiving intravenous alteplase within 4.5h of stroke onset.
NO SIGNIFICANT DIFFERENCE IN STUDY POPULATIONS:

<table>
<thead>
<tr>
<th>CHARACTERISTIC</th>
<th>INTRAVENOUS t-PA ALONE (n=35)</th>
<th>COMBINED INTRAVENOUS t-PA AND ENDOVASCULAR THERAPY (n=35)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of randomized subjects</td>
<td>35</td>
<td>35</td>
</tr>
<tr>
<td>Age (years) - Mean (SD)</td>
<td>70.2 ± 11.8</td>
<td>68.6 ± 12.3</td>
</tr>
<tr>
<td>Male sex - no. (%)</td>
<td>17 (49)</td>
<td>17 (49)</td>
</tr>
<tr>
<td>BL NIHSS score, Median (IQR)</td>
<td>13 (9-19)</td>
<td>17 (13-20)</td>
</tr>
<tr>
<td>History of hypertension - no. (%)</td>
<td>23 (66)</td>
<td>21 (60)</td>
</tr>
<tr>
<td>History of diabetes - no. (%)</td>
<td>8 (23)</td>
<td>2 (6)</td>
</tr>
<tr>
<td>Time from stroke onset to initiation of alteplase (min) - Median (IQR)</td>
<td>145 (105-180)</td>
<td>127 (93-162)</td>
</tr>
</tbody>
</table>

Site of vessel occlusion - no. (%)
- Internal carotid artery (ICA) 11 (31)
- First segment of middle cerebral artery (M1) 18 (51)
- Second segment of middle cerebral artery (M2) 6 (17)

STUDY RESULTS:

Primary outcomes:
- Median Reperfusion at 24 hr – (IQR)
  - CombTherapy Group: 73 (55 to 91)
  - Alteplase group: 100 (100 to 100)

Early neurologic improvement: Reduction ≥ 8 points on NIHSS or a score of 0–1 at 3 days - no. (%)
- CombTherapy Group: 13 (37)
  - Alteplase group: 28 (80)

Secondary outcomes:
- Independent outcome (mRS 0-2) at 90 days - no. (%)
  - CombTherapy Group: 14 (40)
    - Alteplase group: 25 (71)
- Final mTICI 2B-3 in patients who had an initial occlusion angiography - no./total no. (%)
  - CombTherapy Group: N/A
    - Alteplase group: 25/29 (86)
- Death - no. (%)
  - CombTherapy Group: 7 (20)
    - Alteplase group: 0 (0)
  - CombTherapy Group: 17 (13-20)
  - Alteplase group: 20 (57)
  - CombTherapy Group: 11 (31)
  - Alteplase group: 4 (11)

Statistically significant improvement in the rate of functional outcomes at 90 days with intervention using the Solitaire FR device as primary treatment.1

1 Generalized OR 2.0 (95% CI 1.2-3.8; p=0.006)

STUDY CONCLUSION:
In ischemic stroke patients with a proximal cerebral arterial occlusion and salvageable tissue on CT perfusion imaging, early thrombectomy with the Solitaire FR stent thrombectomy device improves reperfusion, early neurologic recovery and functional outcome compared with alteplase alone.