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(54) Title: THERAPEUTIC USE OF A RECOMBINANT ERYTHROPOIETIN HAVING HIGH ACTIVITY AND REDUCED SIDE EFFECTS

(57) Abstract: The invention discloses several novel therapeutic properties and methods of treatment using the recombinant erythropoietin prepared by expression from the Apa I restriction fragment of human genomic erythropoietin DNA transformed into baby hamster kidney cells (BHK) according to U.S. Patent No. 5,688,697 to Powell. This recombinant erythropoietin designated herein as Epoetin Omega is shown to possesses several unexpected and superior qualities over other recombinant erythropoietins such as those designated Epoetin Alfa and Beta which are prepared from genomic or cDNA expressed in Chinese Hamster Ovary (CHO) according to U.S. Patent Nos. 4,703,008 and 5,955,422 to Lin. The superior properties of Epoetin Omega include, but are not limited to, a much higher potency, a much more rapid response (*i.e.* no latency), longer effective serum levels, much lower antigenicity in human subjects, therapeutic activity in subjects non-responsive to the other epoetins, fewer adverse side effects such as incidents of thrombosis, reduced nausea, reduced pain at the site of injection, reduction in body pain, and most significantly, the absence of, or reduced risk of, increased blood pressure or hypertension. These novel properties provide for novel therapeutic methods including, treatment of anemia and treatment of conditions other than anemia such as fatigue or vascular pain, treatment in patients adversely effected by hypertension such as patients with heart conditions or at increased risk of thrombosis, treatment in oncology settings with and without chemotherapy or radiation therapy, and treatment with novel dosing regiments that include much lower doses and lower administration frequencies of as few as once per week or less.

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