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Identifying Gaps in Competitive Intelligence and Business Development Strategy:

New Opportunities in the PD-1/PD-L1 Development Landscape

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Objective

Should companies operating in the IO space look to other targets? Or, might there still be valuable opportunities discoverable through analysis? We used analysis and visualization tools to leverage drug competitor and clinical trial data to identify gaps in a crowded target area (PD-1/PD-L1).

Introduction

Despite the first PD-1 inhibitors gaining approval just five years ago, the competitive landscape is maturing at an incredible rate. Keeping abreast of this rate of change is a challenge for anyone operating in the IO space, including both PD-1 developers and those companies seeking to test their cancer drugs in combination with this important new therapeutic backbone. In order to be successful, it is important to seek partnerships and design clinical trial programs that yield first-in-class opportunities and product differentiation, while minimizing the inevitable redundancy in such a competitive market.

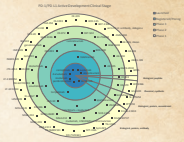
Method

We searched Citeline's Trialtrove and Pharmaprojects databases for all drugs and all industry-sponsored clinical trials for PD-1 or PD-L1 inhibitors. These were visualized and analyzed using BizInt Smart Charts tools to map areas of intensive trial activity and potential options for differentiation.

As of January 2019, Pharmaprojects identified 207 PD-1 or PD-L1 antagonists with only 1 listed as Discontinued and 59 at No Development Reported. The focus is almost entirely on cancer: 68 indications out of 82 listed for the drugs are in oncology. Trialtrove showed 2,306 trials involving a PD-1/PD-L1 drug, with 1,776 listing at least one as a primary drug.

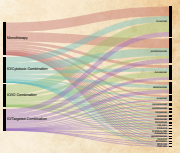
Results – Summary

There are many ways to view the drug landscape for a target. The bullseye plots each drug, making it clear that this is a very active area with primarily biologics.

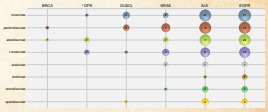


We identified opportunities at the indication level by creating heat maps and bubble charts from the Pharmaprojects search results. By visualizing indications by phase of development, we were able to identify and exclude highly competitive indications and focus on opportunities where development was limited to early stages.

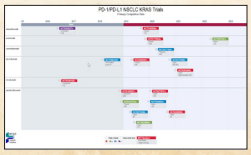
By analyzing visualizations of Trialtrove data, we identified additional opportunities in a highly competitive area, NSCLC. We built a flow diagram to quickly see which drugs have trials for specific types of combinations and which may only have been tested as monotherapy.



We can use a heat map or bubble chart to identify opportunities for differentiation. Correlating PD-1/PD-L1 drugs with selected patient segments reveals competitor development strategy as well as gaps.



We selected a biomarker (KRAS) with potential for competitive differentiation for further exploration. We then built a trial timeline and table to validate our selection by reviewing enrollment, timing and other trial details.



See inside for more details on study results and visualizations.

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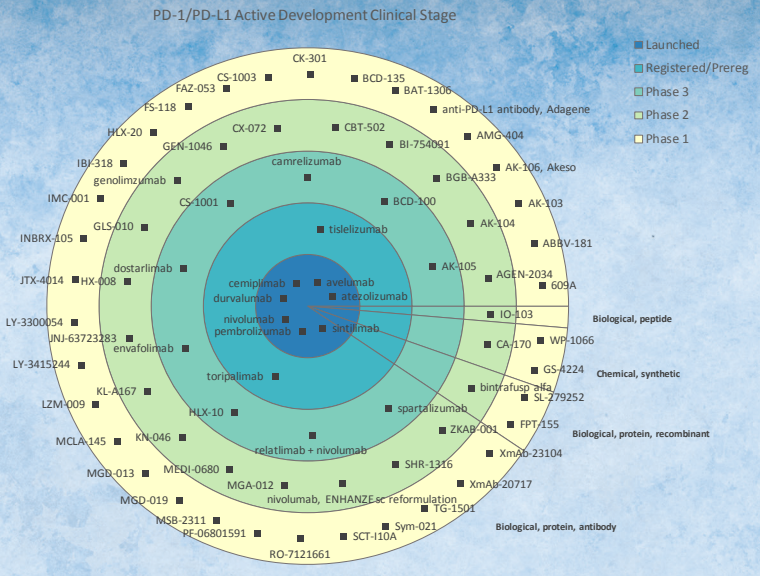
Results - Visualizations

PD-1/PD-L1 Pipeline - Visualizing the Drug Landscape

There are many ways to view the drug landscape for a target. The bullseye plots each drug, making it clear that this is a very active area with primarily biologics.



