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BioCentury Extra for Friday, October 13, 2006

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FRIDAY'S TOP STORY

FDA wants another Aranesp trial

Amgen (AMGN) said it received an approvable letter from FDA for Aranesp darbepoetin alfa for every-two-week dosing and once-monthly maintenance dosing to treat anemia in chronic kidney disease (CKD) patients not on dialysis. AMGN said the agency asked for additional clinical data for the once-monthly regimen, including an additional clinical trial, and additional label language and clarification of submitted data for the every-two-week regimen. The company said it is working with FDA to resolve the issues.

Aranesp is approved for weekly dosing to treat anemia in CKD patients on dialysis or not on dialysis, and weekly and every-three-week dosing for chemotherapy-induced anemia in patients with non-myeloid malignancies. AMGN, which made the announcement after market close, was off \$0.87 to \$73.22 on Friday.

FINANCIAL NEWS

Pharmacopeia raises \$25 million

PCOP raised \$25 million through the sale of 5.8 million shares at \$4.28 to undisclosed institutional investors. PCOP sold the shares to underwriters CIBC World Markets and Merriman Curhan Ford, who then sold the shares to investors. Investors also received five-year warrants to purchase 1.5 million shares at \$5.14. PCOP's dual angiotensin and endothelin receptor antagonist (DARA) is in preclinical testing to treat hypertension and diabetic neuropathy. PCOP was up \$0.17 to \$4.45 on Friday.

Advancis falls on Keflex guidance

AVNC fell \$1.04 (20%) to \$4.19 on Friday after the company cut its 2006 sales guidance for its Keflex cephalosporin products to \$7-\$10 million from \$16-\$17 million. The company cited lower-than-expected retail pharmacy stocking of Keflex 750 mg, which was approved in May. AVNC also said it expects to have \$4-\$6 million in cash at year end. Previously, the company expected to have \$12-\$13 million. AVNC bought U.S. rights to the cephalosporin antibiotic from Eli Lilly (LLY) in 2004.

COMPANY NEWS

France approves BioAlliance's Loramyc

BioAlliance (Euronext:BIO) received French approval for Loramyc miconazole to treat oropharyngeal candidiasis in immunodepressed patients. BIO expects to launch the product next year in France, which is acting as the reference state under the mutual recognition procedure. The extended-release buccal tablet, which is formulated using BIO's Lauriad delivery technology, is in U.S. Phase III testing for oropharyngeal candidiasis in HIV-positive patients. BIO, which made the announcement after market close, was off EUR 0.19 to EUR 12.70 on Friday.

Gaboxadol delayed

Merck (MRK) and H. Lundbeck (CSE:LUN) pushed back their timeline for submitting an NDA for gaboxadol to treat insomnia to mid-2007 from the first quarter of next year. The partners said that the delay is due to slower-than-expected enrollment in ongoing Phase III trials. The companies partnered to develop and commercialize the GABA A receptor agonist in the U.S. in 2004. On Friday, LUN was off DKK1.75 to DKK137.

Roche submits Herceptin MAA

Roche (SWX:ROZ) submitted an MAA to EMEA for Herceptin trastuzumab to treat advanced HER2-positive and hormone receptor-positive breast cancer. The submission included data from the Phase III TAnDEM study, in which use of the drug doubled the median progression free survival from 2.4 months to 4.8 months. Herceptin is already approved in the EU for metastatic and early-stage HER2-positive breast cancer. Genentech (DNA) markets the humanized MAb against HER2 in the U.S. On Friday, DNA was off \$0.67 to \$82.74.

TB Alliance gets EUR 9M from Ireland

BioCentury 100™ & BioCentury London Indicators

▲ 100™: 1622.14	+ 3.77
Advance/Decline: 52/42	
▼ London: 541.28	- 1.12
▲ DJIA: 11960.51	+ 12.81
▲ Nasdaq: 2357.29	+ 11.11
▲ S&P 500: 1365.62	+ 2.75
▼ DRG: 351.98	- 0.77
▲ FTSE 350: 3209.4	+ 18.40
▲ IXK: 1033.75	+ 6.84

BioCentury 100™ Top 5 Advancers

Maxygen Inc.	+\$0.50
deCode genetics Inc.	+\$0.32
Cerus Corp.	+\$0.34
Albany Molecular Research Inc.	+\$0.47
Emisphere Technologies Inc.	+\$0.32


BioCentury 100™ Top 5 Decliners

Isis Pharmaceuticals Inc.	-\$0.27
Human Genome Sciences Inc.	-\$0.37
United Therapeutics Corp.	-\$1.51
Idenix Pharmaceuticals Inc.	-\$0.18
Kos Pharmaceuticals Inc.	-\$0.91


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The Global Alliance for TB Drug Development (TB Alliance) said it received EUR 9 million (\$11.3 million) from the Irish government to develop tuberculosis drug candidates. The TB Alliance has two compounds in the clinic and nine in preclinical development or discovery. The organization said it likely will need a further \$100 million to bring one of its candidates to market. In May, it received a \$104 million grant from the Bill & Melinda Gates Foundation  (see [BioCentury, June 19, 2006](#)).

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All Times EST unless noted

POLITICS & POLICY**CMS announces drug data sharing**

The Centers for Medicare & Medicaid Services announced Friday the release of a proposed regulation on the use of claims data from the Medicare Part D prescription drug program for research on drug safety, effectiveness and utilization patterns. The announcement came on the last day in office for CMS Administrator Mark McClellan, who has made Part D data sharing a high priority  (see [BioCentury, May 16, 2005](#)).

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Under the proposal, FDA, other government agencies, and academic researchers would be able to correlate data from Medicare Part D with CMS data on hospitalization, physician services and drugs administered in hospitals and physicians' offices. Part D data could be used to determine potential cost savings in chronic disease management from more effective adherence to recommended prescription drug therapies, CMS said. It also could be used to identify populations that are not receiving evidence-based recommended drug therapies, the agency said. CMS data releases would be subject to safeguards designed to prevent the release of information that could identify individual patients. CMS is requesting public comment on privacy protection provisions in the proposed rule.

CLINICAL NEWS**Crystal structure of IDE revealed**

Researchers from the University of Chicago and colleagues published in *Nature* the crystal structure of insulin-degrading enzyme (IDE) complexed with insulin B chain, beta amyloid peptide (1-40), amylin and glucagon. The protease is involved in the clearance of insulin and beta amyloid peptide, aggregates of which are associated with Alzheimer's disease (AD). The authors said the findings could help in designing IDE-based therapies to control cerebral beta amyloid and blood sugar concentrations.

BioCentury Extra: Susan Schaeffer (Managing Editor). Michael Flanagan (News Editor). Jeff Cranmer, Sam Dennis (Chicago), Andy Heller (Chicago), Michael Klein, Urooj Mujtaba, Ruth Truong, Steve Usdin (Washington). All contents Copyright © 2006 BioCentury Publications, Inc. ALL RIGHTS RESERVED. No part of this publication may be photocopied, reproduced or retransmitted in any form without written consent of the publisher. BioCentury®; The Bernstein Report on BioBusiness®; The BioCentury 100; The Clear Route to ROI are trademarks of BioCentury Publications, Inc., PO Box 1246 San Carlos CA 94070. The contents of this publication are not warranted by the publisher for a particular use or purpose, and the contents contained herein do not constitute investment advice. All use is governed by the BioCentury User Agreements.