27TH ANNUAL CANCER PROGRESS KEY CONCLUSIONS & RECOMMENDATIONS

On March 8th-9th 2016, Defined Health convened the 27th annual Cancer Progress meeting in New York City. Since 1985, Cancer Progress has served as a unique forum for an insightful and frank discussion about the scientific progress being made in oncology from the perspectives of clinical, regulatory, commercial, payer, patient advocacy, and investor stakeholders. As a companion piece to the meeting (or a primer for those who were unable to attend), the following summarizes some key takeaways and their implications for those looking to establish or maintain relevance in this fast-paced competitive landscape. The section entitled *Demonstrating PoR Amid the IO Frenzy* discusses the current high-intensity excitement surrounding immuno-oncology, how we got here, and what it will take for biotechs to build and showcase their unique value proposition amongst so much clamor. *Closed vs. Open-Sourced Models* speaks to the evolution and implications of two overarching BD strategies being taken by Pharma and public entities looking to play a role in the curation of emerging IO regimens. *How Much is a Human Life Worth?* asks a question that draws wildly divergent answers and addresses the nice problem of how to pay for real innovation after decades of incrementalism. Finally, *You Say Myeloma I Say Melanoma* discusses two seemingly different cancer types that nonetheless share unexpected and instructive similarities.

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unconventional insight

DEMONSTRATING PoR AMID THE IO FRENZY

Immuno-Oncology (IO) has taken the world of cancer therapeutics by storm. Even a whiff of the immune system is enough to attract partnering interest to fledgling oncology platforms, be it in the hands of Biotech newcos or even academia. When the dust has settled, however, proven concepts will quietly fade unless their relevance has been demonstrated early on.

This fervor, which is completely unprecedented in oncology (or any other therapeutic areas for that matter) is predicated on a hope that was first glimpsed with the "tail" of Yervoy's Kaplan Meier curve in late-stage melanoma (Figure 1), and subsequently bolstered by those of Opdivo, Keytruda and, most recently, Opdivo + Yervoy. If the combination of two checkpoint inhibitors can increase the proportion of metastatic patients still alive after two years, the layering of additional IO modalities (vaccines, costims, cytokines, cell therapy) and more "traditional" therapeutic approaches (chemo, radiation, TKIs, mAbs) might be able to widen the margins still further. In other words, there is hope that durable remissions may ultimately be achievable across different cancers and lines of therapy as we learn how to navigate the path towards tumor eradication and long-term immune surveillance.

Walking that path involves the right monitoring and sequencing/combination strategies. Unlike genetic mutations which seem to be relatively static over time (though of course subject to selective pressure such as that imposed by targeted therapy), the presence or absence of

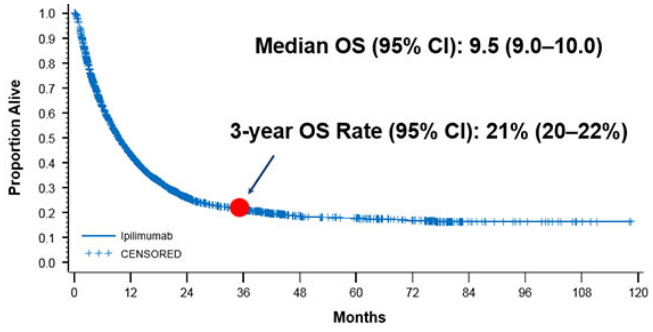

Figure 1: Long-Term Follow-Up of Melanoma Patients Treated With Yervoy
(Source: Hodi, ECCO 2014)

Jeff Bockman, PhD
Vice President
Defined Health

"We have to get out of the box and think of other ways to approach dealing with cancer. The more tangible one that we have evidence of now is of course immuno-therapy because If you're going to deal with a foe that is heterogeneous and plastic, what better way to do that than the immune system which has its own tremendous diversity and plasticity."

immune correlates (TILs, PDL1, ICOS) which might confer sensitivity to an IO approach are far more dynamic. By paying careful attention to such markers and their reaction to different perturbations, one can track the conversion of an otherwise IO-resistant "cold" tumor into one that is IO-sensitive or "hot". Furthermore, there are certain molecular characteristics (mutational and/or neoepitope burden) which seem poised to predict which tumors are most likely to respond to IO, regardless of their tissue of origin. KOLs say we're only beginning to glimpse the true potential of IO, an approach that will ultimately be poised to address many of the more challenging cancer patient populations.