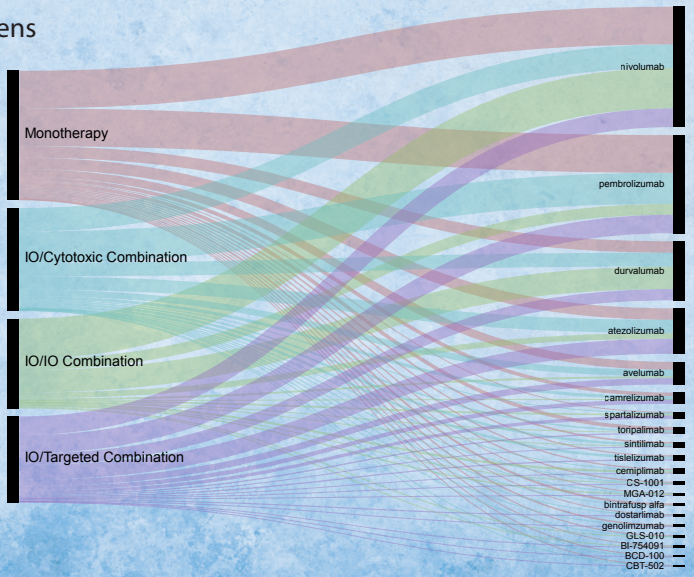
PD-1/PD-L1 Pipeline - Identifying Underserved Indications

From the Pharmaprojects data, we selected indications where development has not exceeded Phase 2. This bubble chart shows these selected indications by phase of development. Note several hematological cancer indications still in earlier stage of development as well as some signs of activity in other therapeutic areas.

PD-1/PD-L1 Trials - Potential Partners for IO Combination Regimens

This flow diagram shows the number of trials for top PD-1 drugs by type of combination. We can see what proportion of trials include which combination.

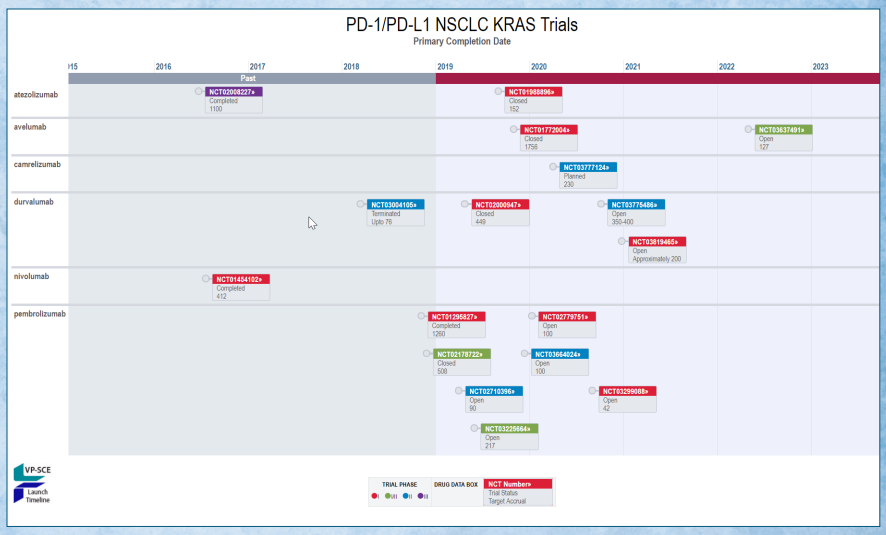
Nivolumab and pembrolizumab are clearly the two most studied PD-1 inhibitors, and vary in their developers' approaches to preferred combination trials. Over a third of these trials now involve combination regimens, with the IO-IO combination emerging as slightly more prevalent.



