15 February 2023
EMA/86030/2023
Veterinary Medicines Division

Committee for Veterinary Medicinal Products (CVMP)

CVMP assessment report for Prolevare (EMEA/V/C/006117/0000)

INN: oclacitinib maleate

Submitted under Article 21 of Regulation (EU) 2019/6 (Informed consent)

Assessment report as adopted by the CVMP with all information of a commercially confidential nature deleted.

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Introduction

The applicant Zoetis Belgium submitted on 29 August 2022 an application for a marketing authorisation to the European Medicines Agency (The Agency) for Prolevare, through the centralised procedure under Article 21 of Regulation (EU) 2019/6, i. e. "informed consent". The cross-referred medicinal product is Apoquel film-coated tablets for dogs (EU/2/13/154/002, EU/2/13/154/021, EU/2/13/154/004, EU/2/13/154/024, EU/2/13/154/006, EU/2/13/154/027).

The eligibility to the centralised procedure was agreed upon by the CVMP on 13 April 2022 as an informed consent application.

In addition to being an informed consent application, the present application is also considered to be a duplicate application of Apoquel film-coated tablets for dogs.

The dossier has been submitted in line with the requirements for submissions under Article 21 of Regulation (EU) 2019/6, an informed consent application.

The applicant demonstrated permission (letter of access) to use the technical documentation on quality, safety and efficacy submitted by Zoetis Belgium SA in respect of the already authorised veterinary medicinal product Apoquel film-coated tablets for dogs (EU/2/13/154/002, EU/2/13/154/021, EU/2/13/154/004, EU/2/13/154/024, EU/2/13/154/006, EU/2/13/154/027). The dossier includes data for Part 1A and 1B, as described in Annex I (points 1 to 6.4) of Regulation (EU) 2019/6.

At the time of submission, the applicant applied for the following indications:

"Treatment of pruritus associated with allergic dermatitis in dogs."

"Treatment of clinical manifestations of atopic dermatitis in dogs."

The active substance of Prolevare is oclacitinib maleate, a janus kinase (JAK) inhibitor which inhibits the production of pro-inflammatory cytokines in various types of cells. The target species are dogs.

Prolevare contains 3.6, 5.4 or 16 mg oclacitinib maleate and each strength is presented in packs of 100 tablets, either in aluminium/PVC/Aclar or aluminium/PVC/PVDC blisters.

The rapporteur appointed is Rory Breathnach and the co-rapporteur is Niels Christian Kyvsgaard.

On 15 February 2023, the CVMP adopted an opinion and CVMP assessment report.

On 24 April 2023, the European Commission adopted a Commission Decision granting the marketing authorisation for Prolevare.

Part 1 - Administrative particulars

Summary of the Pharmacovigilance System Master File

The applicant has provided a summary of the Pharmacovigilance System Master File (PSMF) which fulfils the requirements of Article 23 of Commission Implementing Regulation (EU) 2021/1281. Based on the information provided, the applicant has a PSMF with reference number PSMF-ZOETIS-BE1930-v1 in place, has the services of a qualified person responsible for pharmacovigilance and the necessary means to fulfil the tasks and responsibilities required by Regulation (EU) 2019/6.

Manufacturing authorisations and inspection status

Active substance

Manufacture of the active substance oclacitinib maleate takes place at sites within and outside the EEA. A Qualified Person (QP) declaration for the active substance manufacturing sites was provided from the QP at Zoetis Belgium, the EU batch release site on behalf of all QPs involved. The declaration was based on on-site audits by the manufacturing site responsible for batch release. The audits took place within the last three years.

Finished product

Manufacture, packaging and stability testing of the finished product take place outside the EEA. Batch release within the EEA takes place at Zoetis Belgium SA, Louvain-la-Neuve, Belgium. GMP certification, which confirms the date of the last inspection and shows that the sites are authorised for the activities indicated above, has been provided.

Manufacture, packaging, batch control testing, stability testing and batch release of the finished product takes place in the EEA at Pfizer Italia s.r.l., Italy. GMP certification, which confirms the date of the last inspection and shows that the site is authorised for the activities indicated above, has been provided.

Overall conclusions on administrative particulars

The summary of the PSMF is considered to be in line with legal requirements.

The GMP status of the active substance and of the finished product manufacturing sites has been satisfactorily established and is in line with legal requirements.

Part 2 – Quality

This application is an informed consent application of Apoquel film-coated tablets for dogs.

The quality data in support of this application are identical to the up-to-date quality data of the dossier for Apoquel film-coated tablets for dogs, which has already been assessed and approved by the CVMP (including any post-authorisation procedures).

Therefore, no quality data have been submitted in support of this application. This is appropriate given the legal basis of this application (i.e. informed consent).

Part 3 – Safety documentation (Safety tests)

This application is an informed consent application of Apoquel film-coated tablets for dogs.

The safety data in support of this application are identical to the up-to-date safety data of the dossier for Apoquel film-coated tablets for dogs, which has already been assessed and approved by the CVMP (including any post-authorisation procedures).

Therefore, no safety data have been submitted in support of this application. This is appropriate given the legal basis of this application (i.e. informed consent).

In addition, signal management will be aligned with that for Apoquel film-coated tablets for dogs, and annual submissions will follow the same proposed due dates as for Apoquel film-coated tablets for dogs.

Part 4 – Efficacy

This application is an informed consent application of Apoquel film-coated tablets for dogs.

The efficacy data in support of this application are identical to the up-to-date efficacy data of the dossier for Apoquel film-coated tablets for dogs, which has already been assessed and approved by the CVMP (including any post-authorisation procedures).

Therefore, no efficacy data have been submitted in support of this application. This is appropriate given the legal basis of this application (i.e. informed consent).

Part 5 – Benefit-risk assessment

Prolevare contains the janus kinase (JAK) inhibitor oclacitinib maleate as active substance and is presented in three different strengths (3.6, 5.4 or 16 mg oclacitinib maleate) supplied in packs containing 100 tablets in aluminium/PVC/Aclar or aluminium/PVC/PVDC blisters. The route of administration is oral and the product is indicated for the treatment of pruritus associated with allergic dermatitis in dogs as well as the treatment of clinical manifestations of atopic dermatitis in dogs.

This marketing authorisation application has been submitted as an informed consent application in accordance with Article 21 of Regulation (EU) 2019/6. Thus, the quality, safety and efficacy data of Prolevare are identical to that of Apoquel film-coated tablets.

Consequentially, and in line with the assessment of data provided in the framework of the initial marketing authorisation application, as well as within all post-authorisation procedures for Apoquel film-coated tablets, the CVMP considers that the benefit-risk balance for Prolevare is positive. Details on the scientific discussion of Apoquel film-coated tablets can be found in the European Public Assessment Report (EPAR) published on the EMA website.

In addition, signal management will be aligned with that for Apoquel film-coated tablets for dogs, and annual submissions will follow the same proposed due dates as for Apoquel film-coated tablets.

Post-authorisation measures

Not applicable.

Conclusion

This application for Prolevare is based on an informed consent to use the quality, safety and efficacy data contained in the marketing authorisation of Apoquel film-coated tablets, complemented by appropriate administrative information. The Committee for Veterinary Medicinal Products (CVMP) considers that the application for Prolevare is approvable, since the marketing authorisation application satisfies the requirements for an informed consent authorisation set out in the legislation (Regulation (EU) 2019/6).

The CVMP considers that the benefit-risk balance is positive and, therefore, recommends the granting of the marketing authorisation for the above mentioned veterinary medicinal product.