Not surprisingly, the money has followed the science (and frighteningly, there is now science following the money); the US is emerging from the most thunderous biotech bull run in history. As a result, there is currently a bolus of young companies awash in money and many tech transfer officers pounding the pavement. While the share price for the vast majority of companies that have issued an IPO since 2013 are trading below their initial list price, the raises have been done and the money is being put to work. Despite the correction that followed the recent boom, the fact remains that there is a great deal of science that is currently being supported and translated.

But is there sufficient demand to support all of that amazing science? Partnering deals are being reported almost daily, many with eye-popping

upfront payments from Pharmas looking to gain access to early-stage programs, and the proportion of approved oncology drugs tracing its roots to ex-Pharma sources is steadily increasing (Figure 2). Still, for every small player that signs a marquee deal, there are many who struggle to reach first base. In this buyer's market, the need to go beyond Proof of Concept to demonstrate Proof of Relevance or PoR (a term coined by Defined Health's Ed Saltzman), is more important than ever.

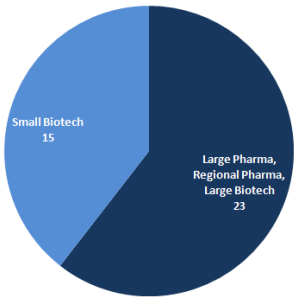

Figure 2: 40% of Approved Oncology Drugs (2013-5) Originated in Small Biotechs
(Source: Adis R&D Insight, EvaluatePharma)

How, then, is PoR achieved within this rapidly evolving competitive landscape? How can a company not only close a deal, but perhaps even drive a bidding war over its asset? A lot will depend on luck, of course: being in the right place at the right time. But optimal positioning doesn't happen in a vacuum. Oncology, perhaps more than any other therapeutic area, is highly fluid with respect to how and where individual assets can be purposed (i.e., within and across cancer types). This phenomenon is becoming all the more apparent as the pendulum swings toward immunotherapies that could, in theory, work in almost any cancer patient provided that an immune response can be properly mobilized. With the first wave of IO (namely, immune checkpoint inhibitors) breaking all around us (Figure 3), prescient biotechs are now looking to leverage next generation approaches (including new takes on old approaches such as therapeutic vaccines) that are able to capitalize on the fluidity of oncology and excitement surrounding IO combination strategies.

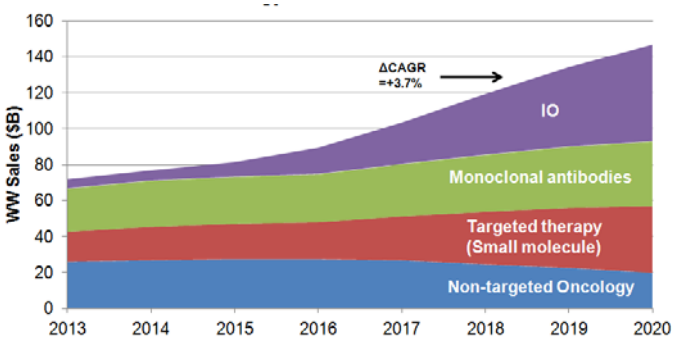

Figure 3: Growth of WW Oncology Product Revenues Largely Driven By 1st-Wave IO Assets
(Source: EvaluatePharma)

Cancer Progress featured a number of companies advancing some of these approaches in back-to-back IO-focused panels chaired by Defined Health's Jeff Bockman. Data emerging from Heat Biologics, for example, suggests that activity of its vaccine is inversely correlated with antitumor immunity at baseline, a potentially powerful complement to checkpoint inhibitors and other IO modalities currently exhibiting the opposite trend. NexImmune is developing artificial antigen-presenting cells (aAPCs) that can be adorned with a suite of surface markers and thereby introduce a more direct approach to antigen-mediated immune recognition and stimulation. NanoString is focusing on the importance of global and dynamic biomarker analyses as a means to predict and adapt IO-based therapeutic decisions.

