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For Immediate Release

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Otsuka submits initial marketing authorization application to the European Medicines Agency for vadadustat for the treatment of adults with anemia associated with chronic kidney disease

Otsuka Pharmaceutical Co., Ltd. announces that Otsuka Pharmaceutical Netherlands B.V. has submitted an initial marketing authorization application to the European Medicines Agency (EMA) for vadadustat, an investigational oral hypoxia-inducible factor prolyl hydroxylase (HIF-PH) inhibitor, for the treatment of anemia associated with chronic kidney disease (CKD) in adults. Vadadustat was developed in Europe under a collaboration and license agreement between Akebia Therapeutics, Inc. and Otsuka Pharmaceutical Co. Ltd.

Anemia is a commonly diagnosed complication among patients suffering with chronic kidney disease, and if left untreated, it may affect patient quality of life.*[1]

In June 2020, Japan's Ministry of Health, Labour and Welfare approved vadadustat, marketed under the trade name Vafseo™, as a treatment for anemia due to CKD in both dialysis-dependent and non-dialysis-dependent adult patients.*[2] Akebia submitted a New Drug Application for the same indication to the U.S. Food and Drug Administration in March 2021.*[3]

About vadadustat

Vadadustat belongs to a class of drugs known as hypoxia-inducible factor prolyl hydroxylase (HIF-PH) inhibitors. HIF-PH inhibitors utilize the body's response to low oxygen, which includes an increase in production of endogenous erythropoietin*[4] (a hormone that stimulates the bone marrow to produce red blood cells*[5]).

About anemia due to Chronic Kidney Disease (CKD)

Anemia is common in patients with CKD and has multiple causes. Healthy kidneys produce erythropoietin (EPO), a hormone that stimulates the bone marrow to produce red blood cells. Diseased kidneys may produce insufficient EPO reducing the production of red blood cells which can contribute to anemia. Other causes include blood loss from hemodialysis and low levels of iron and folic acid. Treatment is partly dependent on the severity of anemia, and for more severe cases can include iron supplements and erythropoiesis-stimulating agents.*[6]

References

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*2. Akebia Therapeutics, Inc. June 2020. Akebia Therapeutics Announces Approval of Vadadustat in Japan for the Treatment of Anemia Due to Chronic Kidney Disease in Dialysis-Dependent and Non-Dialysis Dependent Adult Patients. Available from: https://ir.akebia.com/news-releases/news-release-details/akebia-therapeutics-announces-approval-vadadustat-japan [Last accessed: October 2021].

*3. Akebia Therapeutics, Inc. March 2021. Akebia Submits New Drug Application (NDA) to the FDA for Vadadustat for the Treatment of Anemia Due to Chronic Kidney Disease in Adult Patients on Dialysis and Not on Dialysis. Available from: https://ir.akebia.com/news-releases/news-release-details/akebia-submits-new-drug-application-nda-fda-vadadustat-treatment [Last accessed: October 2021].

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*5. Kidney Care UK. A–Z of kidney health. Available from: https://www.kidneycareuk.org/about-kidney-health/z-kidney-health/ [Last accessed: October 2021].

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