

## In the Era of Immune Checkpoint Inhibitor Therapy, Can We Safely Expand to Patients with Immunodeficiency?

We have read with great interest the recent issue of the *Journal of Immunotherapy and Precision Oncology*, which is edited by Dr. Joud Hajjar. It illuminated the area of cancer immunotherapy in immunosuppressed patients.<sup>[1]</sup> This is a very important matter in the immunotherapy field because these patients are notoriously more susceptible to developing a variety of different cancers, and there is limited advancement in new drug development for them.

In recent years, the treatment of cancer has evolved with our understanding of the immune checkpoint pathway. This effort has paid off by the approval of several new drugs, such as programmed death 1/L1 and cytotoxic T-lymphocyte-associated antigen 4 antibodies. Currently, those agents are available for patients with many types of malignancies including, but not limited to, melanoma, kidney cancer, bladder cancer, lung cancer, and others. Although many patients are receiving immune checkpoint inhibitor (ICI) therapies, we still have limited knowledge regarding the efficacy and safety in cancer patients with an immunosuppressed condition because these individuals were often excluded from the original trials that led to the approval of those agents.

Recently, we and others challenged the exclusion of these “forgotten” patients, and we have been able to obtain real-world data on the efficacy and safety of ICIs in the immunocompromised population.<sup>[2,3]</sup> Some of the recent studies showed that ICIs are both safe and efficacious in HIV-positive patients with various malignancies, including Kaposi sarcoma, non-small cell lung cancer, melanoma, Merkel-cell carcinoma, and Hodgkin’s lymphoma.<sup>[3,4]</sup> Currently, several prospective studies are also examining the use of ICIs in multiple tumor types among patients with HIV infection.

Due to exclusion criteria, cancer patients with HIV infection are underrepresented in cancer clinical trials, including those with ICIs. There is an unmet need for prospective trials with ICIs that are designed for HIV-positive patients to explore the biology and outcome in this population. Furthermore, there is already a body of evidence that support the use of those agents in HIV-infected patients, and these patients should not be excluded from immunotherapy clinical trials. Hajjar is to be commended for highlighting this critical issue.<sup>[1]</sup>

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### Mehmet Asim Bilen<sup>1,2</sup>, Razelle Kurzrock<sup>3</sup>

<sup>1</sup>Department of Hematology and Medical Oncology, School of Medicine, Emory University, Atlanta, GA, USA, <sup>2</sup>Winship Cancer Institute of Emory University, Atlanta, GA, USA, <sup>3</sup>UC San Diego School of Medicine, San Diego, CA, USA

#### Address for correspondence:

Dr. Razelle Kurzrock,  
UC San Diego School of Medicine, San Diego, CA, USA.  
E-mail: [rkurzrock@ucsd.edu](mailto:rkurzrock@ucsd.edu)

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