### Phase 3 GAIA: Investigator Sponsored Trial

**CLL13-Trial of the GCLLSG in cooperation with HOVON, NCLLSG and SAKK.**

A study to compare the efficacy and safety of obinutuzumab + venetoclax vs FCR/BR vs rituximab + venetoclax vs obinutuzumab + ibrutinib + venetoclax frontline in patients with CLL without del(17p) or TP 53 mutation.

<table>
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<tr>
<th>1L CLL (N=920)</th>
<th><strong>Randomized to:</strong></th>
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<td>Arm A</td>
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<td>Arm C</td>
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<td>Arm D</td>
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**Endpoints**

**Co-Primary**
- MRD negativity rate between GV and FCR/BR, and PFS between GIV and FCR/BR

**Key Secondary**
- Investigator assessed PFS and MRD between all 4 arms, ORR, CR/CRi

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**Key Eligibility Criteria**

- 1L CLL (iwCLL criteria)
- CIRS score ≤ 6
- Only patients without del(17p) or TP53 mutation are eligible

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**CIRS** = cumulative illness ratings scale, GCLLLSG = German CLL Study Group, MRD = minimum residual disease, HOVON = Stichting Hemato-Oncologie voor Volwassenen Nederland, NCLLSG = Nordic CLL Study Group, PFS = progression-free survival, SAKK = Swiss Group for Clinical Cancer Research


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Venetoclax is being codeveloped by AbbVie and Genentech, a member of the Roche Group.