Trial Drug for Osteoporosis

by MS. LAWANA

Hope on the Horizon

A trial of Merck Company's new innovative experimental osteoporosis drug shows a reduction in fracture risk. Odanacatib, the new medication, is considered to be more convenient than the older class of drugs for osteoporosis, known as bisphosphonates. News of this novel drug was so effective that it made shares of Merck stock rise more than 3%.

The Merck Company reports that it expects to take a few more months to finish the clinical trial involving Odanacatib, which originally began in 2007. After this, they expect to continue with an extension trial to assess certain safety issues that were found by the Data Monitoring Committee. Merck officials will submit regulatory applications for the United States, Japan and Europe for the approval of Odanacatib this year.

Odanacatib: Oral Drug Taken Once a Week

Odanacatib is an oral drug that is taken once a week. Sales of Merck's drug Fosamax reached $3 billion in 2007 but because that medication went generic, those sales plummeted in 2008. Fosamax use has also decreased due to many safety concerns, such as a severe jaw bone disease called osteonecrosis. Wall Street analysts forecast that Odanacatib's annual sales will be around $400 million by the year 2016.

Osteoporosis is a bone disease that is notoriously difficult to treat. Just two years ago, the FDA cleared Amgen's RANK ligand inhibitor Prolia (denosumab). This drug improved upon the efficacy of other osteoporosis treatments. Now patients are shying away from Prolia because the injectable drug is considered a nuisance to take. Odanacatib is an oral drug, which is much easier to administer and tolerate.

New Osteoporosis Drug Targets Different Pathways

According to Merck, Odanacatbi inhibits bone absorption of the enzyme cathepsin K and once approved, it will be the first in its class to go on the market. Fosamax and Prolia both increase bone mass by shutting down osteoclasts, but they also prohibit the formation of new bone. Odanacatib, on the other hand, allows for the creation of new bone and doesn't have any drawbacks.

This new osteoporosis drug, Odanacatib, targets different pathways to influence bone formation. The early data from the clinical trial show that regulatory measures are ahead of schedule. The interim analysis data have not been released yet, but human trials are beginning and researchers report that this new drug can improve bone mineral density almost twice as much as Fosamax.

A Fraction of the Fractures

There were previous cathepsin K inhibitor drugs that produced numerous side effects, so trials were halted. However, Merck has not reported an unusual rate of side effects with Odanacatib. Regardless, practicing

physicians are reserving judgment until long-term clinical data from ongoing research studies are released. Many osteoporosis researchers feel that overall safety and efficacy should be of utmost importance when considering any new treatment for osteoporosis.