PD-1/PD-L1 Biomarkers - Opportunity for Competitive Differentiation

This bubble chart shows trials for NSCLC by primary drug and biomarkers. The timeline and table below show trials for a selected biomarker, KRAS.

The timeline shows timing along with trial phase and status. Looking at atezolizumab and avelumab in the trial timeline, there are signs of KRAS as a strategic focus: a broader trial followed by a more focused trial.



Citeline TrialTrove: PD-1/PD-L1 KRAS Trials

	Trial Title	Primary Drugs - PD1	Primary Drugs	Trial Phase	Trial Status	Target Accrual	Start Date	Primary Completion Date	Trial Tags
1	A Phase III, Open-Label, Multicenter, Randomized Study to Investigate the Efficacy and Safety of Atezolizumab (Anti-PD-L1 Antibody) Compared With Docetaxel in Patients With Non-Small Cell Lung Cancer After Failure With Platinum Containing Chemotherapy	atezolizumab	atezolizumab	III	Completed	1100	2014-03-11 (Actual)	2016-06-22 (Actual)	Expanded Indication PGX - Patient Preselection/Stratification
2	A Phase Ib Study of the Safety and Pharmacology of Atezolizumab Administered With Cobimetinib in Patients With Locally Advanced or Metastatic Solid Tumors	atezolizumab	cobimetinib (oral tablet) atezolizumab	I	Closed	152	2013-12-27 (Actual)	2019-09-01 (Anticipated)	Biomarker/Efficacy IO/Targeted Combination PGX - Patient Preselection/Stratification
3	A Phase Ib/II Study To Evaluate Safety And Clinical Activity Of Avelumab In Combination With Binimetinib With Or Without Talazoparib In Patients With Locally Advanced Or Metastatic Ras-mutant Solid Tumors	avelumab	binimetinib talazoparib avelumab	I/II	Open	127	2018-08-15 (Actual)	2022-05-01 (Anticipated)	Biomarker/Efficacy IO/Targeted Combination PGX - Biomarker Identification/Evaluation PGX - Patient Preselection/Stratification
4	A Phase I, Open-label, Multiple-ascending Dose Trial to Investigate the Safety, Tolerability, Pharmacokinetics, Biological and Clinical Activity of Avelumab (MSB0010718C) in Subjects With Metastatic or Locally Advanced Solid Tumors and Expansion to Selected Indications	avelumab	avelumab	I	Closed	1756	2013-01-31 (Actual)	2019-10-31 (Anticipated)	Biomarker/Efficacy Expanded Indication PGX - Patient Preselection/Stratification
5	Phase II Study of SHR-1210(Anti-PD-1 Antibody) Combination With Apatinib Versus Pemetrexed and Carboplatin in Subjects With KRAS Mutant Stage IV Non-squamous Non-small Cell Lung Cancer	camrelizumab	apatinib camrelizumab	II	Planned	230	2019-02-01 (Anticipated)	2020-04-01 (Anticipated)	IO/Targeted Combination PGX - Patient Preselection/Stratification

The table provides further details, revealing that the atezolizumab trials focus on different segments and combinations, while the avelumab trials suggest a strategic focus on KRAS.

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Conclusions

Drug pipeline and clinical trials data combined with analysis and visualization tools facilitate better strategic decisions for companies operating in the IO space and beyond. PD-1 developers can use these insights to maintain a competitive and differentiated development program, while smaller companies can find the optimum partner for their combination strategy.

By beginning our analysis of the target landscape at the drug level, we identified potential opportunities in a landscape presumed to be dominated by a few high profile drugs. Opportunity lies with indications where our analysis shows development only in early phases, rather than the "me-too" approach. The tools also support detailed review of the competitive landscape for these opportunities.

Visualizations built from clinical trial data reveal additional opportunities in this competitive space. We identified potential partners by visualizing trials by drug and combination. And, we identified a key biomarker by starting with a broad visualization and using a timeline and table to focus on competitors' development strategy.

The broad to narrow data-centric approach employed here should be equally applicable to other indications and therapeutic areas. Starting with the full landscape and analyzing both drug and clinical trials intelligence allows identification of opportunities that could be missed with a narrow focus on a few known competitor companies or drugs.

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