

Glenmark Pharmaceuticals to Launch DCGI-approved BRUKINSA® in India to Advance Treatment of Hematological Malignancies

Mumbai, India, June 9, 2025: Glenmark Pharmaceuticals Ltd. (Glenmark) a research-led, global pharmaceutical company, has announced the upcoming launch of zanubrutinib in India following approval by the Drugs Controller General of India (DCGI).

Zanubrutinib will be marketed in India under the brand name BRUKINSA®, an innovative therapy developed by BeiGene (now BeOne Medicines), a global oncology leader committed to delivering advanced treatments for cancer patients worldwide. BRUKINSA is the first and only Bruton's tyrosine kinase (BTK) inhibitor approved in India for the treatment of five distinct B-cell malignancies: chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL), Waldenström macroglobulinemia (WM), mantle cell lymphoma (MCL), marginal zone lymphoma (MZL), and follicular lymphoma (FL).¹

Globally, BRUKINSA is approved in more than 70 countries, supported by compelling clinical evidence from pivotal trials including ALPINE, ASPEN, and SEQUOIA.² This extensive clinical program underscores BRUKINSA's proven efficacy, strong safety profile, and broad therapeutic value.

The introduction of BRUKINSA brings an innovative treatment option at a time when India continues to face a significant burden from serious and difficult-to-treat haematological malignancies. According to various sources, someone in India is diagnosed with blood cancer every five minutes, and an estimated 70,000 people die from the disease each year.^{3,4} BRUKINSA addresses a critical unmet need with its differentiated pharmacological profile, demonstrating high response rates and durable disease control across multiple B-cell malignancies as shown in pivotal clinical trials. BRUKINSA's flexible dosing regimen (once or twice daily) supports personalized care.¹ In the head-to-head ALPINE study in relapsed/refractory chronic lymphocytic leukemia, BRUKINSA demonstrated a lower rate of serious cardiac events (1.9% vs. 7.7%) and fewer treatment discontinuations due to cardiac issues (0.3% vs. 4.3%) compared with ibrutinib.⁵

"We look forward to bringing BRUKINSA to India in the coming months as part of our ongoing partnership with BeiGene (now BeOne Medicines)," **said Alok Malik, President and Business Head - India Formulations, Glenmark Pharmaceuticals Ltd.** "This launch marks a significant milestone in our innovative oncology portfolio, offering patients in India with access to a globally trusted therapy with proven efficacy and safety. It underscores Glenmark's ongoing commitment to providing effective and advanced treatments for patients with haematological malignancies."

Adam Roach, Senior Vice President and Head of Japan and Asia Pacific region for BeiGene (to be renamed BeOne Medicines) commented, “The introduction of BRUKINSA in India marks an important step in our ongoing mission to expand patient access to innovative oncology treatments across the Asia Pacific region. We are proud to support Glenmark in bringing this therapy to patients in India, furthering our shared commitment to improve healthcare outcomes globally.”

About BRUKINSA® (zanubrutinib)

BRUKINSA is an orally available, small molecule inhibitor of Bruton’s tyrosine kinase (BTK) designed to deliver complete and sustained inhibition of the BTK protein by optimizing bioavailability, half-life, and selectivity. With differentiated pharmacokinetics compared with other approved BTK inhibitors, BRUKINSA has been demonstrated to inhibit the proliferation of malignant B cells within a number of disease-relevant tissues.

BRUKINSA 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. Additionally, BRUKINSA is also the only BTK inhibitor to demonstrate PFS superiority to a first-generation BTK inhibitor in a Phase 3 study. The global BRUKINSA clinical development program includes about 7,100 patients enrolled in 30 countries and regions across more than 35 trials. BRUKINSA is approved for at least one indication in more than 75 markets, and more than 200,000 patients have been treated globally.

About Glenmark Pharmaceuticals Ltd.

Glenmark Pharmaceuticals Ltd. (BSE: 532296 | NSE: GLENMARK) is a research-led, global pharmaceutical company, having a presence across Branded, Generics, and OTC segments; with a focus on therapeutic areas of respiratory, dermatology and oncology. The company has 11 world-class manufacturing facilities spread across 4 continents, and operations in over 80 countries. Scrip 100 positions Glenmark amongst the Top 100 biopharmaceutical companies ranked by Pharmaceutical Sales in 2023; while Generics Bulletin places it in the Top 50 Generics and biosimilar companies ranked by sales in 2024. Glenmark’s Green House Gas (GHG) emission reduction targets have been approved in 2023 by the Science Based Target initiative (SBTi), making it only the second pharmaceutical company in India to achieve this. The organization has impacted over 3.3 million lives over the last decade through its CSR interventions. For more information, visit www.glenmarkpharma.com. You can follow us on LinkedIn (Glenmark Pharmaceuticals) and Instagram (Glenmark_pharma).

About BeOne (formerly BeiGene)

BeOne Medicines, formerly known as BeiGene, is a global oncology company domiciled in Switzerland that is discovering and developing innovative treatments that are more affordable and accessible to cancer patients worldwide. With a portfolio spanning hematology and solid tumours, BeOne is expediting development of its diverse pipeline of novel therapeutics through its internal capabilities and

collaborations. With a growing global team of more than 11,000 colleagues spanning six continents, the Company is committed to radically improving access to medicines for far more patients who need them. To learn more about BeOne, please visit www.beonemedicines.com and follow us on [LinkedIn](#), [X](#), [Facebook](#) and [Instagram](#).

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Date of preparation: 28 May 2025

References:

1. BRUKINSA[®] India Product Information.
2. BeiGene Data on File
3. Ferlay J, Ervik M, Lam F, Colombet M, Mery L, Piñeros M, et al. *Global cancer observatory: Cancer today. India Fact Sheet*. Lyon, France: International Agency for Research on Cancer; 2022. Available from <https://gco.iarc.who.int/media/globocan/factsheets/populations/356-india-fact-sheet.pdf> accessed April 2024.
4. Shalby Multi-Specialty Hospitals. *Blood Cancer – A growing burden to Indian Society*, <https://www.shalby.org/blood-cancer-a-growing-burden-to-indian-society/#:~:text=According%20to%20various%20sources%2C%20India,year%20because%20of%20blood%20cancer> accessed May 2025.
5. Brown JR et al. *N Engl J Med* 2023; 388:319–32 (including supplementary data).

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