

Official Blog of the American Journal of Kidney Diseases

#SCM16: Vadadustat and Anemia

Posted on April 29, 2016 by *AJKDblog* in *Interview, Meeting Coverage* // 0 Comments



Dr. Volker Haase (VH), from Vanderbilt University in Nashville, Tennessee, discusses his abstract for the National Kidney Foundation's 2016 Spring Clinical Meetings (SCM16), [Vadadustat Maintains Stable Hemoglobin Levels in Dialysis Patients Converting From Erythropoiesis-Stimulating Agent \(ESA\)](http://www.ajkd.org/article/S0272-6386%2816%2900353-X/pdf) (<http://www.ajkd.org/article/S0272-6386%2816%2900353-X/pdf>), with Dr. Kenar Jhaveri, AJKD Blog Editor.

AJKDblog: *Why don't you tell us a little about your research and abstract being presented at the NKF 2016 Spring Meetings?*

VH: Anemia is a common complication for patients with chronic kidney disease (CKD) and management of anemia is a critical element of care. The current standard of care for anemia are injectable preparations of recombinant erythropoiesis-stimulating agents (ESAs) coupled with iron supplementation to stimulate hemoglobin production. However, due to increased safety concerns with injectable ESAs, including substantial hemoglobin (Hb) oscillations and excursions, and increased risk of cardiovascular disease (CVD), there is an increased need for an alternative approaches to anemia therapy. Vadadustat is a promising novel oral agent that stabilizes hypoxia-inducible factor (HIF), which mimics the body's physiologic mechanism for stimulating erythropoiesis and iron metabolism under hypoxic conditions.

In this study, we investigated whether vadadustat can maintain Hb levels in hemodialysis (HD) patients converting from ESAs. Among the three vadadustat doses evaluated, all maintained Hb levels within the targeted range, with only one patient in the 300 mg qd cohort experiencing a single Hb excursion to 13.1 g/dL. The dialysis procedure did not impact the plasma level of vadadustat. Furthermore, repeated dosing of vadadustat over a 16-week period did not result in the accumulation

of vadadustat or its metabolites. Serious adverse events (SAEs) were reported in 13 patients, within the expected range for this dialysis population with multiple comorbidities. None of the SAEs were considered drug-related, and there were no deaths.

AJKDblog: *Does stabilizing HIF increase or decrease risk of cancer in the CKD/ESRD population?*

VH: In addition to Hb oscillations and an increased risk of CVD, use of ESAs has also been associated with increased rates of tumor progression in patients with cancer. Since the HIF pathway regulates multiple physiologic responses to hypoxia, a potential concern of targeting this pathway is the increased production of vascular endothelial growth factor (VEGF), which has been linked to tumor progression and metastasis. Despite these theoretical concerns, we previously showed in our [Phase 2 studies](http://akebia.com/wp-content/themes/akebia/img/media-kit/abstracts-posters-presentations/20151102-Ph2b_Subgroups_Oral_ASN_2015_Final_no-b-u.pdf) (http://akebia.com/wp-content/themes/akebia/img/media-kit/abstracts-posters-presentations/20151102-Ph2b_Subgroups_Oral_ASN_2015_Final_no-b-u.pdf) that treatment with vadadustat does not lead to increased VEGF levels at any dose studied.

AJKDblog: *Where do you and your group go from here?*

VH: Akebia recently initiated the PRO₂TECT program, consisting of two randomized, active-controlled, global Phase 3 studies to test the efficacy and safety of vadadustat in patients with non-dialysis-dependent CKD. INNO₂VATE, a similarly-designed Phase 3 program, will commence in 2016 for patients with anemia who are receiving chronic dialysis.

Disclosure: Editorial support for the preparation of Dr. Haase's interview was provided by Lucid Partners Ltd and funded by Akebia. Dr. Haase serves on the scientific advisory board of Akebia. The opinions expressed within the interview are those of the author.

—

All Spring Clinical Meeting abstracts are available in the [May issue](http://www.ajkd.org/issue/S0272-6386%2815%29X0018-7) (<http://www.ajkd.org/issue/S0272-6386%2815%29X0018-7>) of AJKD.

Check out more [AJKDblog coverage](https://ajkdblog.org/tag/2016-spring-clinical-meetings/) (<https://ajkdblog.org/tag/2016-spring-clinical-meetings/>) of the NKF's 2016 Spring Clinical Meetings (#SCM16 (<https://twitter.com/hashtag/SCM16?src=hash>))!

- 2016 Spring Clinical Meetings
- anemia
- HIF
- Jhaveri
- NKF

This site uses Akismet to reduce spam. [Learn how your comment data is processed.](#)

Archives

Posts by Type

Social Media



RSS - Posts

Links

- [AJKD.org](#)
- [Submit to AJKD](#)
- [National Kidney Foundation](#)
- [Nephrology Blogs](#)

Copyright © 2018 [Blog at WordPress.com.](#)