Oncology Competitive Landscape, April 2020: Searching for White Space

Abstract

It is always a challenge to prioritize indications with an oncology asset. Most drug candidates have multiple applications across a wide set of malignancies and a complex set of competition with an overwhelming competitive landscape with thousands of trials. First Principles Advisory Group (FPA) often helps our clients develop frameworks to navigate this complex array of strategic options. Our clients tend to know their own molecule's strengths across tumors, but often do not have the resources to integrate that knowledge with an up-to-date comprehensive market view.

To assist in this process, First Principles created a framework to analyze 21 solid tumors and hematologic malignancies, which can also easily integrate any company's technology into its rubric to determine the best white spaces for development. By merging the management team's scientific knowledge with FPA's market expertise, any company can perform a lean, yet rigorous review of the landscape and plan scenarios, evaluate options, and determine the best path forward.

This report is valuable in its own right, providing insight on the slivers of white space in the oncology therapeutic area, and also as a missing link for any firm that wants to analyze the oncology market, in order to prioritize its clinical research rigorously.

The cost for this study is $2,500 and it includes a 125-page pdf formatted in PowerPoint and an Excel database of key commercial and technical parameters for each malignancy, along with extensive documentation of source material and data.

Methodology

Landscape assessment is one our areas of expertise.. FPA has deep experience in conducting landscape analyses across several malignancies. For oncology, FPA has developed a methodology for landscape analysis, which can be customized to inform broad strategic decisions faced by oncology executives, such as indication prioritization, competitive response, TPP development, and others. Below is a highlight of the methodology we developed and the subject of this report.

Parameter Selection:

We selected a broad set of parameters across commercial, clinical, and regulatory variables that are most relevant to decision-makers. These include:

Commercial factors

- Prevalence
- Growth rate
- Standard of care
- Key classes of drugs approved
- Key classes of drugs in the pipeline
- # of candidates in Ph 2 & 3
- 5-year survival rate
- Key unmet need
- Recommendations
- Average annual cost of Tx
- Impact of generics

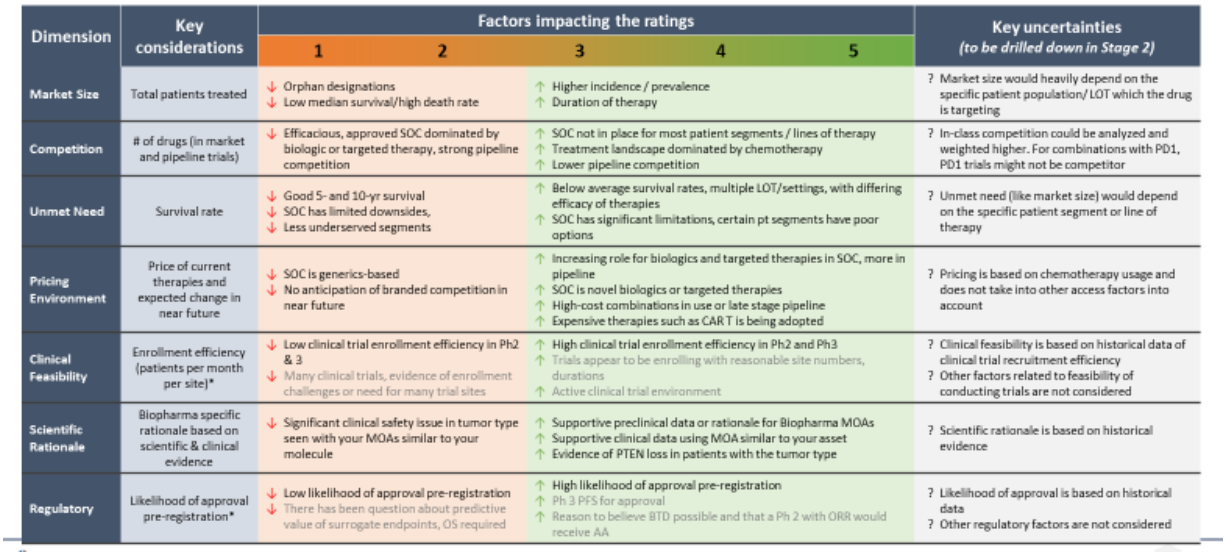
Technical factors

- Quality of clinical endpoints
- Trial duration & size (phase 2, 3)
- Cold / hot tumors
- Likelihood of response to Biopharma targets
- Drugs in the pipeline with your MOA
- Key biomarkers approved / in development
- Opportunity for expedited approval
- Opportunity for orphan / voucher
- Additional FDA guidance
- Acceptability of surrogate endpoint

Each of these parameters maps to a “dimension” and each malignancy is scored across the set of dimensions:

1. Market size
2. Competition
3. Unmet need
4. Pricing environment
5. Clinical feasibility
6. Scientific rationale
7. Regulatory

The image below shows some of the factors we considered in assigning ratings.



