

# Hepatocellular Carcinoma Market Gains Momentum as Immunotherapy and Targeted Treatments Redefine Care | CI Insights

*Hepatocellular carcinoma market transforms as immunotherapies, targeted drugs, and novel combinations shift standards and spark new competition.*

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[Hepatocellular carcinoma \(HCC\)](#), the most common form of primary liver cancer, is undergoing a significant transformation in its therapeutic and competitive landscape. Accounting for approximately 75% of all primary liver cancers, HCC is closely linked to chronic liver disease, particularly cirrhosis. Over 85% of patients diagnosed with HCC also have underlying cirrhosis, making disease management particularly complex due to the dual challenge of treating cancer and maintaining liver function.



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As HCC therapies evolve, the intersection of immunotherapy and biomarker-driven innovation offers a pivotal moment for pharma leaders to rethink strategy and differentiation.”

*DataM Intelligence*

Although HCC is relatively uncommon in the United States, its incidence is steadily increasing, primarily due to the spread of hepatitis C virus (HCV) and the growing prevalence of non-alcoholic fatty liver disease (NAFLD). Globally, HCC is the sixth most commonly diagnosed cancer and the third leading cause of cancer-related deaths. These statistics underscore the urgency of effective treatment strategies and the emergence of new therapeutic classes aimed at improving outcomes and expanding treatment options.

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Shifting Standards: From TKIs to Immunotherapy

Historically, the treatment of advanced or unresectable HCC was dominated by tyrosine kinase inhibitors (TKIs), particularly sorafenib (Nexavar) by Bayer. Approved in 2007, sorafenib was the first systemic treatment to show a survival benefit in HCC and remained the standard of care for over a decade. However, its modest survival benefit and notable side effect profile left room for innovation.

That innovation arrived in the form of immunotherapy. The combination of atezolizumab (Tecentriq), a PD-L1 inhibitor from Roche, and bevacizumab, an anti-VEGF antibody, has emerged as a new frontline standard. This regimen demonstrated superior overall survival (OS) and progression-free survival (PFS) compared to sorafenib in the landmark IMbrave150 trial, fundamentally shifting the treatment paradigm. The success of this combination has paved the way for broader integration of immunotherapy in HCC, with multiple companies now investing heavily in this space.

AstraZeneca, for example, has introduced the STRIDE regimen, combining durvalumab (Imfinzi) and tremelimumab (Imjudo). This dual immunotherapy approach has shown encouraging results, offering a checkpoint inhibitor-based alternative for patients who may not tolerate anti-angiogenic agents.

Bristol Myers Squibb (BMS) also plays a significant role in the second-line space with its combination of nivolumab (Opdivo) and ipilimumab (Yervoy). Similarly, Merck's pembrolizumab (Keytruda) remains a key player in refractory settings and is being evaluated in multiple combination studies aiming to improve long-term disease control.

#### Targeted Therapies Still Relevant, but Shifting

Despite the rise of immunotherapy, TKIs continue to serve a vital role, especially in patients who are not candidates for immunotherapy. Lenvatinib (Lenvima), developed by Eisai, is approved for frontline treatment and is often used as an alternative to sorafenib. Regorafenib (Stivarga) remains an option for patients who progress on sorafenib, while cabozantinib (Cabometyx) from Exelixis is approved for both second- and third-line settings. Additionally, ramucirumab (Cyramza) by Eli Lilly has found a niche in patients with elevated alpha-fetoprotein (AFP), a biomarker that correlates with poor prognosis.

This mix of immunotherapy and targeted treatments reflects the heterogeneity of HCC and the need for a personalized approach to care. Liver function, tumor burden, patient performance status, and biomarker expression all influence treatment selection, further emphasizing the importance of developing differentiated, flexible regimens.

#### Robust Pipeline Promises Disruption

The development pipeline for HCC is vibrant, with a variety of immuno-oncology agents, novel targets, and biomarker-driven approaches advancing through clinical trials. Agents targeting the TGF- $\beta$  pathway, Wnt signaling, bispecific antibodies, and other innovative mechanisms are poised to enter a market that is increasingly receptive to innovation.

Many of these emerging therapies aim not just to improve survival, but also to enhance safety, reduce toxicity, and offer more convenient administration methods. Oral or subcutaneous options, extended dosing intervals, and lower immune-related adverse event (irAE) profiles are among the top priorities for developers seeking to capture patient and provider preference.

#### Competitive Landscape: Leaders, Challengers, and Niche Players

Roche continues to lead the front-line market with the Tecentriq-bevacizumab combination, supported by strong clinical data and broad physician adoption. AstraZeneca is quickly gaining market share with its STRIDE regimen, while BMS and Merck maintain strong positions in the second-line and combination trial landscape.

Bayer and Eisai still play key roles in early-line therapy where immunotherapy may not be suitable, and Exelixis and Eli Lilly remain important in biomarker-driven and post-immunotherapy settings.

This competition is intensifying, not only in terms of clinical performance but also in cost, convenience, and real-world outcomes. As the payer landscape evolves, cost-effectiveness and value-based access models are becoming increasingly critical for market access.

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#### The Target Opportunity Profile (TOP): What New Therapies Must Deliver

To succeed in the increasingly crowded HCC space, new therapies must meet or exceed a range of clinical and commercial benchmarks. Our Target Opportunity Profile (TOP) outlines these requirements:

- Efficacy: Therapies must at least match existing combinations in OS and PFS, with a preferred target of extending survival and increasing objective response rates.
- Safety: A lower incidence of Grade  $\geq 3$  adverse events and better immune-related AE profiles are crucial for real-world adoption.
- Differentiation: Novel mechanisms, compatibility with other therapies, and biomarker utility offer competitive advantages.
- Convenience: Oral or less frequent dosing options can improve adherence and reduce clinic burden.
- Cost and Access: Competitive pricing, quality-adjusted life years (QALY) support, and companion diagnostics can enhance payer alignment and market penetration.

#### Conclusion

The hepatocellular carcinoma treatment landscape is entering a dynamic new era, characterized by innovation, competitive intensity, and patient-centered development. With both approved therapies and pipeline agents bringing new mechanisms and combination strategies to the

forefront, stakeholders must remain agile and forward-looking.

For pharmaceutical companies, biotech firms, and investors, understanding this evolving ecosystem is critical. Competitive intelligence, real-world data integration, and a clear view of the Target Opportunity Profile can inform product development, portfolio strategy, and market access decisions.

As the science advances and patient expectations grow, the race to improve outcomes in HCC will favor those who can combine clinical excellence with strategic execution.

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