

## BGB-16673 and Mezigdomide

# The anatomy of a Drug to Watch

Key evaluation criteria in hematologic cancers and how BGB-16673 and mezigdomide were selected as Drugs to Watch 2026

Clarivate analysts rely on actionable data and market intelligence from our suite of products to identify each year's Drugs to Watch — the blockbusters and treatment paradigm-shifters.

### Identifying the next breakthroughs for hematologic cancers

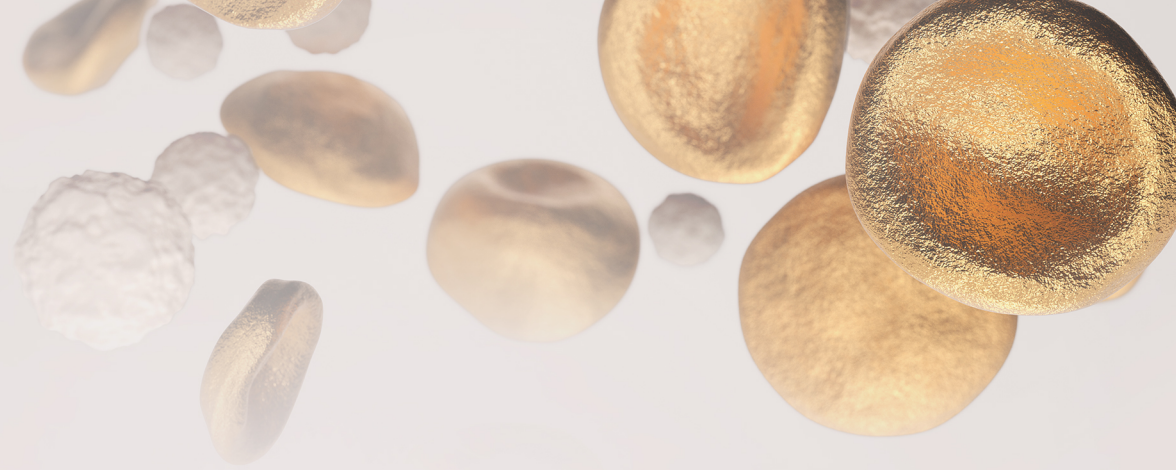
An accelerating wave of innovation across targeted therapies, immuno-oncology and cell-based modalities is redefining standards of care and shaping where the next transformative advances in hematologic malignancies are likely to emerge. To identify the breakthroughs, the first step is translating the evidence base into a clear view of which drugs are likely

to launch and succeed within the Drugs to Watch target timeframe.

### Mapping the therapeutic landscape: Cortellis Competitive Intelligence

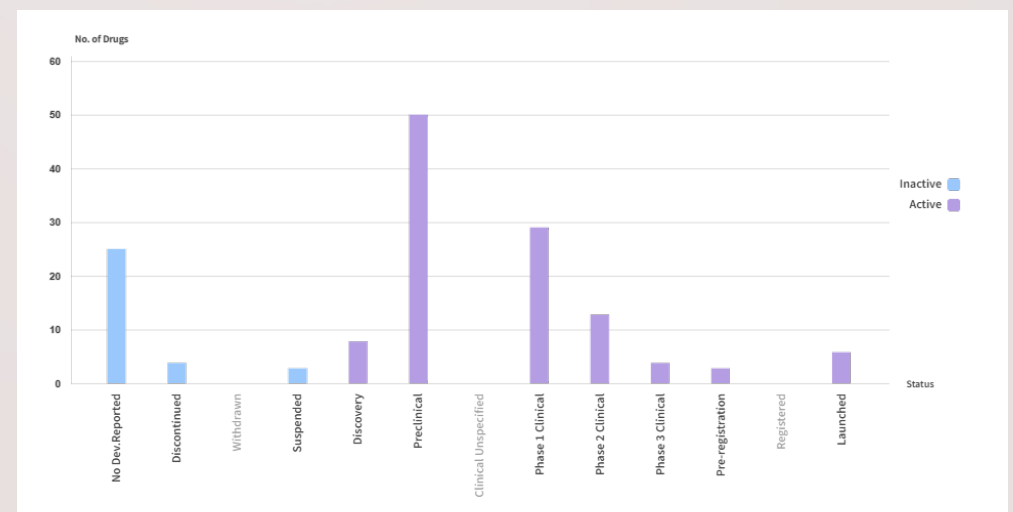
Our analysts gain a broad view of the status and potential success of drugs for hematologic cancers using Cortellis Competitive Intelligence, which:

- Covers the entire development lifecycle
- Provides clinical, deals, regulatory and patent intelligence for each drug and company
- Predicts the likelihood and timing of drug launches with the Drug Timeline & Success Rates statistical modeling methodology and ML-based predictive analytics



By reviewing the therapeutic landscape, Clarivate analysts narrow the field to a short list of assets that warrant deeper investigation as Drugs to Watch, such as targeted protein degraders in hematologic cancers.

