CLAIMS

[Claim 1]. Use of an anti-FcRn antibody or an antigen-binding fragment thereof in the manufacture of a medicament for treating or preventing ~~Graves' ophthalmopathy~~Thyroid Eye Disease in a patient in need thereof, wherein the medicament is suitable for administration to the patient comprises (i) a therapeutically effective amount of the antibody or antigen-binding fragment; or (ii) a pharmaceutical composition comprising at least one pharmaceutically acceptable carrier and a therapeutically effective amount of the antibody or antigen-binding fragment~~.~~

~~2. The use of claim 1~~, wherein the antibody or antigen-binding fragment comprises a heavy chain variable region comprising an amino acid sequence of SEQ ID No: 27 (HCDR1), an amino acid sequence of SEQ ID No: 28 (HCDR2), and an amino acid sequence of SEQ ID No: 29 (HCDR3); and a light chain variable region comprising an amino acid sequence of SEQ ID No: 30 (LCDR1), an amino acid sequence of SEQ ID No: 31 (LCDR2), and an amino acid sequence of SEQ ID No: 32 (LCDR3).

[Claim 2~~3~~]. ~~3.~~The use of claim 1 ~~or claim 2~~, wherein the antibody or antigen-binding fragment comprises (i) a heavy chain variable region comprising an amino acid sequence of SEQ ID No: 6; and a light chain variable region comprising an amino acid sequence of SEQ ID No: 16 or (ii) a heavy chain variable region comprising an amino acid sequence that is at least 90% identical to SEQ ID No: 6; and a light chain variable region comprising an amino acid sequence that is at least 90% identical to SEQ ID No: 16.

[Claim 3]. The use of claim 1 or claim 2, wherein the antibody or antigen-binding fragment binds to FcRn with a KD (dissociation constant) of 0.01 to 2 nM at pH 6.0 or pH 7.4.

[Claim 4]. The use of any one of claims 1 to 3, wherein the antibody, antigen-binding fragment, or pharmaceutical composition is to be administered subcutaneously.

[Claim 5]. The use of any one of claims 1 to 4, wherein the antibody, antigen-binding fragment, or pharmaceutical composition is to be administered as a fixed dose.

[Claim 6]. The use of any one of claims 1 to 5, wherein the antibody, antigen-binding fragment, or pharmaceutical composition is ~~suitable for administration~~to be administered once weekly or once every 2 weeks (bi-weekly).

[Claim 7]. The use of any one of claims 1 to 6, wherein the therapeutically effective amount of the antibody or antigen-binding fragment is:

a. ~~about~~ 200 to 300 mg, 300 to 400 mg, ~~about~~ 400 to 500 mg, or ~~about~~ 500 to 600 mg to be administered once weekly;

b. ~~about~~ 340 mg to be administered once weekly;

c. ~~about~~ 550 to 650 mg, ~~about~~ 650 to 750 mg, or ~~about~~ 750 to 850 mg to be administered once weekly; and/or

d. ~~about~~ 680 mg to be administered once weekly.

[Claim 8]. The use of any one of claims 1 to 7, wherein the therapeutically effective amount of the antibody or antigen-binding fragment is at least one dose of about 680 mg, followed by at least one dose of about 340 mg.

[Claim 9]. The use of claim 8, wherein the at least one dose of about 680 mg is to be administered subcutaneously or intravenously and/or wherein the at least one dose is about 340 mg is to be administered subcutaneously.

[Claim 10]. The use of claim 8, wherein the at least one dose of about 680 mg is ~~about~~ 3 doses and/or wherein the at least one dose of about 340 mg is ~~about~~ 3 doses.

[Claim 11]. The use of any one of claims 1 to 10, wherein the antibody, antigen-binding fragment, or pharmaceutical composition is to be administered alone or in combination with at least one additional therapeutic agent.

[Claim 12]. The use of any one of claims 1 to 11, wherein treatment reduces the level of at least one IgG in a sample from the patient.

[Claim 13]. The use of claim 12, wherein the at least one IgG comprises anti-TSHR IgG and/or anti-IGF-1R IgG.

[Claim 14]. The use of claim 13, wherein treatment reduces the level of anti-TSHR IgG and/or anti-IGF-1R IgG in a sample from the patient by at least ~~about~~ 30%, ~~about~~ 40%, ~~about~~ 50%, ~~about~~ 60%, ~~about~~ 70%, or ~~about~~ 80%.

[Claim 15]. The use of any one of claims 1 to 14, wherein treatment reduces the level of total serum IgG in a sample from the patient.

[Claim 16]. The use of claim 15, wherein treatment reduces the level of total serum IgG in a sample from the patient by at least ~~about~~ 40%, ~~about~~ 50%, ~~about~~ 60%, ~~about~~ 70%, or ~~about~~ 80%.

[Claim 17]. A kit comprising an anti-FcRn antibody or an antigen-binding fragment thereof and

instructions for use of the antibody or antigen-binding fragment for use in treating or preventing Thyroid Eye Disease~~Graves' ophthalmopathy~~ in a patient in need thereof~~.~~

~~18. The kit of claim 17~~, wherein the antibody or antigen-binding fragment comprises a heavy chain variable region comprising an amino acid sequence of SEQ ID No: 27 (HCDR1), an amino acid sequence of SEQ ID No: 28 (HCDR2), and an amino acid sequence of SEQ ID No: 29 (HCDR3); and a light chain variable region comprising an amino acid sequence of SEQ ID No: 30 (LCDR1), an amino acid sequence of SEQ ID No: 31 (LCDR2), and an amino acid sequence of SEQ ID No: 32 (LCDR3).

[Claim ~~19~~18]. The kit for use of claim 17~~ or claim 18~~, wherein the antibody or antigen-binding fragment comprises (i) a heavy chain variable region comprising an amino acid sequence of SEQ ID No: 6; and a light chain variable region comprising an amino acid sequence of SEQ ID No: 16 or (ii) a heavy chain variable region comprising an amino acid sequence that is at least 90% identical to SEQ ID No: 6; and a light chain variable region comprising an amino acid sequence that is at least 90% identical to SEQ ID No: 16.

[Claim 19]. The kit for use of claim 17 or claim 18, wherein the antibody or antigen-binding fragment binds to FcRn with a K_D (dissociation constant) of 0.01 to 2 nM at pH 6.0 or pH 7.4.

[Claim 20]. The kit for use of any one of claims 17 to 19, wherein the kit further comprises at least one additional therapeutic agent.