SUMMARY

abrocitinib

CIBINQO 50 mg, 100 mg and 200 mg

film-coated tablets

Indication extension

Adopted by the Transparency Committee on 17 July 2024

Summary of opinion

Favourable opinion for reimbursement in the indication "treatment of moderate to severe atopic dermatitis in adolescents 12 years and older who are candidates for systemic therapy."

Transparency Committee's conclusions

Clinical Benefit

- Atopic dermatitis is not usually a serious disease, but in its moderate to severe forms it has a significant impact on the quality of life of patients and marked psychosocial repercussions.
- This is a medicinal product intended to have a suspensive effect on symptoms.
- The efficacy/adverse effects ratio is high.
- It is a first-line systemic therapy to be reserved for adolescents (12 years or older) with moderate to severe atopic dermatitis, in the event of inadequate response to topical treatments.

Public health benefit

Considering:

- the seriousness of the disease in its severe forms requiring systemic therapy and its significant impact on patients' quality of life;
- the high prevalence of the disease in adolescents (14.3%);
- the medical need that is partially met in adolescents with moderate to severe atopic dermatitis who are candidates for systemic therapy;
- the partial response to the identified need given:

- a demonstrated impact versus placebo in adolescents aged ≥ 12 years with moderate to severe atopic dermatitis who are candidates for systemic therapy:
  - in terms of morbidity (in particular, for IGA 0 or 1 responses with a reduction ≥ 2 points, EASI-75 response and reduction of pruritus), as monotherapy or in combination with topical corticosteroids,
  - but with no evidence of an additional impact in terms of morbidity or quality of life versus other systemic therapies,

– the absence of an expected or demonstrated additional impact on the organisation of care and the patient's life pathway,

CIBINQO (abrocitinib) is unlikely to have an additional impact on public health.

Considering all these elements, the Committee deems that the clinical benefit of CIBINQO 50 mg, 100 mg and 200 mg (abrocitinib) film-coated tablets is substantial in the MA indication in adolescents 12 years and older.

The Committee issues a favourable opinion for inclusion of CIBINQO 50 mg, 100 mg and 200 mg (abrocitinib) film-coated tablets in both the list of covered drugs for outpatients and the list of covered drugs for inpatients approved for use in adolescents 12 years and older in the indication and at the MA dosages.

➔ **Recommended reimbursement rate for inclusion in the list of covered drugs for outpatients: 65%**

Clinical Added Value

Considering:

– demonstration in phase 3 studies of good methodological quality having included patients with moderate to severe atopic dermatitis who are candidates for systemic therapy:
  - the superiority of abrocitinib 100 mg and 200 mg compared to placebo, with a statistically significant difference, as monotherapy, in adult or adolescent patients (16 to 20% of the study population):
    - in terms of IGA 0 or 1 responses, EASI-75 response and reduction of pruritus (ranked secondary endpoints) after 12 weeks of treatment (JADE MONO 1 and 2 studies),
    - in terms of maintenance of the effect of treatment, with a higher probability of the absence of flares during the maintenance period (up to 40 weeks) in the abrocitinib groups than in the placebo group (JADE REGIMEN study),
  - the superiority of abrocitinib 100 mg and 200 mg compared to placebo, with a statistically significant difference, in combination with topical corticosteroids, in adolescent patients ≥ 12 years, on the EASI-75 or IGA 0 or 1 response and on the reduction of pruritus (only at week 2 for the 100 mg strength) after 12 weeks of treatment (JADE TEEN study),

– exploratory results suggesting maintenance of clinical responses (IGA 0 or 1 and EASI-75) for up to 96 weeks of follow-up (JADE EXTEND study);

– the medium-term safety profile of abrocitinib, primarily marked by nausea, headaches, acne, herpes simplex and CPK elevations;

but:

- the lack of evidence of an impact in terms of quality of life, even though moderate to severe atopic dermatitis has a significant psychological, emotional and social impact on patients' lives,
- the risks of major cardiovascular events, malignancies, serious infections and all-cause mortality associated with the JAK inhibitor class of drugs making it necessary to limit exposure of patients to these medicinal products and restrict their use in some patients, although these risks are lower in the paediatric population;
- the absence of data enabling the role of abrocitinib to be assessed compared to the other first-line systemic therapies (IL inhibitors and JAK inhibitors) with an MA in adolescents, in the absence of comparative data with these treatments, which can be justified by their concomitant development,

the Committee deems that CIBINQO 50 mg, 100 mg and 200 mg (abrocitinib) film-coated tablets provides no clinical added value (CAV V) in the care pathway for the treatment of moderate to severe atopic dermatitis in adolescents 12 years and older who are candidates for systemic therapy, which includes three interleukin inhibitors (dupilumab, tralokinumab and lebrikizumab) and one JAK inhibitor (upadacitinib).