But what about those companies that are swimming parallel to the shore? Several small biotechs were represented by panelists in a session at Cancer Progress entitled "From Novel Science to Clinical Development: Stories from Small Biotechs", each of which helped shed some light on the question of what it takes to demonstrate PoR for approaches that are not directly linked to immune stimulation or derepression. Symphogen, for example, was able to drive a lucrative partnership with Baxalta largely based on its domain expertise in mAb mixtures. This partnership could potentially address some of the growing concerns about pricing control and asset interchangeably that will likely be enforced by payers in an increasingly cost-conscious environment. Glycomimetics is

generating evidence to support the ability of its selectin antagonist to augment the potency of adoptive cell transfer approaches, and thereby carve out its own niche within an increasingly crowded and competitive landscape. And Syndax is generating data that could help make the case for its type 1 HDAC inhibitor, entinostat, as an important component of different immune checkpoint-based regimens.

No matter how much a company wants to believe that its approach is the best, and only one capable of addressing a certain gap in the IO armamentarium, multiple therapeutic modalities are being developed (Figure 4), each of which may well be capable of achieving the desired effect within a given setting. The onus is thus squarely on the shoulders of the individual biotechs to demonstrate Proof of Relevance if they hope to be more than a mere blip in history. As a knowledge-based consulting firm, Defined Health has worked with numerous large and small biopharma clients in order to gain a deeper understanding of how each can best to position themselves within the rapidly evolving competitive IO landscape.

A common theme emerges from all of this: a keen understanding of the competitive landscape, key scientific, clinical, and commercial drivers, and ultimately the rationale necessary to guide the positioning of an asset or platform technology, are all essential components to achieving relevance and dominance within the IO landscape. Without them, it is impossible to effectively communicate how and why your value proposition is differentiated from that of your competition. In the cacophony of the IO era, a resounding voice with a clear message is critical for companies to survive and thrive.

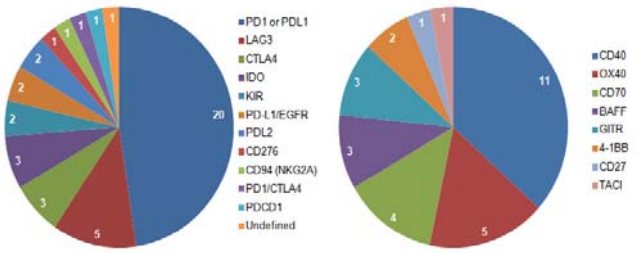

Figure 4: Checkpoint (Left) and Costimulatory (Right) IO Assets in Clinical Development
(Source: Adis R&D Insight, Thomson Reuters Cortellis)

CLOSED- VS. OPEN-SOURCED MODELS

Appropriately given their wherewithal and commercial expertise, certain Large Pharmas are emerging as aggregators of regimen components and have the privilege of deciding which components are most likely to play a role in future treatment algorithms. Going forward, there will be little room for multiple disparate entities to negotiate the value and corresponding price that their individual assets should command in a combination regimen. Large firms will likely make that choice with their wholly owned or licensed components, as they have in HIV and HCV before. However, the question remains unanswered as to whether closed-sourced approaches such as those of BMS, Merck, and Roche will ultimately win out over open-sourced approaches being explored particularly by later entrants like AstraZeneca, as well as public "cancer moonshot" initiatives.

