MedicalXpress

Xgeva approved for rare, non-malignant tumor

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(HealthDay)—Xgeva (denosumab) has been approved by the U.S. Food and Drug Administration to treat giant cell tumor of the bone (GCTB), a rare tumor that's most often non-cancerous.

The tumor usually affects adults between ages 20 and 40, although it may also develop in adolescents, the FDA said Thursday in a news release. It typically doesn't spread, although in rare cases it can become cancerous and travel to the lungs.

As a non-cancerous tumor, GCTB destroys bone as it becomes larger, causing pain, fractures and loss of mobility. Xgeva has been approved in cases where the tumor can't be surgically removed, or might lead to a severe outcome such as loss of a limb, the agency said.

Xgeva, approved under the FDA's expedited review program, was evaluated for this use in two clinical trials involving a total of 305 adults and adolescents. Common side effects included joint pain, headache, nausea, fatigue, back pain and extremity pain.

Women of childbearing potential should use "highly effective" contraception while taking Xgeva, since the drug can harm a fetus, the FDA warned.

The drug was first approved in 2010 to prevent fractures when cancer has spread to the bone. It's marketed by Amgen, based in Thousand Oaks, Calif.

More information: The FDA has more about this approval.