14 September 2017
EMA/CHMP/449509/2017
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Tookad

padeliporfin

On 14 September 2017, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Tookad, intended for the treatment of adult patients with adenocarcinoma of the prostate. Tookad is administered as part of focal vascular-targeted photodynamic therapy (VTP). The applicant for this medicinal product is STEBA Biotech S.A.

Tookad will be available as a powder (183 mg and 366 mg) for solution for injection. The active substance of Tookad is padeliporfin, a sensitiser used in photodynamic/radiation therapy (ATC code: L01XD07). When activated with laser light, padeliporfin triggers a cascade of pathophysiological events resulting in focal necrosis within a few days.

The benefits with Tookad are its ability to improve the probability of a negative biopsy at 24 months and delay disease progression compared with active surveillance (periodic monitoring of known prostate cancer).

The most common side effects are urinary and reproductive system disorders.

The full indication is:

"Tookad is indicated as monotherapy for adult patients with previously untreated, unilateral, low-risk, adenocarcinoma of the prostate with a life expectancy ≥ 10 years and:

- Clinical stage T1c or T2a,
- Gleason Score ≤ 6, based on high-resolution biopsy strategies,
- PSA ≤ 10 ng/mL,
- 3 positive cancer cores with a maximum cancer core length of 5 mm in any one core or 1-2 positive cancer cores with ≥ 50% cancer involvement in any one core or a PSA density ≥ 0.15 ng/mL/cm^3"

It is proposed that Tookad be restricted to hospital use only. It should only be used by personnel trained in the vascular-targeted photodynamic therapy (VTP) procedure.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

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Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.