Immune checkpoint inhibitors are highly likely to augment or altogether supplant many of the currently entrenched oncology drugs, which gives the Pharma (like BMS, Merck, and Roche) that owns them the power to dictate terms and shape the strategies of platform-wielding biotechs vying for a seat at the table. With its acquisition of Medarex and aggressive R&D stance, BMS is generally considered the pace- and trend-setter in IO (though mavericks like Novartis and Amgen would likely disagree). In addition to advancing their in-house assets, BMS is judiciously choosing collaborators and potential commercial partners (Bavarian Nordic, Five Prime, Neon) in order to exploit the fruits of external innovation without having to cede much in the way of ownership. Based on the data generated in their combination studies, it is companies like BMS that will ultimately decide which assets are worth licensing or acquiring, and therein play an outsized role in the forging of future treatment algorithms.

By contrast, AstraZeneca, with its relatively

belated decision to throw a hat in the IO ring, has apparently decided that there will be room for more than one dominant force in the market. AZ has ostensibly opened its doors to potential collaboration in an effort to establish and build upon its beachhead in the IO marketplace, which will ultimately be necessary to defend the decision of its CEO and shareholders to thwart off a hostile takeover bid from Pfizer (which notably, and perhaps prematurely, hived off its CTLA4 inhibitor tremelimumab to AZ's MedImmune unit). The key question is whether the open-sourcing model adopted by AZ (exemplified in its willingness to collaborate) will ultimately allow it to effectively compete with the controlled closed-source approach being taken by BMS and others. The former may well benefit from a much wider (or at least cost-efficient) range of shots on goal, albeit with a much smaller proportion of concomitant returns from such efforts.

Keynote speakers at Cancer Progress illustrated the interplay between closed- and open-sourced paradigms within the evolving oncology therapeutic landscape. Peter Kolchinsky, founder and Managing Director of RA Capital Management, discussed how he and his team base their investments on the positioning of assets in the TechAtlas, a nuanced and yet distilled mapping of assets owned by different entities within the competitive landscape. The oncology region of this map embraces the notion of combination regimens, and identifies those entities best positioned to address extant gaps as investment targets. While efficacy and safety will continue to be key metrics upon which a therapeutic is assessed, issues such as cost, convenience, and tolerability may start to have a real impact over time. An allogeneic cell therapy is more convenient (and hence, more attractive) than an autologous one, and safety/tolerability will be a key consideration in a future where oncology providers and payers have the luxury of being picky about such parameters. Patrick Soon-Shiong, the founder of Abraxis and now the burgeoning NantWorks, also endorsed the aggregation of different modalities as a means to finally be able to properly manage cancer patients in his Day 2 keynote lecture. It's worth noting that his holdings are both far-ranging and potentially comprehensive, focusing on cell-based and more traditional therapeutic approaches, diagnostics, cloud-based health records, mobile apps, and more.

While his companies collectively represent his ambitious attempt to own the cancer care continuum within a single network, Dr. Soon-Shiong also spoke of his leadership role in the Cancer Moonshot program recently announced by President Obama and spearheaded by Vice President Biden, an initiative that will be open-sourced in its embrace of big data, precision medicine, and collaboration above all. Dr. Kolchinsky likewise spoke about his role in the Cancer Moonshot program. His group at RA was tapped by Mr. Biden to craft an adaptive trial design (MICAT) to select the most deserving assets that should be included in combination regimens ultimately advancing to the clinic. And nonprofit patient groups like MMRF and LLS (both represented by panelists at Cancer Progress) are supporting efforts to identify the right treatment for the right patient, regardless of which company is developing it.

Given that an anti-PD1 or PDL1 mAb will likely serve as the backbone for many of the future treatment regimens, the threat of a company like AZ that has embraced open-sourcing may help bring BMS or Merck to the table as participants in such collaborative approaches. Thus, while many are scratching their heads as to the rationale behind developing a 3rd, 4th, or 5th in class anti-PD1, the presence of such assets will clearly help dictate the shape of things to come, even if the role of each individual entity is far from certain.

HOW MUCH IS A HUMAN LIFE WORTH?

