

Future Trends and Insights

Expert analysis of the oncology competitive landscape

At a glance

The Oracle Life Sciences CancerMPact Future Trends and Insights module explores potential changes in treatment practices in the U.S., EU and Japan based on a critical evaluation of ongoing pivotal clinical trials, recently published clinical data, and regulatory advances / setbacks.

Future Trends and Insights allows clients to understand:

Context and implications behind clinical development:

Expert Oracle Life Sciences commentary that explores more than the stated clinical trial results to explore potential positioning strategies and likelihood of approval

Potential developmental risks, threats and opportunities:

Sheds light on the potential trends and events that can pose threats to, or present opportunities for, agents in development

Size and nature of unmet needs:

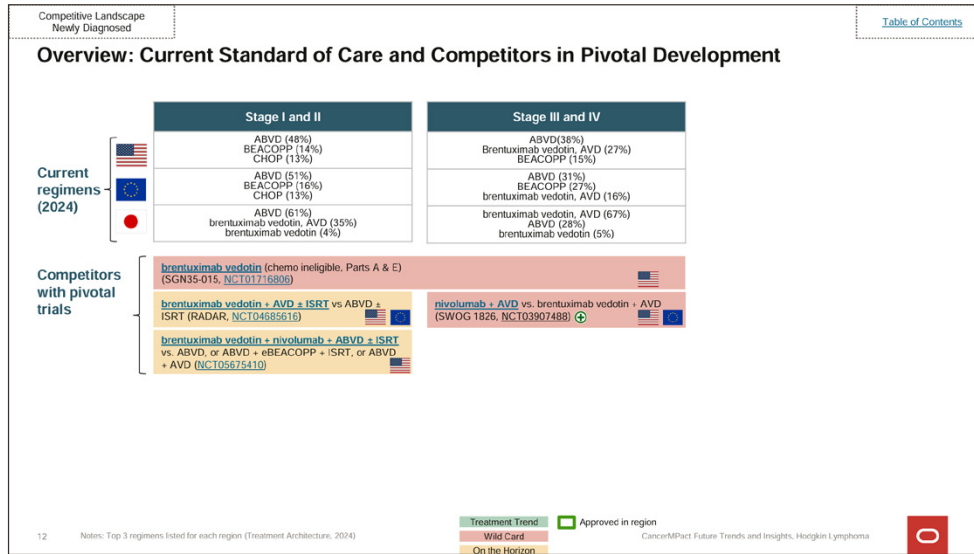
Highlights opportunities for companies to develop new therapies

Features of Future Trends and Insights:

- Global overviews of pivotal development across all treatment settings
- Oncology expert opinion on competitor regimens, including comparative outlook analyses relative to the competitive set and region-specific insights
- Detailed trial and regulatory approval timelines within the U.S., EU, and Japan
- Alignment with Oracle Life Sciences CancerMPact Treatment Architecture to place the competitive landscape in context with current standards of care
- Detailed summaries of ongoing pivotal development programs and relevant clinical data
- Continuous competitive monitoring with every 3-month updates, to keep you abreast of changes in pivotal trial starts and status, regulatory actions, and published data



Gain confidence with your clinical and commercial decision making in an evolving oncology landscape



Competitive Landscape
Newly Diagnosed

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Details for Ongoing Pivotal Trials

