### Table 15  Criteria for patient eligibility at baseline and primary outcomes evaluation.

#### Criteria for patient eligibility

**Inclusion criteria**

- a. Active Graves’ orbitopathy (GO): patients with a Clinical Activity Score (CAS) ≥ 4/10 (exception ≥ 3/10 if severe impairment of motility and only minor inflammatory symptoms)
- b. Moderate-to-severe GO, defined as having at least one of the following signs: lid retraction ≥ 2 mm, moderate or severe soft tissue involvement, exophthalmos ≥ 3 mm above normal for race and gender, inconstant or constant diplopia
- c. No previous treatment for GO (glucocorticoids (GCs), orbital radiotherapy (ORT), immunosuppressive drugs, orbital decompression) except for local measures (e.g. artificial tears) at baseline
- d. Euthyroidism
- e. Afterwards treatment with intravenous GCs with or without combination with ORT (12-20Gy)
- f. Age 18–80 years
- g. Duration of GO ≤ 12 months
- h. Complete examination before therapy and 6 ± 2 months later

**Exclusion criteria**

- a. Insufficient documentation of baseline or follow-up examination
- b. Dysthyroid optic neuropathy (DON)
- c. Duration of GO > 12 months
- d. Lack of steroid treatment or more than one course of systemic steroids

#### Primary outcomes evaluation

Overall ophthalmic outcome was defined as follows:

- a. Improvement, when at least two of the following outcome measures improved in one eye, without deterioration in any of these measures in either eyes: i) reduction in palpebral aperture by at least 1 mm; ii) reduction in any of the class 2 signs of NOSPECS by at least two grades; iii) reduction in exophthalmos by at least 2 mm; iv) improvement of > 8 degrees in motility or improvement in diplopia (disappearance or improvement of ≥ 5 points in scoring of the field of binocular field of single vision); v) improvement in CAS by at least 2 points.
- b. Deterioration, when DON or two of the following occurred: i) increase in palpebral aperture by at least 1 mm; ii) increase in any of the class 2 signs of NOSPECS by at least two grades; iii) increase in exophthalmos by at least 2 mm; iv) deterioration of > 8 degrees in motility or worsening of diplopia (appearance or reduction of ≥ 5 points in scoring of the field of binocular field of single vision).
- c. No change. When there were no changes or changes smaller than previously defined in any of the mentioned parameters.

Modified ophthalmic outcome was defined as follows:

- a. Improvement, when at least two of the following outcome measures improved in one eye, without deterioration in any of these measures in either eyes: i) reduction in palpebral aperture by at least 1 mm; ii) reduction in any of the class 2 signs of NOSPECS by at least two grades; iii) reduction in exophthalmos by at least 2 mm; iv) improvement of > 8 degrees in motility or improvement in diplopia (disappearance or improvement of ≥ 5 points in scoring of the field of binocular field of single vision).
- b. Deterioration, when DON or two of the following occurred: i) increase in palpebral aperture by at least 1 mm; ii) increase in any of the class 2 signs of NOSPECS by at least two grades; iii) increase in exophthalmos by at least 2 mm; iv) deterioration of > 8 degrees in motility or worsening of diplopia (appearance or reduction of ≥ 5 points in scoring of the field of binocular field of single vision).
- c. No change. When there were no changes or changes smaller than previously defined in any of the mentioned parameters.