SUMMARY

somapacitan

SOGROYA, 5 mg/1.5 ml, 10 mg/1.5 ml, 15 mg/1.5 ml

solution for injection in pre-filled pen

Initial inclusion

Original French opinion adopted by the Transparency Committee on 31 January 2024

The legally binding text is the original French opinion version

Transparency Committee's conclusions

Clinical Benefit

Growth hormone deficiency in children and adolescents

- Childhood growth hormone deficiency is a condition with variable aetiologies (idiopathic or secondary to pituitary damage), which may be isolated or combined with other pituitary deficiencies. It is manifested as short stature and variable symptoms, primarily combining weight gain, metabolic risk, asthenia and impairment of quality of life.
- This is a symptomatic medicinal product.
- The efficacy/adverse effects ratio is high.
- It is a first-line treatment in view of the available therapies based on daily somatropin and weekly somatrogon.

Public health benefit

Considering:

- the seriousness of the disease and its rarity,
- the partially met medical need,
- the partial response to the identified need given:
  - the absence of demonstration of an additional impact on morbidity and mortality or quality of life in a non-inferiority study versus daily somatropin;
  - an expected additional impact on the organisation of care and on the care and/or life pathway of patients (school, family life of the child/carers, leisure activities, stays away from home, etc.) due to the improved administration conditions for the medicinal product thanks to longer intervals between injections (weekly instead of daily). This expected optimisation of the care

pathway for patients and their families is particularly useful in paediatric and adolescent patients, given the treatment compliance and adherence difficulties reported by patient associations, in particular,

SOGROYA (somapacitan) is likely to have an additional impact on public health in the paediatric population.

Growth hormone deficiency in adults

- Growth hormone deficiency in adults may be related either to a childhood deficiency that continues into adulthood or, more commonly, to a deficiency acquired after adolescence, either idiopathic or secondary to a tumour of the pituitary gland or pituitary region or, more rarely, to a severe head injury. It is manifested as metabolic and lipid disorders, a change in body composition, central obesity, as well as reduced bone density and muscle strength, which can impair quality of life.
- This is a symptomatic medicinal product.
- The efficacy/adverse effects ratio is moderate.
- It is a first-line treatment in view of the available therapies based on daily somatropin.

Public health benefit

Considering:

- the seriousness of the disease and its rarity,
- the partially met medical need,
- the partial response to the identified need given:
  - the absence of demonstration of an additional impact on morbidity and mortality or quality of life in a placebo-controlled superiority study, despite the fact that a comparison with somatropin was possible;
  - the absence of any demonstrated additional impact on the organisation of care;
  - an expected additional impact on the organisation of care and on the care and/or life pathway of patients (work life, everyday life, etc.) due to the improved administration conditions for the medicinal product thanks to longer intervals between injections (weekly instead of daily), but to a lesser extent than in the paediatric population,

SOGROYA (somapacitan) is unlikely to have an additional impact on public health in the adult population.

Considering all these elements, the Committee deems that the clinical benefit of SOGROYA (somapacitan) 5 mg/1.5 ml, 10 mg/1.5 ml, 15 mg/1.5 ml solution for injection in pre-filled pen is:

- **substantial in the replacement of endogenous growth hormone (GH) in children aged 3 years and above, and adolescents with growth failure due to growth hormone deficiency (paediatric GHD),**
- **moderate in the replacement of endogenous growth hormone (GH) in adults with growth hormone deficiency (adult GHD).**

The Committee issues a favourable opinion for inclusion of SOGROYA (somapacitan) 5 mg/1.5 ml, 10 mg/1.5 ml, 15 mg/1.5 ml solution for injection in pre-filled pen in both the list

of covered drugs for outpatients and the list of covered drugs for inpatients approved for use in the MA indication and dosages.

➔ **Recommended reimbursement rate for inclusion in the list of covered drugs for outpatients: 100%**

Clinical Added Value

Growth hormone deficiency in children and adolescents

Considering:

- demonstration of the non-inferiority, after 52 weeks, of somapacitan weekly injections compared to NORDITROPIN (somatropin) daily injections (clinically relevant comparator) on annualised height velocity in a paediatric population;
- the safety profile of somapacitan, which appears to be similar to that of somatropin in studies, with adverse reactions marked, in particular, by pain, headaches and fatigue;

and despite:

- limited follow-up of the efficacy of somapacitan, with an estimated annualised height velocity after 1 year of treatment;
- uncertainties with respect to the long-term efficacy and safety related to exposure to increased levels of non-physiological IGF1, concerning, in particular, tumour risks (benign and malignant), impaired glucose tolerance/glucose metabolism and the development of anti-GH antibodies;
- the absence of robust data on the impact of treatment on quality of life and the patient's care pathway, but with an expected impact for the patient and carers related to simplification of the dosing regimen for this young population;

the Committee deems that SOGROYA (somapacitan) 5 mg/1.5 ml, 10 mg/1.5 ml, 15 mg/1.5 ml solution for injection in pre-filled pen provides no clinical added value (CAV V) compared to NORDITROPIN (somatropin) in the replacement of endogenous growth hormone (GH) in children aged 3 years and above, and adolescents with growth failure due to growth hormone deficiency (paediatric GHD),

Growth hormone deficiency in adults

Considering:

- demonstration of the superiority, after 34 weeks, of somapacitan weekly injections compared to placebo on truncal fat mass;
- the safety profile of somapacitan, which appears to be similar to that of somatropin in studies, with adverse reactions marked, in particular, by pain, headaches and fatigue;

and despite:

- limited follow-up of the efficacy of treatment, with assessment of truncal fat mass after 34 weeks;
- the absence of demonstration of the efficacy of somapacitan administered by weekly injection compared to somatropin administered by daily injection (clinically relevant comparator), despite a comparison being possible;
- uncertainties with respect to the long-term efficacy and safety, in particular exposure to increased levels of non-physiological IGF1, concerning, among others, tumour risks (benign and

malignant), impaired glucose tolerance/glucose metabolism and the development of anti-GH antibodies;
- limited data on safety in patients with poorly controlled type 2 diabetes, who represent a non-negligible proportion of adult patients with GHD;
- the absence of robust data on the impact of treatment on quality of life and the patient's care pathway related to simplification of the dosing regimen;

the Committee deems that SOGROYA (somapacitan) 5 mg/1.5 ml, 10 mg/1.5 ml, 15 mg/1.5 ml solution for injection in pre-filled pen provides no clinical added value (CAV V) in the current care pathway for the replacement of endogenous growth hormone (GH) in adults with growth hormone deficiency (adult GHD), which includes the relevant comparators.

Other Committee recommendations

➔ Packaging

The packaging is appropriate to the prescribing conditions, based on the indication, dosage and treatment duration.

➔ Special recommendations in view of the quality and safety of care requirements related to the medicinal product

The Committee recommends exception drug status for SOGROYA (somapacitan).

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