

FOREWORD

Clinical development strategy



JON WIGGINTON MD currently serves as portfolio Chief Medical Officer, Cullinan Oncology and Advisor at MPM Capital. Dr. Wigginton most recently served as the Chief Medical Officer at MacroGenics, where he led the company's evolution of a fully-integrated, clinical-stage cancer immunotherapy organization. Previously, he served as the Therapeutic Area Head, Immuno-Oncology, Early Clinical Research at Bristol-Myers Squibb. There, he oversaw early clinical development of the BMS Immuno-Oncology portfolio, served in governance role for discovery research, and co-led the BMS International Immuno-Oncology Network (II-ON). These efforts included several studies defining proof-of concept for both anti-PD-1 and anti-PD-L1 antibodies in patients with a variety of

solid tumors, and for the anti-PD-1/anti-CTLA-4 combination in patients with melanoma. During his academic career, Dr. Wigginton served as Head of the Investigational Biologics Section, Center for Cancer Research, NCI, where he led an integrated basic, translational and clinical research effort focused on combination immunotherapy in preclinical models and early clinical studies. Dr. Wigginton also served previously as president of the Society for Immunotherapy of Cancer (SITC). Dr. Wigginton received his M.D. and B.S. in Biology, with distinction, from the University of Michigan.

Immuno-Oncology Insights 2020; 1(1), 83–85

DOI: 10.18609/ioi.2020.009

Hopefully, you will find value in this inaugural issue of *Immuno-Oncology Insights*, a new journal dedicated to the rapidly growing field of immuno-oncology. Launched by the team at BioInsights, *I-O Insights* has been initiated to provide a unique venue for dialogue across the full spectrum of stakeholders in the field of immuno-oncology, including academia, government, scientific organizations, industry and the financial community, as we all work together to advance the field for our patients. It goes without saying that the field is moving rapidly, and it is both highly visible and complex. Innovation and highly impactful decision-making for the field occurs not only in academia, but also extensively across each of these key stakeholder groups. The intention of the journal will be to stimulate dialogue across a broad range of topics, and across the full spectrum of stakeholders, a unique model compared to other publications. The journal will use a mix of original review articles, opinion pieces, interviews, expert roundtables and podcasts to promote dialogue between these communities. Original publication of peer-reviewed primary research findings will not be included in these issues – rather, original published data will be analyzed and placed in a broader strategic context by contributors.

Consistent with this emphasis, the inaugural issue provides input from a broad range of individuals spanning the stakeholder groups mentioned above. From the Icahn School of Medicine, Tomohiro Enokida, Caitlin Carr and Nina Bhardwaj, internationally recognized expert in dendritic cell biology, provide perspectives regarding optimization of the clinical development of immunotherapy combinations. One of the challenges for cancer immunotherapy is that despite the well-justified excitement, the majority of patients still do not respond to treatment. Much work remains to be done in understanding the mechanistic explanations for this resistance, and how it can be overcome. Seema Gupta and Samir Khleif from the Georgetown University School of Medicine provide commentary regarding these mechanisms,

and introduce the concept of “iatrogenic resistance”, where the efficacy of a combination may be undermined based on the induction of un-addressed compensatory mechanisms and/or sub-optimal sequencing and scheduling of the individual components of the regimen.

From the biotech space, Fernanda Arnaldez (MacroGenics) and Jon Wigginton (Cullinan Oncology) provide a perspective piece on where we have come from, where we stand, and what the future may hold as we navigate various challenges to advance the field. From the pharma sector, Roy Baynes, Chief Medical Officer at Merck, discusses the experience with clinical development of checkpoint inhibitors to date, and future opportunities for the field. Coming from a discovery organization, Michael Quigley, the new head of research at Gilead, emphasizes the critical importance of staying focused on the science and leveraging basic biology to optimize our chances of success. Scientific organizations like the Society of Immunotherapy of Cancer (SITC), the Cancer Research Institute (CRI) and the Parker Institute for Cancer Immunotherapy (PICI) are important forces in facilitating progress in the field. Jill O'Donnell-Tormey, influential CEO of the CRI, reflects on the history and role of the CRI, including their Clinical Accelerator and CRI Venture Fund initiatives. Offering broad perspectives from the financial community, leading biotech and immuno-oncology analyst Daina Graybosch (SVB Leerink) comments on challenges and opportunities for combination immunotherapy.

Finally, in a roundtable discussion, Jason Luke (University of Pittsburgh Medical Center), Justin Fairchild (Parker Institute for Cancer Immunotherapy), Reni Benjamin (JMP Securities) and consultant Robin Taylor have an energetic discussion regarding lessons learned in developing combination therapies. They suggest that identification of agents like anti-PD-1/anti-PD-L1 antibodies, that are broadly active across many tumors, is likely a once-in-a-generation event in clinical development. To sustain progress, they stress the

importance of cooperation and collaboration between companies, developing a more systematic approach to maximize learnings from patient samples in a transparent manner, and emphasize the critical theme of tying the science closely to the clinical trial, even if it means focusing trials on smaller populations to optimize the chances of success

I am sure that the BioInsights team will look forward to your feedback, as well as your

future contributions, as *I-O Insights* is mobilized over the coming months. Let's see where this goes.

AFFILIATION

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AUTHORSHIP & CONFLICT OF INTEREST

Contributions: All named authors take responsibility for the integrity of the work as a whole, and have given their approval for this version to be published.

Acknowledgements: None.

Disclosure and potential conflicts of interest: Wigginton JM is a prior employee and shareholder of MacroGenics Inc. He is a current employee and shareholder, Cullinan Oncology. Wigginton JM has several patents or patents pending related to targeting PD-I, PD-LI and combination immunotherapy regimens. All are assigned to prior employees.

Funding declaration: Wigginton JM a paid consultant for Western Oncolytics, Gossamer Bio, Herbour Biomed and Reuge Biotechnologies.

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Article source: Invited.

Revised manuscript received: Oct 5 2020; **Publication date:** Oct 8 2020.