EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

23 June 2022
EMA/635264/2022
Human Medicines Division

# Assessment report for paediatric studies submitted according to Article 46 of the Regulation (EC) No 1901/2006

## Triumeq

dolutegravir / abacavir / lamivudine

Procedure no: EMEA/H/C/002754/P46/011

## Note

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

**Official address** Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
**Address for visits and deliveries** Refer to www.ema.europa.eu/how-to-find-us
**Send us a question** Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

| Status of this report and steps taken for the assessment | | | | |
|---|---|---|---|---|
| **Current step** | **Description** | **Planned date** | **Actual Date** | **Need for discussion** |
| ☐ | Start of procedure | 2022-04-25 | 2022-04-25 | ☐ |
| ☐ | CHMP Rapporteur Assessment Report | 2022-05-30 | 2022-05-30 | ☐ |
| ☐ | CHMP members comments | 2022-06-13 | 2022-06-13 | ☐ |
| ☐ | Updated CHMP Rapporteur Assessment Report | 2022-06-16 | 2022-06-16 | ☐ |
| ☒ | CHMP adoption of conclusions: | 2022-06-23 | 2022-06-23 | ☐ |

## Table of contents

# 1. Introduction

In April-2022, the Marketing Authorisation Holder (MAH) submitted the final Clinical Study Report (CSR) of non-interventional post marketing surveillance study 204731 "Re-examination Report for Post-marketing Surveillance (PMS) of Triumeq® Tablet (dolutegravir sodium, abacavir sulfate, lamivudine)", in accordance with Article 46 of Regulation (EC) No1901/2006, as amended.

This data was submitted as a Post-Authorisation Measure (PAM 011). Study 204731 is not part of any Paediatric Investigation Plan (PIP). A short critical expert overview was also provided.

No amendments to the Product Information (PI) were submitted as part of this procedure.

# 2. Scientific discussion

## *2.1. Information on the development program*

Study 204731 is not part of any PIP.

## *2.2. Information on the pharmaceutical formulation used in the study*

Triumeq (Dolutegravir sodium 50 mg, abacavir sulfate 600 mg, lamivudine 300 mg) film-coated tablet.

## *2.3. Clinical aspects*

### 2.3.1. Introduction

The MAH submitted a final report for Study 204731 "Re-examination Report for Post-marketing Surveillance (PMS) of Triumeq® Tablet".

Re-examination period: 09 June 2015 to 08 June 2021.

### 2.3.2. Clinical study 204731

***Re-examination Report for Post-marketing Surveillance (PMS) of Triumeq® Tablet (Dolutegravir sodium, abacavir sulfate, lamivudine)***

Primary objectives: This PMS was conducted in the adult and adolescent patients from 12 years of age (with weight at least 40 kg) living with human immunodeficiency virus-1 (HIV-1) who were treated with Triumeq tablet to identify the occurrence and incidence of adverse events/adverse drug reactions and comprehend the factors affecting the safety and effectiveness in the post-marketing context of study drug.

Participants: Among those with the surveillance completed, 3 subjects 'who have taken the study drug prior to the contract date', 1 subject 'who have taken the study drug prior to the consent date' and 3 subjects 'with follow-up failure' were excluded and thus a total of 656 subjects were included in the safety evaluation. Among them, 484 subjects, excluding 172 subjects '"unassessable" in the comprehensive evaluation results by the investigator', were included in the Effectiveness Analysis Set.

| | |
|---|---|
| Number of subjects with eCRF retrieved (surveillance completed) | 663 subjects |
| Number of subjects in the Safety Analysis Set | 656 subjects |
| Number of subjects in the Effectiveness Analysis Set | 484 subjects |

Demographic and baseline data: Among 656 subjects in the Safety Analysis Set, 'Male' accounted for 94.82% (622/656 subjects), and 'Female' 5.18% (34/656 subjects). The mean age of 656 subjects in the Safety Analysis Set was 42.19±13.95 years, ranging from the minimum of 18.00 years to the maximum of 81.00. During this re-examination period, there were no subjects in pregnancy and/or lactation in the Safety Analysis Set.

Results: There were no Adverse Events (AEs) reported for the single adolescent participant enrolled in the study.

***Assessor's comment:***

Only one adolescent patient, between 12-18 years of age, participated in the non-interventional post marketing surveillance study. There was no AE reported for this patient and no individual patient data on efficacy was presented.

# 3. Rapporteur's overall conclusion and recommendation

This Article 46 submission concerns a non-interventional post marketing surveillance study 204731 which is not part of any PIP and is submitted as a PAM. No concerns are raised, the study does not significantly contribute to the safety and efficacy data of Triumeq considering only one adolescent patient participated in the study. In EU, Triumeq is currently approved in adolescents above 12 years of age weighing at least 40 kg.

☒ **Fulfilled:**

No regulatory action required.