The historical disconnect between value and price in oncology, and questions about economic sustainability in the face of true innovation, were among the many topics discussed by panelists at

the Cancer Progress session "Parsing the Data, Vetting the Value", moderated by Ed Saltzman of Defined Health. The pharmaceutical industry is truly unique with regard to the level of disconnect between consumer pressure and cost of consumables. Consumers (patients) are only marginally involved in the choice of or payment for products, which are largely dictated by physicians and payers, respectively. Whereas price tags in other therapy areas, the majority of which are comprised of chronic and/or non-life threatening diseases, have been held in check to some extent, oncology had been one of the last bastions of premium pricing in the US.

One question that has repeatedly dogged oncology drug makers is the correlation between value and price. In an industry that has garnered outsized returns for incremental benefits, the prospect of capturing a proportionate ROI for actual cures in a sustainable and acceptable manner presents a daunting challenge. One conference attendee went so far as to ask panelists how much a human life is worth. European payers such as NHS have an answer for this: ≤£30k (~$43k) per QALY. In the US, drug developers have drawn criticism for routinely charging >$100k annually per patient for drugs which provide only incremental improvements in outcomes. What does this mean for those investing hundreds of millions with the hope of inflecting value and, ultimately, reaching the market with their anticancer drug candidate? Further, what is the value and price potential for emerging immunotherapies (either alone or in combination), which may offer the prospect of a cure rather than mere incremental gains? These are tough questions to ask (let alone answer), but one thing remains clear: industry must do a better job of communicating its value proposition in order to maintain sustainability.

Drugs are priced for the initial indication in which they're approved, which is almost always in pretreated (and hence profoundly drug-resistant) patient settings. US drug prices have historically increased at a rate of ~5% per year. And yet, there is no bump in price for a drug if and when it

Ed Saltzman
President
Defined Health

"For years, I mean it was a terrible thing to say, but people used to attend this meeting and we used to say, 'Isn't it [the title, Cancer Progress] an oxymoron?' It's far from an oxymoron anymore. We are making really exciting progress and the excitement, you can feel it. It's palpable. You can see it and most importantly it's about patients and patients are doing better. That's great. But economically, we have some real challenges to make this work."

expands upward in the treatment algorithm, despite the fact that earlier intervention should be worth more to payers than salvage therapy. In one of the more extreme examples, Celgene's Revlimid appears poised to expand into pre-symptomatic multiple myeloma based on evidence that it can prevent transition to active disease, an application which would offset billions of dollars in downstream costs (more on this later). One cannot argue with the fact that the budgetary impact to payers and bottom line for drug makers increases as a drug moves into earlier lines of therapy. Furthermore, US payers are particularly incentivized to control (or eliminate altogether) unit pricing since patients tend to migrate from plan to plan over time. Regardless, while payers and other stakeholders tend to disparage what they regard as hefty price tags for drugs that offer incremental gains in advanced disease settings, one could argue that industry is in fact justified in capturing returns given the potential for long-term societal benefit from branded drugs and their generic offspring. Either way, mechanisms must be put into place that more closely connect value and price or, at the very least, facilitate communication about the rationale behind their perceived disconnect.

Interestingly, there appears to be little correlation between the resources that go into making a drug

and the price set for that drug. PhRMA and various Pharma companies routinely cite the lengthy timeline and >$1B in R&D costs for a single drug as justification for premium pricing. On the other hand, Merck's Keytruda was approved in record time (Figure 5) without any concomitant discount to its list price.

Figure 5: Keytruda Development Timeline Vs. Orphan and Non-Orphan Oncology Benchmarks

(Source: novasecta.com)

Peter Bach, MSKCC health economist and a panelist at Cancer Progress, introduced the metaphor of oncology drug pricing in the US as a buffet, with the pricing of every new cancer drug as being the equivalent of stuffing one's plate or running back to load back up before the all-you-can-eat portion closes forever. Interestingly, while Cancer Progress was in session, CMS announced that it would be initiating a series of pilot programs, including risk-sharing agreements, reference pricing, and indication-based pricing, all with the ultimate aim of reducing "net Medicare spending, without limiting coverage or benefits, while maintaining or improving patient care." While the ultimate fate of such programs is unclear (lobbying organizations such as PhRMA and BIO have been mounting a tremendous campaign to counter them), CMS and other payers are nonetheless clearly looking to incent physicians to prescribe drugs based on their effectiveness rather than cost. Perhaps we're starting to hear rumblings of last call at the buffet.

