ORACLE

CancerMPact®

Future Trends and Insights

Expert analysis of the oncology competitive landscape

At a glance

The 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:

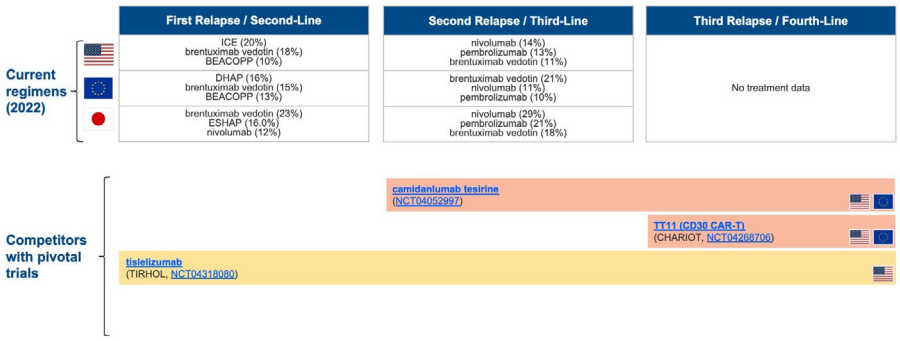
Highlights opportunities for companies to develop new therapies

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 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

Overview: Current Standard of Care and Competitors in Pivotal Development



Pivotal Trial: brentuximab vedotin + AVD ± ISRT

Trial Status

On the Horizon

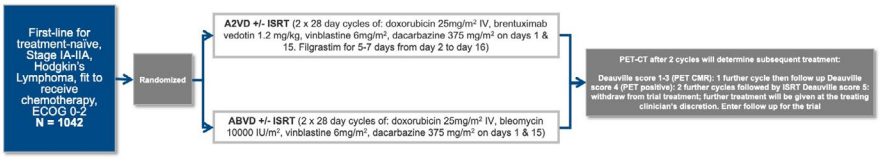
RADAR trial began patient enrollment in Apr 2022 and continues recruitment as of May 2022.

RADAR, NCT04685616	
Phase & design	Phase III, randomized, open label
Sponsor / Collaborator	University College London / Takeda & Canadian Cancer Trials Group
Recruitment geographies	UK
Start date	Apr-14-22
Primary endpoint(s)	PFS
Secondary endpoint(s)	PET-CMR, EFS, OS, Incidence of second cancers and cardiovascular disease, safety and toxicity
Enrollment status	Recruiting (May-22*)
Primary completion date	Sep-30
Anticipated approval	Q4 2031

Mechanism of Action: CD30 targeted ADC + chemo + RT

Rationale for Development:

- This study is evaluating brentuximab vedotin + AVD ± ISRT in early stage, treatment naive Hodgkin's Lymphoma.
- Brentuximab vedotin + AVD is approved and utilized in newly diagnosed patients in Stage III-IV disease based on positive results from the ECHELON-1 trial (NCT01712490), and treatment data suggests that next to ABVD, it is also used in Stage I-II patients[1].
- Now, academic investigators are formally evaluating brentuximab + AVD with or without involved site radiotherapy in early-stage patients compared to standard of care ABVD.



Pivotal Trial Outlook: brentuximab vedotin (elderly / chemo ineligible) (SGEN35-015, NCT01716806)

	brentuximab vedotin (elderly / chemo ineligible)
	Newly Diagnosed
Trial design	1
Clinical factors vs. SoC (ABVD)	
Efficacy	3
Safety	2
Novelty of MOA	2
Dosing / administration	4
Commercial factors	
Launch timing	3
Cost of therapy	4
Experience of manufacturer	5

Rating methodology in appendix — 1 Strong disadvantage … 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

- SGEN35-015 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's Lymphoma patients are over 60, so there may be limited patients eligible for this type of regimen[1].

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 (Yasenchak, *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).

About Oracle Life Sciences

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