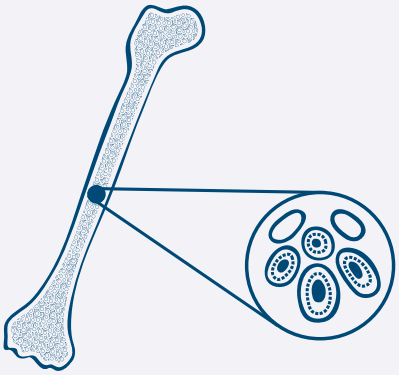
The SEQUOIA Trial

The SEQUOIA trial is a randomized, global Phase 3 trial (NCT03336333) comparing BRUKINSA® (zanubrutinib) to bendamustine plus rituximab (B+R) in patients with treatment-naïve (TN) chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL).

About CLL and SLL



CLL **is the most common form of leukemia in adults in Western countries**, affecting white blood cells or lymphocytes in the bone marrow[1, 2]. SLL shares many similarities with CLL but with cancer cells found mostly in lymph nodes[3].

CLL and SLL are indolent, or slow growing, malignancies, but **have the potential to transform into more aggressive diseases**[1] and patients may **develop resistance to existing therapies**.[1, 4]

Trial Design

The SEQUOIA trial consists of **three cohorts**, with a **target enrollment of 710 patients**.

Cohort 1

Patients without the deletion of chromosome 17p13.1 (del[17p])

Arm A: Patients randomized to receive BRUKINSA 160mg twice daily

Arm B: Patients randomized to receive B+R

Cohort 2

Patients with del(17p)

Arm C: Non-randomized, all patients to receive BRUKINSA 160mg until disease progression, intolerable toxicity or end of study*

Cohort 3

Patients with del(17p) or pathogenic TP53 mutation variant

Arm D (enrollment ongoing): Non-randomized, all patients to receive the combination of BRUKINSA and venetoclax*

**B+R not selected as a treatment due to unfavorable prognosis and poor response in patients with del(17p)*[5]

Primary Endpoints

- The primary endpoint is progression-free survival (PFS) as assessed by independent review committee (IRC) in Cohort 1 (Arm A vs. Arm B)
- Key secondary endpoints:
  - IRC-assessed PFS in Arm C
  - Investigator-assessed PFS
  - IRC- and investigator-assessed overall response rate (ORR)
  - Overall survival (OS)
  - Safety

BRUKINSA is currently approved in China for the treatment of CLL or SLL in adult patients who have received at least one prior therapy. It is not approved for the treatment of CLL or SLL in any other country or territory.

References

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