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(54) Title **ANTIGEN BINDING PROTEINS TO PROPROTEIN CONVERTASE SUBTILISIN KEXIN TYPE 9 (PCSK9)**

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Enclosed is a translation of the patent claims in Norwegian. Please note that as per the Norwegian Patents Acts, section 66i the patent will receive protection in Norway only as far as there is agreement between the translation and the language of the application/patent granted at the EPO. In matters concerning the validity of the patent, language of the application/patent granted at the EPO will be used as the basis for the decision. The patent documents published by the EPO are available through Espacenet (<http://worldwide.espacenet.com>) or via the search engine on our website here: <https://search.patentstyret.no/>

Patentkrav

- 1.** Et monoklonalt antistoff eller et antigenbindende fragment derav for bruk i
behandling eller forebygging av hyperkolesterolemi eller en aterosklerotisk sykdom relatert til forhøyede serumkolesterolnivåer;
eller for bruk for å redusere risikoen for en tilbakevendende kardiovaskulær hendelse relatert til forhøyede serumkolesterolnivåer;
hvori det monoklonale antistoffet eller det antigenbindende fragmentet derav binder til det katalytiske domenet til et PCSK9-protein av aminosyresekvensen til SEKV ID NR: 1, og forhindrer eller reduserer bindingen av PCSK9 til LDLR.
- 2.** Monoklonalt antistoff eller det antigenbindende fragment derav for anvendelse ifølge krav 1, for behandling eller forebygging av hyperkolesterolemi.
- 3.** Monoklonalt antistoff eller det antigenbindende fragment derav for anvendelse ifølge krav 1, ved behandling eller forebygging av en aterosklerotisk sykdom relatert til forhøyede serumkolesterolnivåer.
- 4.** Monoklonalt antistoff eller det antigenbindende fragmentet derav for bruk ifølge krav 3, hvori den aterosklerotiske sykdommen er valgt fra koronar hjertesykdom, koronararteriesykdom, perifer arteriell sykdom, iskemisk eller hemorragisk slag, angina pectoris, cerebrovaskulær sykdom, akutt koronarsyndrom eller hjerteinfarkt.
- 5.** Monoklonalt antistoff eller det antigenbindende fragment derav for bruk ifølge krav 1, hvori det monoklonale antistoffet eller det antigenbindende fragmentet derav er for bruk for å redusere risikoen for en tilbakevendende kardiovaskulær hendelse relatert til forhøyede serumkolesterolnivåer.
- 6.** Monoklonalt antistoff eller det antigenbindende fragment derav for anvendelse ifølge hvilket som helst av kravene 1 til 5, hvori det monoklonale antistoffet eller antigenbindende fragmentet derav administreres sammen med minst ett annet kolesterolsenkende middel.
- 7.** Monoklonalt antistoff eller det antigenbindende fragmentet derav for bruk ifølge krav 6, hvori det minst ene andre kolesterolsenkende middelet er et statin, eventuelt hvor statinet er valgt fra gruppen bestående av atorvastatin, cerivastatin, fluvastatin, lovastatin, mevastatin, pitavastatin, pravastatin, rosuvastatin og simvastatin.
- 8.** Monoklonalt antistoff eller det antigenbindende fragment derav for bruk ifølge hvilket som helst av kravene 1 til 7, hvori det monoklonale antistoffet eller det antigenbindende fragmentet derav er valgt fra gruppen bestående av et humant antistoff, et humanisert antistoff, et kimært antistoff, et multispesifikt antistoff, et rekombinant antistoff, et antigenbindende antistoffragment, et enkeltkjedet antistoff, et diastoff, et Fab-fragment, et F(ab)₂-fragment, et IgG1-antistoff, et IgG2-antistoff, et IgG3-antistoff og et IgG4-antistoff eller et antigenbindende fragment derav.
- 9.** Monoklonalt antistoff eller det antigenbindende fragment derav for bruk ifølge hvilket som helst av kravene 1 til 8, hvori det monoklonale antistoffet eller det antigenbindende fragmentet derav binder til en PCSK9-variant som har en D374Y-punktmutasjon.
- 10.** Monoklonalt antistoff eller det antigenbindende fragment derav for bruk ifølge hvilket som helst av kravene 1 til 9, hvori det monoklonale antistoffet eller det antigenbindende fragmentet derav binder til PCSK9 med en K_d som er mindre enn 1 nM, er mindre enn 100 pM, er mindre enn 10 pM, eller er mindre enn 5 pM.

11. Monoklonalt antistoff eller det antigenbindende fragment derav for anvendelse ifølge hvilket som helst av de foregående kravene, hvori individet er en menneskelig pasient.