Insights from the NICE guidelines for osteoporosis

Publication

BACKGROUND

Osteoporosis continues to be a heavy burden on the UK health system. Though the leading medications have been available for over a decade, the debilitating disease continues to be a focus for many Life Sciences companies. The Centre for Health Technology Evaluation (CHTE) within the National Institute for Health and Care Excellence (NICE) appraised the medications currently available for secondary prevention of fragility fractures most recently in 2011. When entering a market with such well-established competitors, it is crucial to know the variables to keep in mind from trial design through to NICE submission. Here we summarise some important insights from the 99-page document, for biotech or pharma companies entering this field, that are seeking to be better prepared for the regulatory environment.

KEY TAKE AWAY MESSAGES

- Alendronate is tough to beat. Genericized long ago, alendronate comes out well ahead of the market competitors in terms of pharmacoeconomic cost effectiveness, a key measure for guiding NICE's recommendations.
- NICE does not analyze clinical trial results in isolation. The Appraisal Group pooled all Randomized Controlled Trials (RCTs) for each drug in order to find a single Relative Risk Reduction, thus not differentiating between the age groups that entered each trial.
- Fracture results should be measured radiologically. NICE expresses a preference of trial designs that define fracture as a 20% reduction in vertebral height, however it did accept those trials that used a definition of only 15% reductions.
- Health related Quality of Life (QOL) has been largely excluded from major RCTs in osteoporosis. NICE noted that only alendronate and strontium ranelate submitted trials that included QOL outcomes.

ONGOING CHALLENGES

Contention in regards to the cost effectiveness analysis is explained at length in the appraisal document. While each manufacturer provided its own model for calculating cost effectiveness, the Appraisal Group constructed its own model in addition so that each drug could be assessed comparatively. It is important for manufacturers to be aware that the Appraisal Group's model lacks transparency in part, due to confidentiality surrounding the epidemiological literature supplied by WHO to establish Absolute Risk for the osteoporotic population. As the Decision Support Unit was confident in its responses to objections to the model, prospective osteoporosis product manufacturers should expect to undergo the same analysis.

To gain a NICE recommendation comparable to alendronate will be a significant challenge for any company wishing to enter the field. Reviewing guideline history is one way to gain insights into navigating the regulatory environment.

REFERENCE:

Nice Technology Appraisal Guidance 161 (2011) Available from: http://publications.nice.org.uk/alendronate-etidronate-risedronate-raloxifene-strontium-ranelate-and-teriparatide-for-ta161, Retrieved 2013-06-14

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