



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

## Report for the Application Evaluation Decision

The effect of oral Semaglutide on bone  
turnover in patients with T2D: a  
randomized placebo-controlled clinical  
trial (SOBER II)

2023-505959-45-00

## Decision

**MSC:**

Denmark

**Decision:**

Authorised

**Reporting Date:**

07/09/2023

**Tacit decision:**

No

**Application Part:**

## Conditions:

## Reason:

## Justification:

## Deferrals

## Disagreement with Part I

**Submission date:**

07/09/2023