

Retacrit® (epoetin zeta): effective therapy for renal and chemotherapy-induced anaemia

Extensive phase III clinical studies demonstrate efficacy and good safety profile for Retacrit in select patient populations

Erythropoiesis-stimulating agents (ESAs) are effective for treating patients with chemotherapy-induced anaemia [1] and renal anaemia [2]. Retacrit® (epoetin zeta) has been granted marketing approval by the European Commission for the management of anaemia associated with either chemotherapy (administered subcutaneously) or chronic renal failure (CRF; administered intravenously) [3]. With its extensive safety and efficacy data and a comprehensive post-marketing surveillance plan (see Figure 1), Retacrit offers clinicians and patients access to a proven, cost-effective ESA therapy.

Phase III data: chemotherapy-induced anaemia

An open-label, international, 12-week, multiple-dose, phase III study demonstrated the effectiveness and safety of Retacrit for anaemia in 216 patients with cancer who were undergoing chemotherapy and at risk of transfusion [4]. Retacrit steadily and significantly improved haemoglobin (Hb) levels, while safety and the incidence

of adverse events (AEs) were similar to those seen with other epoetins [5, 6]. Clinically significant thromboembolic events occurred in 4.2% of patients, which is similar to findings from comparable studies of other ESAs [7].

Phase III data: chronic renal failure

Two large-scale, 24-week, randomised, verum-controlled (epoetin alfa), phase III studies [8, 9] demonstrated the efficacy and tolerability of Retacrit in patients with CRF undergoing haemodialysis. Retacrit was therapeutically equivalent to epoetin alfa in correcting low (<9 g/dL) Hb levels in 609 patients [8] and in maintaining stable Hb levels in 313 patients (10.5–12.5 g/dL) [9]; mean Hb levels in either treatment arm in both studies were similar. There were no significant differences between the safety profiles of Retacrit and epoetin alfa; both agents were well tolerated and associated with similar numbers and severity of AEs. A total of 745 patients from these two studies continued treatment with Retacrit for 56–108 additional weeks as part of an open-label, follow-up safety study [10]. Retacrit maintained stable Hb levels throughout this study, with no unexpected AEs. During the course of all

Retacrit provides a well studied and proven alternative ESA therapy [8–10].

The articles ‘Therapeutic effects of epoetin zeta in the treatment of chemotherapy-induced anaemia’ (Tzekova et al. [4]), ‘Comparison of the therapeutic effects of epoetin zeta and epoetin alfa in the maintenance phase of renal anaemia treatment’ (Wizemann et al. [9]) and ‘Comparison of the therapeutic effects of epoetin zeta and epoetin alfa in the correction of renal anaemia’ (Krivoshiev et al. [8]) are available at www.cmjournal.com.

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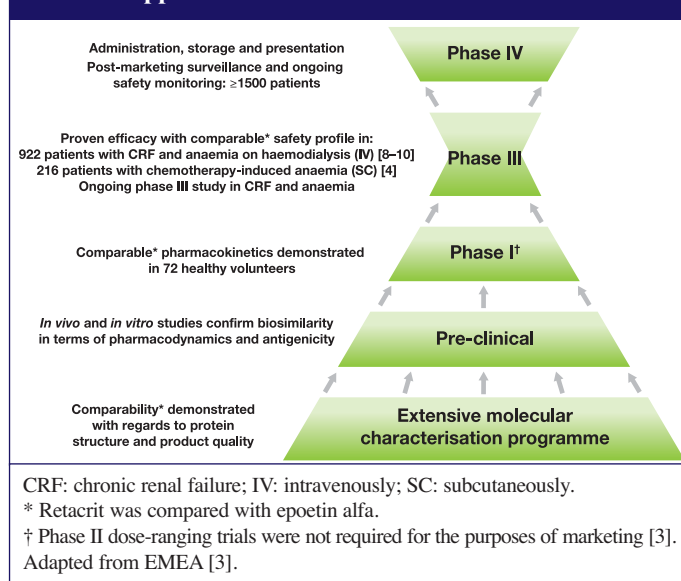
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Figure 1: Clinical and pre-clinical data support marketing approval for Retacrit



phase III studies, no patients developed neutralising or non-neutralising anti-erythropoietin antibodies.

Summary

In extensive phase III clinical studies, Retacrit has demonstrated improved Hb levels in patients undergoing chemotherapy [4] and shown equivalent efficacy and safety to epoetin alfa in correcting and maintaining Hb levels in patients with CRF.

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