Breaking News 18/1/24 TRAVERSE – Fractures

N Engl J Med 2024;390:203-11¹

Dear Colleagues,

As mentioned on the M&M monthly call yesterday, the publication of the TRAVERSE fracture sub-study in the NEJM was due any day. It has now been published.

As with all other TRAVERSE studies, you will be sent a study summary slide deck and 1-page study summary as soon as possible.

To best prepare ourselves for reactive communication, you will find some key messages from the paper and considerations from the medical community here:

There is an associated 5-min video commentary online developed by Medscape (independently of BH) that adds additional context. This can be found at the following link: <u>https://www.medscape.com/viewarticle/999712</u>

As a reminder, please ensure that all material provided by BH Global undergoes the appropriate local medical, compliance, regulatory review before being utilised on a local level.

If you have any questions or concerns related to this study, please do not hesitate to contact me in the first instance.

Richard Jones Global Medical Director – Men's Health



Testosterone Treatment and Fractures in Men with Hypogonadism



Key Messages

- Testosterone treatment in men with hypogonadism improves bone mineral density and quality ¹
- The investigators did not collect data on bone mineral density or strength at baseline. So, we do not know if the groups were matched for bone health status.²
- The overall fracture rate in this sub-study was very low, however, significantly lower in the placebo group (3.5% vs 2.5%).¹
- Fracture incidence increased immediately at the onset of treatment — a finding that would be too rapid to be due to effects on bone mineral density or composition ²
- The rapid divergence between groups is more likely related to behavioural changes. Testosterone might have affected behaviours such as engaging in physical activities associated with fracture risk.²
- Data on behaviour that would increase falls and fractures was not collected. ²
- There was no substantial between-group difference in the incidence of typical osteoporotic clinical fractures of the spine, hip, humerus, and wrist. Ankle and rib fractures that are typically associated with trauma accounted for the majority.²
- The actual incidence of fracture in the study turned out to be lower than estimated in the study's power calculation ²

2. Editorial - Breaking News — Testosterone Treatment and Fractures in Older Men. Mathis Grossmann & Bradley Anawalt DOI: 10.1056/NEJMe2313787

