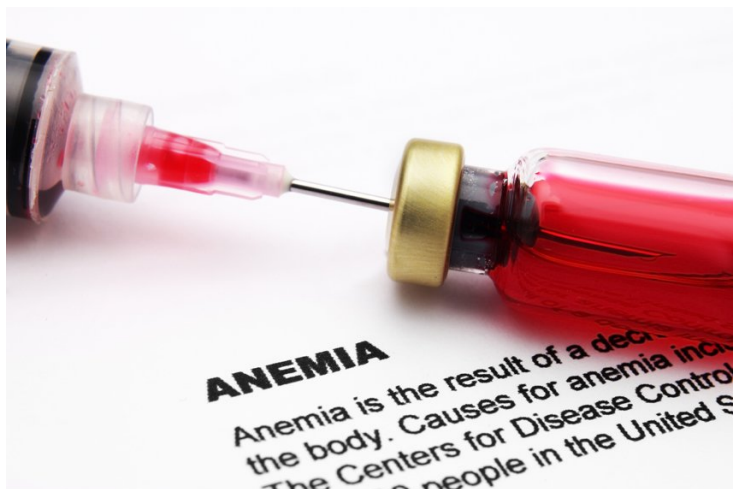


Astellas submits sNDA in Japan for Evrenzo to treat Anemia

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Astellas Pharma Inc. and FibroGen, Inc. has announced the submission of a supplemental New Drug Application (sNDA) to Japan's Ministry of Health, Labour and Welfare to gain marketing approval for Evrenzo® (generic name: roxadustat) for the treatment of anemia associated with chronic kidney disease (CKD) in non-dialysis dependent (NDD) patients. Roxadustat was approved in Japan for the treatment of anemia associated with CKD in dialysis dependent (DD) patients in September 2019 and launched for use in this indication in November 2019.

"The data demonstrates that roxadustat is effective in increasing and maintaining Hb levels within the target range in patients with anemia associated with CKD who are not on dialysis," said Bernhardt G Zeiher, M.D., Chief Medical Officer, Astellas. "This submission is an important next step to bringing roxadustat to even more patients with this condition in Japan, and this is particularly pertinent in the non-dialysis setting where many patients' anemia is currently not treated, or not treated to target."

"We are excited to reach another important milestone for roxadustat and appreciate the joint team's commitment to addressing the significant unmet medical need of patients living with anemia associated with CKD," said K Peony Yu, M.D., Chief Medical Officer, FibroGen.