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(71) Applicant *(for all designated States except US)*: **SANOFI** [FR/FR]; 54, rue La Boétie, F-75008 Paris (FR).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: **HANOTIN, Corinne** [FR/FR]; c/o SANOFI Diabetes, R&D/Development, 54, rue La Boétie, F-75008 Paris (FR). **BESSAC, Laurence** [FR/FR]; c/o SANOFI Diabetes, R&D/Development, 54, rue La Boétie, F-75008 Paris (FR). **CHAUDHARI, Umesh** [US/US]; c/o SANOFI US, R&D Bridgewater, Phase III - Clinical Development, Mail Stop: 55B-415B, 55 Corporate drive Bridgewater, New Jersey 08807 (US).

(74) Agent: **SCHNEIDER, Rudolf**; c/o Sanofi-Aventis Deutschland GmbH, Patents Germany, Industriepark Höchst, Geb. K801, 65926 Frankfurt am Main (DE).

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(54) Title: PHARMACEUTICAL COMPOSITIONS COMPRISING HUMAN ANTIBODIES TO PCSK9

(57) Abstract: The present invention relates to Pharmaceutical compositions comprising an antibody specifically binding to human proprotein convertase subtilisin/kexin type 9 (PCSK9), to methods for treating diseases or conditions in which proprotein convertase subtilisin/kexin type 9 (PCSK9) expression or activity causes an impact by administration of PCSK9-specific antibodies or antigen-binding fragments thereof and preferably by additional administration of an inhibitor of 3-hydroxy-3-methyl-glutaryl-CoA reductase (HMG-CoA reductase). The present invention further relates to PCSK9-specific antibodies or antigen-binding fragments thereof for use in the treatment of diseases or conditions in which PCSK9 expression or activity causes an impact. The present invention also relates to articles of manufacture comprising packaging material, PCSK9-specific antibodies or antigen-binding fragments thereof, and a label or packaging insert indicating which groups of patients can be treated with said antibodies or fragments, which groups of patients must not be treated with said antibodies or fragments, and which dosage regimen should be used. The present invention further relates to methods of testing the efficacy of PCSK9-specific antibodies or antigen-binding fragments thereof for the treatment of certain diseases or conditions and for the treatment of specific sub-groups of patients.