YOU SAY MYELOMA, I SAY MELANOMA

"I can't tell you how many times I've had someone confuse myeloma with my field", quipped MSKCC oncologist and Cancer Progress melanoma session chair Paul Chapman when asked by an audience member about the dizzying progress that has been made in "myeloma…I mean melanoma". Aside from similarities in phonetics, multiple myeloma and advanced melanoma share another interesting trait: until recently, a diagnosis with either had conferred a dismal prognosis, and each now serves as the poster child for clinical and regulatory success in liquid and solid tumor malignancies, respectively, albeit for very different reasons.

Each year our meeting organizers choose two cancers to build panels around, and this year the choice of scheduling back-to-back sessions in melanoma and myeloma on day 1 of Cancer Progress was indeed an interesting one. Not surprisingly given the recent successes, both markets are characterized as having intensely competitive pipelines, so much so that our clients at Defined Health that are looking to better understand optimal positioning (see www.definedhealth.com for more details) are often reluctant to regard either of these indications as viable options for their development-stage assets or platforms. But success begets success. And while we tend to share our clients' reluctance in many cases, opportunities still exist for certain platforms or assets, assuming there is a thorough understanding of the value proposition and ability to address extant unmet needs.

Defined Health's Mike Rice chaired the session on multiple myeloma at Cancer Progress and discussed how 2015 was a banner year for therapy approvals in this disease, with 3 novel agents having received the FDA's blessing in the month of November alone. Median 5-year survival has doubled in the last 3 decades and is now approaching 50%, owing largely to the availability of new therapeutic options such as the IMiDs (Thalomid, Revlimid, Pomylast), proteasome inhibitors (Velcade, Kyprolis, and Ninlaro), and now monoclonal antibodies (Darzalex, Empliciti), each of which had to earn their stripes in heavily pretreated patients. With a median age of diagnosis at 69, perhaps the disease can be kept at bay long enough for

patients to die of old age. And not incidentally, converting a once deadly disease into a chronic disorder that patients can live with has important bottom-line ramifications (Figure 6).

2020 Top 15 Cancer Drugs ($70B)				
Product	Company	Class	2020 Revenue	Patent Expiry
Revlimid	Celgene	IMiD	$10,183	Mar 2022
Opdivo	BMS	PD-1 MAb	$9,276	Dec 2030
Avastin	Roche	VEGF MAb	$6,514	Jul 2019
Imbruvica	Janssen, AbbVie	BTK Inhibitor	$5,877	Nov 2027
Herceptin	Roche	Her2 MAb	$5,805	Jun 2019
Xtandi	Astellas Pharma	Other cytostatics	$5,198	Aug 2027
Rituxan	Roche	CD20 MAb	$5,190	Dec 2018
Keytruda	Merck & Co	PD-1 MAb	$4,311	May 2029
Perjeta	Roche	Her2 MAb	$3,969	Jun 2025
Ibrance	Pfizer	CDK 4/6 Inhibitor	$3,252	Jan 2023
Atezolizumab	Roche	PD-L1 MAb	$2,529	-
Tasigna	Novartis	Abl/c-Kit Inhibitor	$2,378	Jul 2023
Pomalyst	Celgene	IMiD	$2,130	Jun 2025
Kyprolis	Amgen	Proteasome Inhibitor	$1,960	Jun 2026
Jakafi	Incyte	Other cytostatics	$1,868	Dec 2027

Figure 6: MM Will Yield 3 of the Top 15 Oncology Blockbusters in 2020
(Source: EvaluatePharma)

