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(54) Title: PHARMACEUTICAL COMPOSITION FOR THE TREATMENT OF PULMONARY ARTERIAL HYPERTENSION

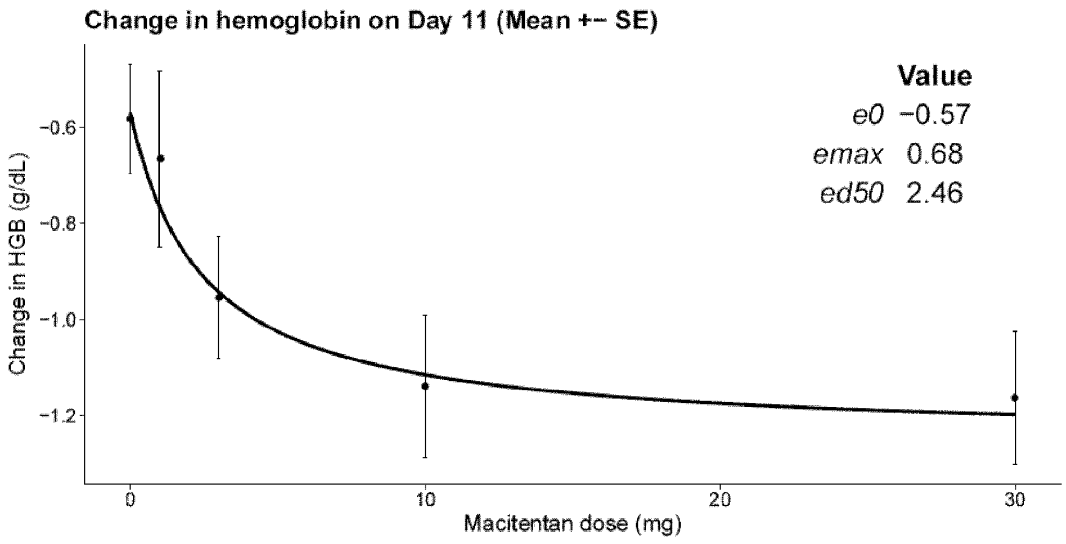


Figure 1

(57) Abstract: The present invention relates to high doses of macitentan, i.e. propylsulfamic acid [5-(4-bromo-phenyl)-6-[2-(5-bromo-pyrimidin-2-yloxy)-ethoxy]-pyrimidin-4-yl]-amide or pharmaceutically acceptable salts, solvates, hydrates or morphological forms thereof, or of aprocitentan, for use in the treatment and/or prevention of pulmonary arterial hypertension (PAH). Moreover, the present invention relates to the use of high doses of macitentan, or of aprocitentan, for the manufacture of a medicament for the treatment and/or prevention of PAH, as well as to a method for the treatment and/or prevention of PAH comprising high doses of macitentan or of aprocitentan. Further, the present invention relates to a dosage regimen for the treatment and/or prevention of PAH as well as to a combination of macitentan, or of aprocitentan, with one or more phosphodiesterase type 5 (PDE5) inhibitors, prostacyclin analogues, prostacyclin receptor agonists or soluble guanylate cyclase stimulators. Therein, PAH is preferably mild or moderate PAH. Moreover, the present

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invention relates to a pharmaceutical composition for the treatment of PAH comprising a high dose of macitentan or of aprocitentan.