Dimension	Key considerations	Factors impacting the ratings					Key uncertainties *(to be drilled down in Stage 2)*
		1	2	3	4	5	
Market Size	Total patients treated	↓ Orphan designations ↓ Low median survival/high death rate		↑ Higher incidence / prevalence ↑ Duration of therapy			? Market size would heavily depend on the specific patient population/ LOT which the drug is targeting
Competition	# of drugs (in market and pipeline trials)	↓ Efficacious, approved SOC dominated by biologic or targeted therapy, strong pipeline competition		↑ SOC not in place for most patient segments / lines of therapy ↑ Treatment landscape dominated by chemotherapy ↑ Lower pipeline competition			? In-class competition could be analyzed and weighted higher. For combinations with PD1, PD1 trials might not be competitor
Unmet Need	Survival rate	↓ Good 5- and 10-yr survival ↓ SOC has limited downsides, ↓ Less underserved segments		↑ Below average survival rates, multiple LOT/settings, with differing efficacy of therapies ↑ SOC has significant limitations, certain pt segments have poor options			? Unmet need (like market size) would depend on the specific patient segment or line of therapy
Pricing Environment	Price of current therapies and expected change in near future	↓ SOC is generics-based ↓ No anticipation of branded competition in near future		↑ Increasing role for biologics and targeted therapies in SOC, more in pipeline ↑ SOC is novel biologics or targeted therapies ↑ High-cost combinations in use or late stage pipeline ↑ Expensive therapies such as CAR T is being adopted			? Pricing is based on chemotherapy usage and does not take into other access factors into account
Clinical Feasibility	Enrollment efficiency (patients per month per site)*	↓ Low clinical trial enrollment efficiency in Ph2 & 3 ↓ Many clinical trials, evidence of enrollment challenges or need for many trial sites		↑ High clinical trial enrollment efficiency in Ph2 and Ph3 ↑ Trials appear to be enrolling with reasonable site numbers, durations ↑ Active clinical trial environment			? Clinical feasibility is based on historical data of clinical trial recruitment efficiency ? Other factors related to feasibility of conducting trials are not considered
Scientific Rationale	Biopharma specific rationale based on scientific & clinical evidence	↓ Significant clinical safety issue in tumor type seen with your MOAs similar to your molecule		↑ Supportive preclinical data or rationale for Biopharma MOAs ↑ Supportive clinical data using MOA similar to your asset ↑ Evidence of PTEN loss in patients with the tumor type			? Scientific rationale is based on historical evidence
Regulatory	Likelihood of approval pre-registration*	↓ Low likelihood of approval pre-registration ↓ There has been question about predictive value of surrogate endpoints, OS required		↑ High likelihood of approval pre-registration ↑ Ph 3 PFS for approval ↑ Reason to believe BTD possible and that a Ph 2 with ORR would receive AA			? Likelihood of approval is based on historical data ? Other regulatory factors are not considered

Data sources:

We used several sources of data in our analysis, bolstered by our in-house experience. We also validated data points across several of these sources, e.g., prevalence across GlobalData, SEER, literature reports, advocacy groups, and the expertise of our analysts and experts. A partial list of data sources used includes (larger table at the end of this summary):

- Third-party sources: GlobalData, proprietary research reports, and others
- Publicly-available data sources: Peer-reviewed literature, clinicaltrials.gov, NCCN, SEER, advocacy groups, FDA
- Propriety FP database tools: Clinical trials data tool (to be available to clients soon)

Scoring and evaluation:

The data and analysis from the above steps were analyzed by industry experts, who added their own experience into the report to assign relevant scores for each malignancy across the seven dimensions. Our experts then developed insights on 1) the current market, 2) pipeline competition themes, 3) Expected landscape evolution and unmet needs, and 4) Development opportunities and challenges.

For profiles of some of our industry experts, visit our website at https://www.fpadvisory.net/people

Summary analysis:

FPA complied insights from the above steps across all malignancies and visualized the aggregated data points to surface insights and trends across malignancies. These top-line takeaways enable decision-making by executives.

Selection of malignancies:

We selected malignancies with large market sizes and which are of general interest. If you would like us to analyze any malignancy that we did not cover, please email us at info@fpadvisory.net.

The report includes the following malignancies and segments:

- Prostate
- Breast (HR+/HER2-)
- Breast (TNBC)
- Lung - NSCLC
- Lung - SCLC
- CRC
- Melanoma
- Kidney
- Pancreatic
- Liver
- GBM
- Ovarian
- Gastric
- AML
- Myeloma
- HL
- FL
- MZL
- DLBCL
- CLL
- MCL

Table of Contents

Sources & References

Government / Public sources	1. Clinicaltrials.gov 2. FDA Approved drugs list 3. FDA Oncology Centre of Excellence 4. FDA Table of Surrogate Endpoints 5. FDA Orphan Drug Designation and Approval 6. SEER Stat 7. NCBI 8. PubMed 9. Pharma company websites 10. Pharma company investor and annual reports 11. Pharma company 10-K filing
Advocacy groups, Non-profits	12. ASCO 13. ASH 14. NCCN 15. Cancer.net 16. Cancernetwork.com 17. Ascopost.com 18. BCPP 19. Cancer Care 20. Skin Cancer Foundation 21. LLS 22. ACS

Proprietary Data and Research Reports	23. Global Data Biomarker Database 24. Global Data Trial Planner 25. Global Data Epidemiology 26. Global Data Feasibility Planner 27. Ipsos Data 28. Cowen therapeutic category outlook 29. FP Internal Competitive Intelligence tool (to be launched soon) 30. FP Whitepapers
Life science news, Journals & Others	31. Medscape 32. OncLive 33. BMC 34. EPR 35. IO News 36. Targetedonc 37. Lymphomanewstoday.com 38. AML-HUB 39. Pharma BlueBook 40. Drugs.com 41. eMedicine 42. Nursing Center 43. A Dictionary of Epidemiology