Figure 1: Clinical pipeline of targeted protein degraders for hematologic cancers in Cortellis Competitive Intelligence



# BGB-16673

## Mutation-agnostic BTK degrader with portfolio-defining potential

### Cortellis Clinical Trials Intelligence

Shows high phase 1/2 response rates across chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL) and other B-cell malignancies, setting the stage for phase 3 head-to-head comparisons.

- Phase 1/2 CaDAnCe-101: high ORR in CLL/SLL of 85.3% including in BTK inhibitor- and BCL2 inhibitor-pretreated and high-risk mutation populations
- Global phase 3 trials: CaDAnCe-302 (BGB-16673 vs investigator's choice in BTK/BCL2 inhibitor-pretreated relapsed/refractory [R/R] CLL/SLL) and CaDAnCe-304 (BGB-16673 vs Jaypirca® [Eli Lilly] in covalent BTK inhibitor-pretreated R/R CLL/SLL)
- Phase 3 CaDAnCe-303 (China): BGB-16673 vs bendamustine/rituximab or rituximab + high dose methylprednisolone in covalent BTK inhibitor-pretreated R/R CLL/SLL

### Disease Landscape & Forecast

Identifies the opportunity for BGB-16673 to offer a novel and effective oral line of therapy for CLL / SLL patients with relapsed or refractory disease.

- BGB-16673 expected to receive initial approval in third-line+ CLL/SLL, with potential expansion into the second-line setting pending positive phase 3 results
- Long treatment durations anticipated to support strong revenue growth
- BTK inhibitors: more than 75% of CLL/SLL therapy sales in 2024 and expected to remain the dominant drug class through 2034, despite anticipated generic erosion of covalent BTK agents from 2028

### Epidemiology Intelligence

Highlights the growing global burden of CLL/SLL, driven by population aging.

- Initial core market: ~34k new second- and later-line CLL/SLL cases in the G7 markets in 2025
- Rising CLL/SLL incidence: the number of diagnosed incident cases worldwide expected to increase by 32% over the period 2025-2035
- Progression on current BTK inhibitors in CLL/SLL driven by resistance mutations in BTK (e.g., C481, gatekeeper and other variants)

### Cortellis Regulatory Intelligence + AI Regulatory Assistant

Highlights accelerated approval pathways in key hematologic indications, with phased expansion into earlier lines.

- Orphan drug designation in the U.S. for mantle cell lymphoma (December 2023) and Waldenström macroglobulinemia (WM) and follicular lymphoma (December 2024); EMA PRIME designation for WM previously treated with a BTK inhibitor (July 2025)
- Fast track designation for R/R MCL (December 2023) and CLL/SLL previously treated with at least two prior lines including a BTK inhibitor and BCL2 inhibitor (August 2024)
- First approvals anticipated in the U.S. and E.U. in 2027, with Japan launch following in 2029

# Mezigdomide

## Refined cereblon degradation with franchise-resetting potential

### Cortellis Competitive Intelligence

Demonstrates differentiation from legacy immunomodulatory drugs (IMiDs), restoring efficacy in triple-class and post-BCMA myeloma and reinforcing franchise durability amid generic pressure.

- Novel oral CELMoD designed to enhance cereblon binding and accelerate degradation of Ikaros/Aiolos, driving both direct antimyeloma and immune-stimulatory effects
- Positioned as a lifecycle successor to pomalidomide (IMNOVID®/POMALYST®, Bristol Myers Squibb) in later-line disease, with iberdomide targeting earlier lines of treatments and as maintenance therapy in Bristol Myers Squibb's portfolio
- Strong activity in triple-class refractory and post-BCMA settings, where treatment options are limited and remissions are short

### Disease Landscape & Forecast

Shows the growing later-line multiple myeloma sales opportunity and underscores mezigdomide's role in preserving cereblon platform relevance and reinforcing long-term revenue stability.

- Multiple myeloma therapy sales expected to grow from \$21.7bn (2024) to \$37.0bn (2034), with R/R lines expanding from \$13.8bn to \$23.9bn (63% → 65% of the market)
- Second-line setting projected to be the single most lucrative segment by 2034 (\$11.1bn), where CELMoDs and new cell therapies will compete
- Uptake in later-line then earlier-line triplets contributing to forecasted sales of \$1.36bn in the G7 markets by 2031, partially offsetting pomalidomide generic erosion

