CARNA BIOSCIENCES

News Release

June 15, 2026
Carna Biosciences, Inc.

Expanded Phase 1b Study Data for Docirbrutinib Demonstrate Robust Response and Favorable Safety Profile at EHA 2026

- *In a poster presentation at EHA 2026, updated data from an expanded Phase 1b study of docirbrutinib demonstrated a favorable safety profile and encouraging clinical responses in heavily pretreated patients with B-cell malignancies.*
- *Robust responses were observed in heavily treated patients with chronic lymphocytic leukemia (CLL). At the 400 mg BID dose (provisional recommended Phase 2 dose [RP2D]), an overall response rate (ORR) of 73% was achieved.*
- *The updated Phase 1b results support the continued clinical development of docirbrutinib into the next phase of investigation.*

Carna Biosciences, a clinical-stage biopharmaceutical company focusing on the discovery and development of innovative therapies to treat serious unmet medical needs, announces that updated safety and efficacy results from the ongoing Phase 1b study of docirbrutinib (AS-1763) were presented at the European Hematology Association (EHA) 2026 Congress on June 13, 2026.

Docirbrutinib is an investigational small molecule drug designed to non-covalently inhibit Bruton's tyrosine kinase (BTK) in a highly selective manner. It is currently under development for the treatment of patients with CLL and other B-cell malignancies who have developed resistance or are intolerant to at least two prior lines of systemic therapy including a covalent BTK inhibitor (NCT05602363).

The poster was presented by Nitin Jain, MD, Department of Leukemia, The University of Texas MD Anderson Cancer Center, with all principal investigators from the participating clinical sites serving as co-authors.

Key presentation highlights:

Poster title: Updated Results from a Phase 1b Study of Non-covalent Pan-mutant BTK Inhibitor Docirbrutinib (AS-1763) in Patients with Previously Treated B-cell Malignancies

- Docirbrutinib is a highly selective, pan-mutant non-covalent BTK inhibitor (ncBTKi) which inhibits both wild-type and various c/ncBTKi-resistant mutations including C481x, T474x and L528x with IC_{50} values of <10 nM and shows strong anti-tumor activity in B-cell lymphoma cell lines harboring resistant BTK mutations including a kinase-dead BTK L528W.

- The poster presented updated results from the ongoing Phase 1b study of docirbrutinib in B-cell malignancies including chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL), mantle cell lymphoma (MCL), Waldenström macroglobulinemia (WM), marginal zone lymphoma (MZL) and follicular lymphoma (FL).
- As of the data cut-off of May 8, 2026, 58 patients (33 CLL, 9 MCL, 4 WM, 6 MZL, 6 FL) were enrolled to 5 dose levels.
- Docirbrutinib demonstrated a favorable safety profile, with no cases of drug-related atrial fibrillation or hypertension and low rates of Grade ≥3 treatment-related adverse events (10%) and treatment discontinuation (2%).
- Promising and durable responses were observed in heavily treated patients with CLL/SLL. At the 400 mg BID (provisional Recommended Phase 2 Dose [RP2D]), robust tumor responses were achieved, with an ORR of 73%. Notably, the high ORR was maintained even among patients double-exposed to cBTKi and B-cell/CLL lymphoma 2 (BCL2) inhibitor (86%). Among 4 patients harboring BTK mutation, 3 patients achieved Partial Response (PR) (ORR 75%), including 1 patient with both BTK C481S and L528W and 1 patient with both BTK C481S and phospholipase C gamma 2 (PLCG2) mutations.
- Robust efficacy was also observed in patients with MCL and WM, with an ORR of 100% including Complete Response (CR) in MCL, and a major response rate of 100% in WM.

About docirbrutinib (AS-1763)

Docirbrutinib is a highly selective, orally bioavailable, non-covalent inhibitor of both the wild type and mutant BTKs for the treatment of CLL and other B cell malignancies. Covalent BTK inhibitors including ibrutinib are key therapeutic options for patients with B cell malignancies. However, patients are reported to develop resistance during the treatment due to substitution of cysteine residue at 481 position with serine (C481S - 2 -mutation) in BTK, which reduces the efficacy of the covalent BTK inhibitors. In addition, the emergence of other types of resistance mutations to non-covalent BTK inhibitor, recently approved pirtobrutinib, has been reported. Docirbrutinib potently inhibited both wild type and those mutant BTKs, strongly suggesting that docirbrutinib will be a new therapeutic option for treating patients with B cell malignancies both having wild type and resistance mutations in BTK. Carna is advancing development of docirbrutinib as a next-generation BTK inhibitor. The Phase 1b study of docirbrutinib is being conducted in the U.S. and dosing in the dose expansion part is ongoing (NCT05602363).

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