

# FDA grants accelerated approval to BeOne's Beqalzi for mantle cell lymphoma

Market Event Summary

# Beqalzi is the first Bcl-2 inhibitor approved by the FDA for MCL

## Event

- On May 13, 2026, the **FDA granted accelerated approval** to BeOne Medicines' **Beqalzi (sonrotoclax)** for the treatment of **relapsed or refractory (R/R) mantle cell lymphoma (MCL) after at least two lines of systemic therapy, including a BTK inhibitor**. Beqalzi is the **first Bcl-2 inhibitor** to gain approval in the United States **for MCL**.
- The approval was based on data from the **Phase 1/2 BGB-11417-201 study**, in which sonrotoclax demonstrated an **overall response rate of 52%**, with a median time to response of 1.9 months, in R/R MCL patients who previously received anti-CD20-based therapy and a BTK inhibitor. After a median follow-up of 14.2 months, **median PFS was 6.5 months**, and the **median response duration was 15.8 months**.

## Background

- MCL is a **rare and aggressive** subtype of **B-cell non-Hodgkin's lymphoma** with limited treatment options, particularly for patients whose disease recurs after multiple lines of therapy.
- Sonrotoclax is the **second Bcl-2 inhibitor** to receive **FDA approval**; venetoclax (AbbVie and Roche's Venclexta / Venclyxto) was approved for CLL / SLL in 2016 and gets some off-label use for MCL.
- Sonrotoclax gained its **first global approval in China** in **January 2026** for this MCL indication, under the brand name **Baiyueda**, and was also approved for patients with **R/R CLL / SLL** who have received **at least one prior systemic therapy**, including a BTK inhibitor.

## Clarivate's takeaways



### Approvals for sonrotoclax in other markets are imminent

Sonrotoclax has been **under evaluation by the EMA** and other regulatory agencies for R/R MCL since January 2026, and Clarivate anticipates that a conditional marketing authorization will be granted **in the EU before the end of 2026**.



### Combination approaches could broaden its use in MCL

**Sonrotoclax + zanubrutinib** is being evaluated versus zanubrutinib in R/R MCL patients in the **Phase 3 CELESTIAL-RRMCL study**, which could lead to **traditional approval** of sonrotoclax and the use of this agent in **earlier lines of MCL treatment**.



### Key future sales opportunities lie in CLL approvals

Sonrotoclax is also under extensive clinical development for **CLL**, which is the **largest segment of the NHL & CLL market** in terms of sales. To gain traction in this market, sonrotoclax would need to demonstrate safety, efficacy, and/or convenience **benefits over venetoclax-based combinations**. No head-to-head data are available yet; however, sonrotoclax is reportedly a more potent and specific Bcl-2 inhibitor with a shorter half-life, resulting in **lower drug accumulation**, and it inhibits venetoclax-resistant Bcl-2 variants such as G101V. BeOne is also investigating a **simplified ramp-up schedule** with sonrotoclax that could improve the convenience of administration.

# About the author



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Dr. Willoughby has more than 12 years of experience in oncology research and drug discovery. She has been the principal analyst for several market forecasting and competitive intelligence projects for a range of hematological malignancy and solid tumor indications. Prior to joining Clarivate, she was a Sara Borrell Postdoctoral Fellow at IDIBAPS-Hospital Clinic in Barcelona, and a postdoctoral fellow at IRB Barcelona. She obtained her Ph.D. at Newcastle University in the United Kingdom. Dr. Willoughby also holds a B.Sc. (Honors) in medical biochemistry with industrial experience from the University of Manchester and an M.Res. in cancer research from Newcastle University.

### Clarivate coverage of non-Hodgkin's lymphoma

- Non-Hodgkin's Lymphoma and Chronic Lymphocytic Leukemia | [Disease Landscape and Forecast](#) | G7 | last updated April 2026
- Non-Hodgkin's Lymphoma and Chronic Lymphocytic Leukemia | [China In-Depth](#) | China | published December 2025
- B-cell Non-Hodgkin's Lymphoma | [Current Treatment](#) | US | published April 2026
- B-cell Non-Hodgkin's Lymphoma | [Treatment Sequencing](#) | US | published April 2026
- B-cell Non-Hodgkin's Lymphoma | [Epidemiology](#) | Global | published September 2025



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