OPINION ON MEDICINAL PRODUCTS

paliperidone palmitate

BYANNLI 700 mg and 1000 mg,

sustained-release suspension for injection in prefilled syringe

First assessment

Adopted by the Transparency Committee on 9 November 2022

SUMMARY

The legally binding text is the original French opinion version

- **Schizophrenia**
- **Sectors: Community and Hospital**

Key points

Approval for reimbursement for the maintenance treatment of schizophrenia in clinically stable adult patients treated with paliperidone palmitate injections given every month or every three months.

Therapeutic improvement?

No therapeutic improvement in relation to TREVICTA 350 mg and 525 mg in the treatment of schizophrenia patients.

Role in therapeutic strategy?

"Conventional" (first-generation) antipsychotics and "atypical" antipsychotics have been shown to be effective in the treatment of schizophrenia, in particular on positive symptoms, and are considered as the conventional drug-based treatment. Atypical antipsychotics (risperidone, olanzapine, aripiprazole, paliperidone, quetiapine) are recommended as a first-line approach especially for adolescents, on account of their superior safety profile.

Antipsychotic monotherapy is preferable, if possible in oral form. The minimum effective dose should always be sought.

The therapeutic strategy for these patients is not solely based on optimising the antipsychotic treatment, but also includes psychosocial rehabilitation interventions and treatment of any comorbidities (psychiatric and somatic).

Role of the medicinal product

BYANNLI (injected every six months) is a treatment option for patients treated with TREVICTA (injected every three months) at 350 mg or 525 mg doses, or with XEPLION (injected every month) at 100 mg or 150 mg doses, not requiring dose adjustments, provided that spacing out injections does not adversely affect the patient's medical follow-up, especially when initiating treatment. The doses in which BYANNLI is available are not suitable for patients receiving injections of XEPLION 25 mg, 50 mg and 75 mg once a month, or injections of TREVICTA 175 mg and 263 mg once every three months.

Committee's conclusions

Actual Clinical Benefit

- The progression profiles of schizophrenia patients are characterised by wide diversity, from severe regression requiring long-term institutional care to symptomatic remission enabling integration into a *normal* work and social life; scenarios between the two extremes are the most common. Schizophrenia is frequently associated with psychiatric and somatic comorbidities. The disorder has particularly deleterious effects on adolescents' development and psychosocial adaptation. The risks of suicide and accidental death are notable.
- BYANNLI (paliperidone palmitate) 700 mg and 1000 mg, six-monthly intramuscular injection, is a maintenance treatment of schizophrenia in clinically stable adult patients treated with paliperidone palmitate injections given every month or every three months.
- BYANNLI is a medicinal product used to treat symptoms or prevent psychotic relapse.
- The efficacy/adverse effect ratio of BYANNLI 700 mg and 1000 mg is moderate in the short term (12 months), and has yet to be assessed in the longer term, especially compared to injectable forms of paliperidone already available, or to the oral form of paliperidone or risperidone.
- Therapeutic alternatives among other atypical antipsychotics are available.
- BYANNLI is a treatment option for adult schizophrenia patients treated with paliperidone palmitate injections every month or every three months (XEPLION 100 mg and 150 mg, TREVICTA 350 mg and 525 mg) requiring no dose adjustment, provided in that spacing out the injections does not adversely affect the patient's medical follow-up; the therapeutic strategy for these patients is not solely based on optimising the antipsychotic treatment, but also includes psychosocial rehabilitation interventions and treatment of any comorbidities (psychiatric and somatic).

- **Public health benefit**

Considering:

- the severity and adverse effects of schizophrenia,
- the partially met medical need,
- the lack of evidence of an additional impact on morbidity-mortality or quality of life,
- the lack of data supporting a potential additional impact on the care and/or life pathway or on the delivery of care,

BYANNLI is not likely to have an additional impact on public health.

Considering all of these elements, the Committee deems that the actual clinical benefit of BYANNLI is significant in the marketing authorisation indication.

The Committee approves inclusion in the list of proprietary medicinal products qualifying for reimbursement under social security and in the list of proprietary products approved for community use for the marketing authorisation indication and at the marketing authorisation dosages.

Recommended reimbursement rate: 65%

Clinical Added Value

Considering:

- the data in respect of the non-inferiority of BYANNLI 700 mg and 1000 mg (six-monthly injection) compared to TREVICTA 350 mg and 525 mg (three-monthly injection), in terms of preventing relapses in paucisymptomatic patients, over a treatment period limited to 12 months,
- the lack of data supporting improved patient compliance, safety and/or quality of life,
- the medical need partially met by the antipsychotics already available,
- the lack of comparative data versus XEPLION 100 mg and 150 mg (monthly injection)
- the lack of suitable doses for patients treated with XEPLION 25 mg, 50 mg and 75 mg or with TREVICTA 175 mg and 263 mg,

the Committee deems that BYANNLI provides no clinical added value (CAV level V) compared to TREVICTA 350 mg and 525 mg in the treatment of schizophrenia patients.