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Declarations under Rule 4.17:
— *as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))*

(54) Title: PHARMACEUTICAL DRY POWDER INHALATION FORMULATION

(57) Abstract: The present invention relates to pharmaceutical dry powder formulations, comprising (5S)-{[2-(4-carboxyphenyl)ethyl][2-(2-{[3-chloro-4'-(trifluoromethyl)biphenyl-4-yl]methoxy}phenyl)ethyl]-amino}-5,6,7,8-tetrahydroquinoline-2-carboxylic acid of formula (I), preferably in form of one of its salts or solvates or hydrates, preferably (5S)-{[2-(4-carboxyphenyl)ethyl][2-(2-{[3-chloro-4'-(trifluoromethyl)biphenyl-4-yl]methoxy}phenyl)ethyl]-amino}-5,6,7,8-tetrahydroquinoline-2-carboxylic acid monohydrate (I) of formula (I-M-I) or (5S)-{[2-(4-carboxyphenyl)ethyl][2-(2-{[3-chloro-4'-(trifluoromethyl)biphenyl-4-yl]methoxy}phenyl)ethyl]-amino}-5,6,7,8-tetrahydroquinoline-2-carboxylic acid monohydrate (II) of formula (I-M-II) in combination with a lactose carrier, comprising lactose monohydrate as a mixture of coarse lactose and fine lactose, and to the process of manufacturing such pharmaceutical dry powder formulations and its application for use in the treatment of cardiopulmonary disorders, such as pulmonary arterial hypertension (PAH), chronic thromboembolic pulmonary hypertension (CTEPH) and pulmonary hypertension (PH) associated with chronic lung disease (PH group 3) such as pulmonary hypertension in chronic obstructive pulmonary disease (PH-COPD) and pulmonary hypertension with idiopathic interstitial pneumonia (PH-IIP).

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