Zanubrutinib

Disclaimer: This asset is intended for media professionals only.

WHAT IS ZANUBRUTINIB?

Zanubrutinib is an orally available, targeted treatment known as a Bruton's tyrosine kinase (BTK) inhibitor. Zanubrutinib **has the broadest label globally of any BTK inhibitor** and is the only BTK inhibitor to provide the **flexibility of once or twice daily dosing**.

Zanubrutinib is **approved in more than 70 markets**, including the EU, China, Great Britain, Canada, Australia, South Korea, and Switzerland.

Over 180,000 patients have been treated with zanubrutinib to date.

HOW ZANUBRUTINIB WORKS

Zanubrutinib **is designed to shut down (or inhibit) the BTK protein**.

Shutting down the BTK protein is important because this protein sends non-stop signals to cancerous B cells to grow and spread.

Zanubrutinib was **designed to block BTK signaling and keep it shut down around the clock.** This may help stop the signaling in cancerous B cells.

Zanubrutinib has been **shown to block 100% of BTK in blood cells and 94% to 100% of BTK in lymph nodes** when taken at the recommended total daily dose of 320 mg. The clinical significance of blocking up to 100% of BTK on treatment responses has not been established.

With **differentiated pharmacokinetics** compared with other approved BTK inhibitors, zanubrutinib has been demonstrated to **inhibit the proliferation of malignant B cells** within a number of disease-relevant tissues

DISCOVERING THE FULL POTENTIALOF ZANUBRUTINIB

The global zanubrutinib clinical development program includes:

About **7,100 patients enrolled**

In **more than 35 trials**

In **30 countries and regions**

Key trials that supported global regulatory approvals include:

- BGB-3111-206 (NCT03206970): a Phase 2, open label, multicenter, single-arm trial evaluating zanubrutinib in patients with **mantle cell lymphoma (MCL)** who had received at least one prior therapy.
- ASPEN (NCT03053440): a randomized, active control, open-label trial, comparing zanubrutinib and ibrutinib in patients with **Waldenström's macroglobulinemia (WM).**
- BGB-3111-214 (NCT03846427): an open-label, multicenter, single-arm trial that evaluated zanubrutinib in patients with **marginal zone lymphoma (MZL)** who received at least one prior anti–CD20-based therapy.

- SEQUOIA (NCT03336333): a randomized, multicenter, global Phase 3 trial designed to evaluate the efficacy and safety of zanubrutinib in patients with **treatment-naïve chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL).**
- ALPINE (NCT03734016): a global, Phase 3, randomized study of zanubrutinib versus ibrutinib in patients with **relapsed/refractory (R/R) CLL/SLL**.
- ROSEWOOD (NCT03332017): a Phase 2, open-label, randomized study of zanubrutinib plus obinutuzumab in R/R follicular lymphoma.

Other trials in MCL, MZL and FL are ongoing (MANGROVE: NCT04002297; MAHOGANY: NCT05100862).

Regulatory submissions for the tablet formulation of zanubrutinib are currently under review in the United States and European Union (EU).

Zanubrutinib is also being evaluated as part of the ongoing Phase 3 CELESTIAL-TNCLL study (NCT06073821) – the **only fixed-duration trial combining a BCL2 inhibitor (sonrotoclax) and BTK inhibitor (zanubrutinib) designed to show superiority against a contemporary and clinically relevant comparator** (venetoclax plus obinutuzumab).

SELECT IMPORTANT SAFETY INFORMATION

Serious adverse reactions, including fatal events, have occurred with BRUKINSA, including hemorrhage, infections, cytopenias, second primary and cardiac arrhythmias.

Disclaimer: Any information on the products or diseases contained herein is not intended to provide medical advice and/or treatment guidance. The information within is not intended for promotional purposes. Zanubrutinib is not authorized for all indications in all countries; healthcare providers should consult the approved prescribing information in their respective countries.