**Methods**

Newly Diagnosed Invasive Breast Cancer  
**Clinical Stages II-III HER-2**  
**Primary Endpoint:** Pathologic near pathologic complete response

**Methods**

- **NOV-002:**  
  - 60mg SC daily  
  - Docetaxel every 3 weeks  
  - AC every 3 weeks (60/600 mg/m²)

- **Surgery:**
  - AC every 3 weeks
  - Docetaxel every 3 weeks

**Results**

**Efficacy Data / Pathologic Complete Response (pCR)**

<table>
<thead>
<tr>
<th>Efficacy Measure</th>
<th>N = 38 (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Surgically Evaluable PR</strong></td>
<td>15/45 (23.3)</td>
</tr>
<tr>
<td><strong>ER+/PR+</strong></td>
<td>11/33 (33.3)</td>
</tr>
<tr>
<td><strong>ER-</strong> TREND</td>
<td>47/57 (82.5)</td>
</tr>
</tbody>
</table>

**Residual Breast Cancer Burden (RCB)**

<table>
<thead>
<tr>
<th>Residual Breast Cancer Burden (RCB)</th>
<th>N = 41</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>pCR</strong></td>
<td>7 (17.5)</td>
</tr>
<tr>
<td><strong>Non-pCR including RCB</strong></td>
<td>34/41 (82.5)</td>
</tr>
</tbody>
</table>

**Auxiliary Cancer Rate (19 pts with biopsy proven involvement)**

| Average Rate | 1.9 (0.8-7.3) |

**Background**

- The active ingredient in NOV-002 is oxidized glutathione.
- Changes in the ratio of oxidized reduced glutathione controls cellular redox state and can regulate protein function by the reversible formation of mixed disulfides between protein cysteines and glutathione, i.e. glutathionylation.
- Protein glutathionylation by NOV-002 results in pleiotropic effects on cell function including immune stimulation and increased chemoresensitivity of tumor cells.

**Abstract**

**Phase 2 study of neoadjuvant treatment with cellular redox modifier NOV-002 in combination with doxorubicin and cyclophosphamide followed by docetaxel (AC-T) in patients with stage II-III HER-2(-) breast cancer**

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**Objectives**

- Compare the safety and efficacy of NOV-002 combined with AC-T in comparison to historical controls for the treatment of HER-2(-) breast cancer.

**Methods**

- Enrollment of patients with stage II-III locally advanced breast cancer (ER- and/or PR-).
- NOV-002 daily SC for 12 weeks along with every 3 weeks of AC-T (60mg/m² SQ).  
- Surgery for complete breast tumor resection at the end of the study.

**Results**

- **Surgically Evaluable PR:** 15/45 (23.3)
- **ER+/PR+:** 11/33 (33.3)
- **ER-** TREND: 47/57 (82.5)

**Conclusions**

- NOV-002 is a promising agent with potential for improving outcomes in HER-2(-) breast cancer.
- Further study is warranted to confirm these findings in a larger cohort.