

## Amgen

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for adverse effects in patients who use any of the contaminated products, such as vascular events and increased immunogenicity, there had been no actual patient complaints prior to the recall that could be tied to the lamellae.

The recall also involves about 150 lots of Amgen-manufactured Procrit, the version of epoetin alfa sold by Johnson & Johnson unit Centocor Ortho Biotech LP. It's the second Procrit recall for Ortho Biotech, which pulled a batch of the drug in 2008 after identifying cracks in the vials of a single lot.

Hurley confirmed that Amgen's contamination was attributed to an interaction between the drug and the glass vials that occurred over the products' shelf life. Since it's "more common for the issue to appear" in older vials, she said Amgen is reducing expiration dates going forward. The previously 36-month expiration period will be trimmed to 12 months for single-dose vials and to 15 months for multidose vials.

"We are in the process of evaluating other drugs, but we have not found" any similar problems, Hurley added.

Epogen, approved for treating anemia in patients with chronic renal failure on dialysis, recorded 2009 sales of \$2.57 billion. The drug is part of Amgen's top-selling erythropoiesis-stimulating agent franchise, which has taken some hits over the past few years on safety, reimbursement and competitive issues.

But the firm saw some good news earlier this year, when the Centers for Medicare & Medicaid Services proposed a bundling rule with no changes to the target hemoglobin levels for ESAs, and the biggest threat to Epogen – Affymax Inc.'s and Takeda Pharmaceutical Co. Ltd.'s Hematide (peginesatide) – showed troubling cardiovascular safety data in a Phase III program. (See *BioWorld Today*, June 22, 2010, and July 28, 2010.)

Amgen's other ESA Aranesp (darbepoetin alfa) has had a tougher time.

The company blamed last year's 15 percent sales decline on labeling changes and is waiting to assess the potential impact of the Phase III TREAT study, which not only failed to improve mortality and cardiovascular outcomes, but also showed an imbalance of cancer deaths. The FDA's Cardiovascular and Renal Drugs Advisory Committee is set to review those data Oct. 18. (See *BioWorld Today*, Aug. 27, 2009.)

But investors of Amgen continue to focus their attention on RANK ligand inhibitor denosumab, which was launched earlier this year as Prolia in the potential \$1 billion osteoporosis market. Though the firm still is working through reimbursement issues, denosumab expectations have more than offset other pipeline disappointments, most recently the failure of EGFR-targeting Vectibix

(panitumumab) in head and neck cancer. (See *BioWorld Today*, Aug. 12, 2010.)

Denosumab also is under FDA review for preventing skeletal-related events in cancer, a market that analysts have projected to reach \$2 billion. A decision is expected by Nov. 18.

Additional trials are testing the drug in the prevention of bone metastases in prostate cancer patients. ■

## Clinic Roundup

- **Clinical Data Inc.**, of Newton, Mass., reported Phase I data showing that Stedivaze (apadenoson), a selective agonist of the adenosine A2A receptor subtype, demonstrated overall safety and tolerability in patients with asthma and chronic obstructive pulmonary disease (COPD). In an asthma study, Stedivaze treatment did not have any effects on pulmonary function and did not induce bronchoconstriction. Data from the COPD study also showed no effects on pulmonary function, and there appeared to be no association between severity of disease and the overall incidence or severity of treatment-emergent adverse events. Findings were presented at the American Society of Nuclear Cardiology meeting in Philadelphia and published in the *Journal of Nuclear Cardiology*.

- **Enobia Pharma Inc.**, of Montreal, reported that its investigational drug ENB-0040 (asfotase alfa) for hypophosphatasia (HPP) resulted in radiographic improvement of rickets, improvement in muscle strength and agility, and amelioration of pain in six out of seven patients. ENB-040 is an enzyme replacement therapy given by subcutaneous injection. In the trial, it was given to 13 children between 5 and 12 years of age with rickets and gross motor deficits resulting from HPP. ENB-040 has orphan drug and fast-track status.

- **Genta Inc.**, of Berkeley Heights, N.J., started a Phase II trial of tesetaxel in patients with advanced bladder cancer who have developed progressive disease after treatment with a single first-line regimen. The primary endpoint is overall response rate, with secondary endpoints evaluating durable response, disease control, progression-free survival and safety.

- **Intarcia Therapeutics Inc.**, of Hayward, Calif., said final results of its 24-week, 155-patient, Phase II study of ITCA 650 (DUROS continuous subcutaneous delivery of exenatide) in Type II diabetes showed substantial reductions in HbA1c and body weight at all doses. Data were presented at the European Association for the Study of Diabetes meeting in Stockholm, Sweden. A treatment regimen involving a 20 mcg/day starting dose with a transition to 60 mcg/day after week 12 was selected for the Phase III trial, anticipated to start enrollment in early 2011.