

■(4) JP6166717 (formulation)

■Patent owner: Amgen

[Claim 1] A **stable formulation** comprising:

(a) a monoclonal antibody or fragment thereof that specifically binds to PCSK9 comprising the amino acid of SEQ ID NO: 1, present in an amount of 70 to 200 mg/ml, said monoclonal antibody or fragment thereof comprising

(i) a light chain polypeptide comprising a light chain CDR1 that is a CDR1 of SEQ ID NO: 158, a light chain CDR2 that is a CDR2 of SEQ ID NO: 162, and a light chain CDR3 that is a CDR3 of SEQ ID NO: 395, and a heavy chain polypeptide comprising a heavy chain CDR1 that is a CDR1 of SEQ ID NO: 308 or 368, a heavy chain CDR2 that is a CDR2 of SEQ ID NO: 175, and a heavy chain CDR3 that is a CDR3 of SEQ ID NO: 180, or

(ii) a light chain variable region comprising the amino acid sequence of SEQ ID NO: 23 and a heavy chain variable region comprising the amino acid sequence of SEQ ID NO: 49.

(b) 10 to 20 mM sodium acetate,

(c) 0.5 to 10% w/v proline,

(d) 0.004 to 0.01% w/v polysorbate 20 or polysorbate 80, and

(e) a pH of 5.0 to 5.5.