And yet, there is still a big elephant in the room: myeloma remains an incurable disease. Despite dramatic improvements in survival, patients would clearly rather live without the overhang of their persistent diagnosis. And US payers, who had until recently held little sway in oncology, are playing an increasingly influential role with the help of PBM- and CMS-driven initiatives to address mounting financial toxicity. Many believe the application of molecular-guided patient stratification, implementation of minimal residual disease (MRD) as a surrogate endpoint, and expansion of immunotherapies (checkpoint inhibitors, CARTs) into the treatment algorithm, all of which are underway, will be necessary to achieve true cures. What's more, mounting evidence suggests that treatment of pre-symptomatic "smoldering" myeloma patients (e.g., with Revlimid) can delay or even prevent progression to active disease. One could start to envision a future with increased emphasis on early detection and prevention that ultimately mitigates or, in certain cases obviates altogether, the need for aggressive therapy regimens to address symptomatic disease. On the surface, layering a development-stage asset onto 3- and 4 -drug regimens may not seem like an optimal path

Michael C. Rice, MS MBA
Senior Consultant
Defined Health

"Myeloma is a relatively small indication, a relatively rare cancer compared to many of the solid tumors and heme malignancies, and yet it has grown to be one of the largest oncology markets. So, what are the characteristics of myeloma that have made it such an attractive market opportunity? Not only is it the largest market, it also has three of the top oncology drugs and one of the all-time largest selling (at least this projection is to 2020) pharmaceutical products, Revlimid (lenalidomide)."

to market. However, matching targeted therapies with specific molecular subgroups or developing curative therapies that eliminate the need for cumbersome and pricey approaches represent viable positioning strategies in what many regard as an impenetrable market.

As with myeloma, the advent of novel therapies has truly altered the prognosis for patients diagnosed with advanced, metastatic, or recurrent melanoma. Since 2011, seven new drugs have been FDA approved for the treatment of melanoma, including four immunotherapies and three targeted therapies. The checkpoint inhibitors (Yervoy, Keytruda, Opdivo, Yervoy + Opdivo) serve to take the "brakes off" the immune system, while Imlygic is the first oncolytic virus to reach the market. Targeted therapies (Zelboraf, Tafinlar, Mekinist) target common genetic mutations, such as the BRAF V600 mutation, that are found in a subset of melanoma patients. While the targeted therapies serve as validation of the precision medicine paradigm, the ability of immunotherapies to achieve durable remissions for at least a subset of patients (Figure 1) has been the real success story in melanoma, and in oncology at large.

Despite these big wins in melanoma, opportunities still exist particularly for those

assets capable of addressing the >50% of patients who remain resistant to extant options. Novel combinations (e.g. such as those leveraging the positive attributes of an approved oncolytic modality like Amgen's Imlygic), along with completely novel approaches (e.g. Atreca's elite responders, Neon's neoantigen vaccines) may help address those patients that fail to achieve durable responses with approved IO and/or TKI therapy regimens. As there is likely to be more than one means to this end (as discussed previously), those companies that proceed rapidly but intelligently will reap any rewards that remain. Like the tumors it's being enlisted to eradicate, the immune system is itself highly dynamic and will hopefully prove amenable to mobilization even against the most intransigent cases. The winners will be the ones that possess the assets capable of such a feat, the evidence (clinical and, yes, preclinical) necessary to support a compelling narrative, and the timing and placement to achieve relevance amidst the cornucopia of pipeline agents and competitors. In other words, PoR will continue to reign supreme.

About the Authors

Joel S. Sandler, PhD
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As a Senior Consultant with Defined Health, Joel provides insight to various life sciences industry clientele (biotechnology/pharmaceutical) on fundamental issues in drug development and partnering based on a comprehensive analysis of the key scientific, clinical, regulatory, and commercial questions relevant to the client's particular situation. In previous industry roles, Joel was instrumental in the scouting and evaluation of licensing and partnering opportunities for various oncology assets. Prior to his BD&L activities, Joel spent ten years focused on the discovery and characterization of bioactive compounds for cancer and infectious disease research at several leading academic institutions. His work has resulted in numerous grants, patent filings, and peer-reviewed publications. He received his BA with honors from Cornell University, a PhD in Organic Chemistry from UCSD, and was a NIH Postdoctoral Fellow at The Rockefeller University.

