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Local Evidence: Clinical Implications of Phase 3 Trials and the Therapeutic Value of Vadanem in Korea

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Renal anemia remains a major complication in patients with chronic kidney disease (CKD), particularly in dialysis populations. Hypoxia-inducible factor prolyl hydroxylase inhibitors (HIF-PHIs) have emerged as a novel therapeutic class that stimulates endogenous erythropoiesis while improving iron utilization. Vadadustat (Vadanem®), an oral HIF-PHI available in Korea since April 2026, represents a potential alternative to conventional erythropoiesis-stimulating agents (ESAs). Its clinical value should be interpreted in the context of global phase 3 trials, regional studies, and real-world evidence. In the global phase 3 INNO$_2$VATE trial program, vadadustat demonstrated non-inferiority to darbepoetin alfa in maintaining hemoglobin (Hb) levels in dialysis-dependent CKD patients. Cardiovascular safety outcomes, including major adverse cardiovascular events (MACE), were comparable between groups. Japanese phase 3 studies further supported these findings. In hemodialysis patients, vadadustat maintained Hb within target ranges (10–12 g/dL) over 52 weeks and showed consistent non-inferiority across subgroups. In peritoneal dialysis patients, vadadustat effectively achieved and maintained target Hb levels, with favorable changes in iron-related parameters, including reduced hepcidin and increased total iron-binding capacity. Post-marketing evidence from the VIOLET surveillance study demonstrated sustained Hb improvement and no new safety signals, with adverse event rates consistent with clinical trials. Effectiveness was observed across CKD subgroups, including ESA-naïve and ESA-converted patients. Collectively, these data indicate that vadadustat is a clinically effective and well-tolerated oral alternative to ESAs, with comparable efficacy and cardiovascular safety. Its mechanism may offer additional advantages, including improved iron utilization and avoidance of supraphysiologic

erythropoietin exposure. In Korea, where vadadustat is currently the only available HIF-PHI, its value extends beyond efficacy to reduced treatment burden and alignment with evolving anemia management strategies. We hope that vadadustat will represent a meaningful therapeutic option for CKD-related anemia in Korea, supported by consistent evidence from clinical trials and real-world practice.

Keywords: Renal anemia, Chronic kidney disease, Hypoxia-inducible factor, Vadadustat