Trial Arms	brentuximab vedotin (elderly / chemo ineligible, Parts A & E)	nivolumab + AVD vs. brentuximab vedotin + AVD	brentuximab vedotin + AVD + ISRT vs. ABVD + ISRT	brentuximab vedotin + nivolumab + AVD + ISRT vs. ABVD, or ABVD + eBEACOPP + ISRT, or ABVD + AVD
Trial	SGN35-015, NCT01716806	SWOG 1826, NCT03907488	RADAR, NCT04685616	NCT05675410
Sponsor / Collaborator	Pfizer (Seagen) / Bristol-Myers Squibb	NCI	University College London / Iakada & Canadian Cancer Trials Group	NCI
Phase (estimated enrollment)	Phase II (n=131)	Phase III (n=987)	Phase III (n=1042)	Phase III (n=1875)
Registrational geography	USA	USA, EU	USA, EU	USA
Line of Therapy	First-Line	First-line	First-Line	First-line
Patient Segment	Newly Diagnosed, Stage I-IV, unable to have standard chemotherapy treatment	Newly Diagnosed, Stage III-IV	Newly Diagnosed, Stage IA-IIA	Newly-diagnosed, untreated stage I or II cHL
Primary Endpoint	ORR	PFS	PFS	PFS in rapid early responder and slow early responder populations
Start Date	Oct-2012	Aug-2019	Apr-2022	Apr-2023
Status (as of)*	Recruitment complete (Feb-2023)	Recruitment complete (Dec-22)	Recruiting (Jul-2024)	Recruiting (Aug-2024)
Data Readout*	Apr-2023	Mar-2024	Sep-2030	Apr-2031
Estimated Approval Date	Q1-2025	Q3-2025 (U.S.), Q4-2025 (EU)	Q4-2031 (U.S.), Q1-2032 (EU)	Q3-2032

13 *According to clinicaltrials.gov
*Data Readout as reported by company (if actual) or based on estimated Primary Completion date in trial registry (if projected in future)

Treatment Trend: ■ Approved in region, ■ Wild Card, ■ On the Horizon

CancerMPact Future Trends and Insights, Hodgkin Lymphoma

Future Competitor Details
Newly Diagnosed

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Pivotal Trial Outlook: brentuximab vedotin (elderly / chemo ineligible) (SGN35-015, NCT01716806)

	Rating
Trial design	1
Clinical factors vs. SoC (brentuximab vedotin)	3
Efficacy	3
Safety	3
Novelty of MOA	1
Dosing / administration	3
Commercial factors	3
Launch timing	3
Cost of therapy	4
Experience of manufacturer	5

Rating methodology in appendix: 1 Strong disadvantage, 2 Disadvantage, 3 Neutral, 4 Advantage, 5 Strong advantage

Opportunities

- Elderly patients with Hodgkin Lymphoma typically have poorer outcomes than younger patients and are a patient segment of high unmet need given their inability to tolerate multi-agent chemotherapy. The single arm BREVITY study has shown that brentuximab vedotin monotherapy elicits responses (ORR: 84%) in older patients with mOS of 19.5 mos.
- Brentuximab vedotin is already approved and utilized in combination with AVD in this setting and having an effective single agent regimen would be a welcomed treatment option.

Barriers

- SGN35-015 is Phase II, single-arm, multi-part (Parts A-E) trial with an estimated enrollment of 180 patients; however, the company considers Parts A and E cohorts of this trial to be registrational. How these cohorts accrue and what retrospective data will be part of a submission will be key to the approval and success of this agent.
- Only ~30% of newly diagnosed Hodgkin Lymphoma patients are over 60, so there may be limited patients eligible for this type of regimen¹.
- No sign of a regulatory submission since the acquisition of Seagen by Pfizer in Dec-2023

Overall Outlook

- Trial arm A of this study has reported a preliminary ORR of 92% in 26 patients 60 years and older; however, adverse events may limit duration of therapy. Peripheral neuropathy specifically was very common in patients, but other adverse events attributed to chemotherapy were reduced in this trial (Vasanthak, Blood, 2020).
- With a marked improvement in ORR compared to historical responses following standard chemotherapy in this population, brentuximab monotherapy stands to provide an alternative option for older patients with Hodgkin lymphoma which currently have a high unmet need (Evans, Blood, 2013).