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Associate Consultant

Rich's work at Defined Health spans the gamut from opportunity assessments to indication prioritization and the evaluation of partnership opportunities. Since joining the firm in 2015, he has contributed to projects in the oncology, cardiovascular, CNS, and autoimmune and inflammatory disease spaces. Rich received his PhD in Molecular Biophysics & Biochemistry from Yale University, where he determined the crystal structures of the helicase and polymerase that bacteria use to copy their genomes. His studies of bacterial DNA replication culminated in 3 peer-reviewed articles co-authored with his doctoral thesis adviser. Rich was subsequently awarded an NIH postdoctoral fellowship at The Rockefeller University to use X-ray crystallography to study the nuclear pore complex to determine how it opens and closes to allow cellular traffic to move between the nucleus and the cytoplasm. Rich is a founding member of the Entrepreneurial Scientist Advisory Panel, which acted as a liaison between academic scientists and commercial opportunities in New York City as part of the Partnership for New York City.

Leandra Gerena, MS
Senior Research Analyst

Leandra joined Defined Health in 2013 and works on a variety of projects including opportunity assessments, therapeutic area growth strategy identification, and evaluation of partnering opportunities and asset valuations. Her experience ranges across the therapeutic landscape including oncology, CNS, and cardiovascular. She graduated with a BS in Chemical Engineering from the Fu Foundation School of Engineering and Applied Science of Columbia University in 2012 and received a Masters Degree in Biotechnology from the Universidad Autónoma de Madrid.

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27th Annual Cancer Progress

Since 1985, Cancer Progress is the only oncology conference that invites a discussion of scientific progress within the context of development, regulatory, clinical, commercial, and investment perspectives in two days of interactive dialogue. Pivotal topics, frank discussions, vigorous debate, lively audience participation and generous networking throughout the meeting during breaks, luncheons, reception, and dinner combine to make it a highly impactful conference. At this year's Cancer Progress, the current IO renaissance was presented in the light of struggling to prove relevance and how biotechs and Pharma are aiming to do that using both closed and open source models. The complex relationship between these novel therapies and their economic feasibility was likened to a buffet with companies loading up their plates before the sound of the closing bell. Finally, myeloma and melanoma were both featured as shining examples of progress that has been made in cancer treatment.

Keynote Speakers

Peter Kolchinsky, PhD
Managing Partner and Portfolio Manager
RA Capital Management

Patrick Soon-Shiong, MD FRCS (C) FACS
Executive Chairman and Founder
NantHealth

Speakers

Rafael Amado, MD, Adaptimmune
Kenneth C. Anderson, MD, Dana-Farber Cancer Institute
Robert Ang, MD, MBA, Neon Therapeutics
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DEFINED HEALTH: UNCONVENTIONAL INSIGHT

For more than 25 years, Defined Health has been a critical resource in driving valuable partnering deals for clients. We introduced the concept of Proof of Relevance (PoR) as a value driver in early stage partnering and our clients rely on our services for everything from getting a high credible and objective view on program value to optimizing indication selection and development strategy so that it aligns with near term and longer term partnering objectives.

Our clients are a mix of pharma, biotech, specialty pharma companies and the investment community. Our expertise helps companies of all sizes make crucial and often tough decisions – identifying the potential and the challenges for drugs in development, and advising on prioritization of development programs for platform technologies with a clear focus on the value inflection that can be driven by achievement of PoR.

Oncology is our leading therapeutic area, comprising nearly 1/3 of all projects, for clients ranging from small biotechs to big pharma. We have extensive experience across all MOAs and approaches in cancer, across all major and niche solid and liquid tumors. We have worked across both small and large molecule programs (from peptides to monoclonals to RNAi), as well as the full range of immunotherapies including autologous and off-the-shelf platforms, plus other cell, viral and gene therapy approaches.

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