### Epidemiology Intelligence

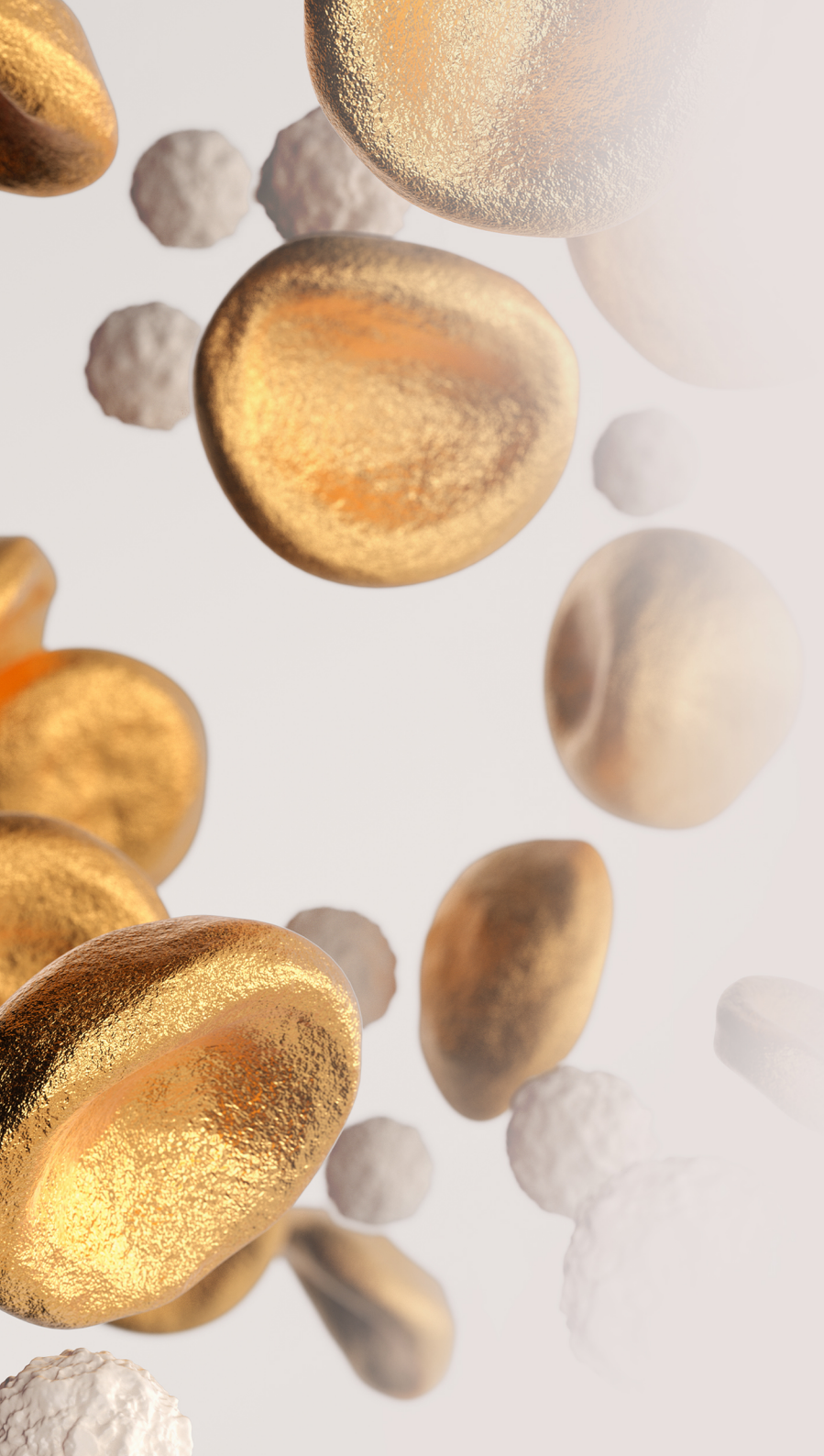
Highlights the growing late-line multiple myeloma burden and the treatment gap created by IMiD resistance, driving demand for more potent cereblon-targeting strategies.

- Core target population: ~95k new second-to-seventh-line R/R multiple myeloma cases in the G7 markets in 2025
- Multiple myeloma: second most common hematologic malignancy worldwide and characterized by progressively shorter remissions with each subsequent line of therapy
- Resistance to IMiD-containing regimens (lenalidomide, pomalidomide) common in later lines, leaving patients reliant on costly cell therapies or combinations with limited durability

### Cortellis Deals Intelligence

Identifies CELMoDs as the strategic evolution of the IMiD franchise, with mezigdomide serving as the linchpin of sustained cereblon-based leadership in multiple myeloma.

- Core component of Bristol Myers Squibb's strategy to transition from legacy IMiDs (REVLIMID®, IMNOVID/POMALYST) to next-generation CELMoDs as generic competition intensifies
- Iberdomide being positioned as a more tolerable, earlier-line successor to lenalidomide, while mezigdomide is the higher-potency option for later, harder-to-treat lines
- The broader CELMoD class narrative in myeloma and beyond, including other cereblon-modulating agents, supported by successful positioning of mezigdomide



## Summary of impact

### BGB-16673

BGB-16673 delivers robust protein degradation in CLL/SLL, effectively overcoming resistance seen with traditional BTK inhibitors in patients with both wild type and mutant BTK. Its mutation-agnostic activity and potential to span multiple lines of therapy position it as a catalyst for the future evolution of the BTK market.

### Mezigdomide

Mezigdomide has the potential to redefine the treatment landscape in later-line multiple myeloma by showing how molecularly refined degraders can reinvigorate a mature modality. Durable franchise relevance is reinforced by its positioning as a lifecycle successor, anticipated superiority in clinical trials and the broader shift toward next-generation CELMoDs.

## Ready to see if your drug is one to watch?

Contact us to learn how integrating intelligence from multiple Clarivate products, powered by AI, drives confident predictions of the potential competitive impact of your drug on the market and patients' lives.

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