27 ¹CancerMPact, Patient Metrics, accessed June 2022

CancerMPact Future Trends and Insights, Hodgkin Lymphoma



Improving business outcomes through empowered decision making

Oracle Life Sciences CancerMPact is an invaluable and comprehensive oncology decision support resource. It can be utilized for market analysis, strategic planning and identification of commercial opportunities in the U.S., Western Europe, Japan and China. This resource is composed of cloud-based integrated modules: Patient Metrics (Patient Metrics – Core, Patient Metrics – Expanded Markets, PM Dashboards, and Biomarker Analysis), Treatment Architecture, Treatment Architecture Trends, and CancerLandscape.

1. Patient Metrics

Best-in-class cancer epidemiology and proprietary patient calculations for target markets.

Patient Metrics Core – U.S., Western Europe, Japan, China – combines epidemiologic data and analysis to estimate incidence (annual new cases of cancer) by stage; restaged 5-, 10-, or 15-year prevalence (annual surviving cancer patients from up to 15 years prior that accounts for progression to later stages); active disease (estimate of treatment-eligible patients by stage that does not include early-stage patients in remission); and treated patient populations by modality (surgery, radiation, drug therapy, etc.), drug regimens and drug agents.

Patient Metrics Expanded Markets – Combines epidemiologic data and analysis to estimate incidence (annual new cases of cancer) by stage; five-year prevalence (annual surviving cancer patients from up to five years prior; and treatable patients for up to 16 tumor types. Available for Argentina, Brazil, Canada, India, Mexico, Russia, South Korea, Taiwan and Turkey.

PM Dashboards – Interactive, multi-country views of the epidemiology and treatment of cancer, making comparisons across geographies, patients and tumors much easier. PM Dashboards features six interactive dashboards to allow you to more quickly and easily evaluate global trends in cancer epidemiology.

Biomarker Analysis – Expert analysis of key oncology biomarker segments. Biomarker Analysis is a global resource based on a thorough review of literature and recently published data that discusses the current and evolving oncology landscape with regard to biomarker segmentation rates and geographic, survival, ethnic, racial and gender differences.

2. Treatment Architecture

In-depth quantitative analysis of oncology drug and modality utilization across all cancer disease stages.

Treatment Architecture assesses the current clinical management of cancer patients by site and stage for all treatment modalities – including surgical, radiologic and systemic agents, as well as untreated patient populations. Treatment Architecture also provides pivotal clinical trial summaries to highlight the benchmark outcomes contributing to standard-of-care designations. Drug utilization is captured for all treatment settings and lines of therapy and by patient type in tumors where biomarkers have segmented the drug market.

3. Treatment Architecture Trends

Analytics for in-depth exploration of historical treatment patterns.

Treatment Architecture (TA) Trends allows for customized data exploration, powerful analytics, and impactful visualization of a wide variety of treatment data. TA Trends provides historical global treatment patterns allowing for analysis of the impact of market events on share and uptake of drugs and drug classes. A broad set of diagnostics, modality, drug, and outcomes data can be queried and filtered by stage, patient segment, drug technology, target, regimen, physician specialty, physician treatment setting and country.

4. Future Trends and Insights

Expert analysis of the changing oncology competitive landscape with focus on ongoing pivotal clinical trials.

Future Trends and Insights explores potential changes in treatment practices in the U.S., Western Europe and Japan based on a critical evaluation of recently published clinical data, regulatory advances/ setbacks and ongoing pivotal clinical trials. It identifies key trends in each tumor market, which can comprise new product introductions or label expansions of marketed products. It also assesses unmet needs for each cancer while continuously monitoring the competitive environment.

5. CancerLandscape

A visual, comprehensive overview of the oncology drug and trial landscape

CancerLandscape combines and standardizes U.S., EU, and Japan trial registries with other data sources to provide a visual and detailed understanding of the oncology trial landscape by company, tumor, drug and target. Users have the ability to filter on detailed clinical and commercial variables, make quick comparisons, uncover trends, and evaluate trial timing and enrollment. Gain insights about the oncology landscape in detail with a simple interface that is updated on a weekly basis. Clinical and scientific support is provided by the Oracle Life Sciences oncology support team.

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