

**Arie Regev, M.D.**  
**Head, Safety Advisory Hub**  
**Eli Lilly and Company**  
[Regev\\_arie@lilly.com](mailto:Regev_arie@lilly.com)



## **Biosketch**

Dr. Regev received his B.Sc. and M.D. degrees from the Hebrew University in Jerusalem, Israel. He completed residency in Medicine and fellowship in Gastroenterology at Rabin Medical Center and Tel Aviv University, where he continued working as attending physician and Associate Chief of Medicine. He subsequently completed clinical fellowship in Hepatology and Transplant Hepatology at the Division of Hepatology of the University of Miami, and Jackson Memorial Hospital in Miami, Florida. After his fellowship he continued working in the Division of Hepatology as full time faculty and subsequently Associate Professor of Medicine and Director of the Hepatology Fellowship Program until 2007. Dr. Regev has conducted numerous clinical trials in the field of viral hepatitis and liver transplantation. He was the principal investigator of a number of NIH funded clinical trials and has served as principal investigator on several investigator initiated and industry supported clinical trials in the area of viral hepatitis and liver transplantation. He is the author of numerous publications in major medical Journals including *American Journal of Gastroenterology*, *Clinical Gastroenterology and Hepatology*, *Journal of Hepatology*, *Liver Transplantation*, *Gut*, *Transplantation*, *Proceedings in Transplantation*, and *Digestive Diseases and Sciences*. He authored several chapters in major medical textbooks including *Schiff's Diseases of the Liver*, *The Clinician's Guide to Liver Disease*, *Viral Hepatitis*, *Requisites in Gastroenterology* and *Advances in Internal Medicine*. Dr. Regev received Teaching and Research Awards at the University of Miami as well as Tel Aviv University. He served as an active member of the *Training and Clinical Policy Committee* of the American Association for the Study of Liver Diseases. In January 2007 Dr. Regev joined Eli-Lilly in a Hepatology Consulting position and as Chair of the Liver and GI Safety Committee in the Global Patients Safety organization. He is currently an adjunct Associate Professor of Medicine at the Division of Gastroenterology and Hepatology of Indiana University, and he heads the Safety Advisory Hub at Eli Lilly and Company.

## **Abstract: DILI due to immunotherapy targeting immune checkpoints – when and how to treat?**

Cancer therapies targeting immune checkpoints provide significant benefit to patients with advanced malignancies, but are associated with considerable risks, including immune-related DILI. Liver injury related to checkpoints inhibitors may range in severity between mild self-limiting abnormalities in aminotransferases and severe hepatitis which may lead to acute liver failure. Presently there is no reliable method to predict which patients will develop immune-related liver injury, and there is no dependable way to identify those who will develop severe liver injury or liver failure. Furthermore, there is no consensus on which level of liver enzyme abnormality should mandate initiation of treatment or discontinuation of immunotherapy. Although most patients who are treated for liver injury respond to corticosteroid therapy, in some cases additional immunosuppressive agents such as mycophenylate mofetil and antithymocyte globulin have been used with varying results. Approaches to monitoring and therapy of such patients are still evolving, and may require studies of large cross-pharma databases to enable better understanding of the natural history and response to therapy of this potentially lethal complication. This presentation will review the published data and evolving approaches to treatment of immune-related liver injury due to cancer therapy targeting immune checkpoints.