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ViroPharma Loses Vancocin Try; FDA Panel Vote Favors Generics

By Donna Young
Washington Editor

SILVER SPRING, Md. – An FDA panel of outside experts Tuesday in a unanimous vote said regulators should allow makers of generic versions of vancomycin to use in vitro dissolution testing alone to demonstrate bioequivalence for products containing the same ingredients in the same amounts as ViroPharma Inc.'s Vancocin.

The FDA's Pharmaceutical Science and Clinical Pharmacology Advisory Committee tabled a vote on whether generic drugmakers should be required to use in vivo testing when their vancomycin products' inactive ingredients, or excipients, differ from Vancocin (vancomycin hydrochloride), a locally acting gastrointestinal drug used to treat *Clostridium difficile* infection (CDI) and enterocolitis caused by *Staphylococcus aureus*.

See ViroPharma, Page 4

Financings Roundup

In Wake of Buyout Speculation, Ariad Bringing in \$31M Publicly

By Jennifer Boggs
Assistant Managing Editor

A week after a combination of promising early ridaforolimus data in cancer and buyout buzz sent shares of Ariad Pharmaceuticals Inc. jumping, the Cambridge, Mass.-based firm priced an offering to raise about \$30.9 million in net proceeds.

The company agreed to sell 19 million shares – 2 million more than anticipated in its initial SEC filing – priced at \$1.75 apiece, a 13 percent discount to Monday's closing price. Underwriters Oppenheimer & Co. and Lazard Capital Markets LLC have a 30-day option to purchase an additional 2.85 million shares to cover any overallotments, which could bring the total gross proceeds to \$38.2 million and net proceeds of \$35.6 million.

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Science Scan: HIV

Newly Found HIV Strain Appears to Be from Gorillas, Not Chimps

By Anette Breindl
Science Editor

HIV is descended from simian immunodeficiency virus, or SIV, which infects chimpanzees, but SIV is pretty much harmless to chimps, who do not get AIDS from it. At least that's the conventional wisdom on HIV/AIDS, which is being challenged by recent findings.

French researchers reported in the Aug. 2, 2009, advance on line edition of *Nature Medicine* that they have isolated a new strain of HIV from a Cameroonian woman that appears to have jumped species from gorillas. The patient currently shows no sign of AIDS, though her viral load has been "consistently high" since her 2004 diagnosis, the authors wrote.

How long the newly identified strain has been circulating

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NEWCO NEWS

Cognition Therapeutics Betting on Oligomer in Alzheimer's Bid

By Catherine Hollingsworth
Staff Writer

Despite mixed results and setbacks in Alzheimer's disease drug development, big pharma still seems to want a seat at the table – good news for new firms such as Cognition Therapeutics Inc., which hopes to secure a partner later this year or in early 2010 for its program aimed at reducing toxic proteins in the brain.

Founded in 2007, Cognition recently closed a \$1.21M Series A financing that will support the company's goal of establishing a preclinical program for its small molecule-targeting AD.

The Pittsburgh-based company plans to use the funds

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Cognition

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to demonstrate proof of concept in animal models and then parlay that into a partnership based on the most promising leads coming out of the program.

Cognition has its eyes set on raising a Series B round to fund chemistry work to make the molecules as potent as possible. The firm is one of several working to develop a disease-modifying drug for AD that reduces beta amyloid proteins in the brain, a possible causative factor in AD that has drawn some skeptics lately.

One widely held view in the scientific community is that a unit of proteins known as oligomers are responsible for blocking memory loss in the early stages of the disease. Other companies are using antibodies to attack toxic beta-amyloid, while Cognition is using a small molecule to inhibit oligomers.

By blocking oligomers, Cognition hopes to fight AD in the early and later stages of the disease, said Susan Catalano, chief scientific officer at Cognition.

Protein monomers involved in learning and memory may be beneficial to the brain, but could turn problematic as they clump together and take on different shapes. "It may be that what you really want to do is target this toxic species and leave normal monomers alone," Catalano said.

Other small molecules in development for Alzheimer's such as beta and gamma secretase inhibitors alter the expression of beta-amyloid and potentially could be given once or twice daily. But secretase inhibitors can affect the amount of monomers expressed in the brain and other parts of the body that may be needed for normal function, Cognition CEO Hank Safferstein said.

Safferstein said his company started looking for a small molecule to target toxic oligomers when it was founded in 2007. "So we are way ahead of the game," he said.

Among the more advanced amyloid blocker programs are Medivation Inc.'s Phase III Dimebon (dimebolin), partnered with Pfizer Inc., and Elan Corp. plc's bapineuzumab, partnered with Johnson & Johnson in a recent \$1.5 billion deal.

Even amid some lackluster results in the Alzheimer's area – Myriad Genetics' Flurizan, Elan Corp. plc and Alzhemed by Neurochem Inc. (renamed Bellus Health) – big pharma has not shied away from the amyloid blocking approach, such as Johnson & Johnson's bet on Elan's bapineuzumab, despite negative Phase II last year.

But Catalano indicated that Cognition continues to see a high level of interest in the company's small-molecule amyloid oligomer blockers.

"Small molecules can be very effective in penetrating the blood-brain barrier and reaching effective concentrations in the brain," she said. Antibodies and other protein therapeutics, on the other hand, do not have the ability to cross the blood-brain barrier in high concentrations

because of their large size. Instead, protein therapeutics remain mainly in the blood plasma compartment, which is thought to "act as a sink," lowering the concentration of therapy in the brain, Safferstein explained.

Protein therapy typically is administered intravenously or subcutaneously, while small molecules can be given orally, he said, pointing out another potential advantage.

Another start-up firm, Sarasota, Fla.-based Archer Pharmaceuticals Inc. also is working to develop a drug that blocks excess amyloid using a version of an existing drug, nilvadipine. Founded in 2008, Archer is a spinout of the Roskamp Institute, which was once part of the University of South Florida. (See *BioWorld Today*, April 23, 2009.)

Archer's basic compound already has been shown in small clinical trials in Japan to have a solid safety profile and efficacy in Alzheimer's disease.

The company is working on other approaches to Alzheimer's disease, including a gamma secretase inhibitor in preclinical development. ■

EARNINGS ROUNDUP

• **Regeneron Pharmaceuticals Inc.**, of Tarrytown, N.Y., reported total revenue of \$90 million for the second quarter, including recognized revenue of \$4.5 million in net sales of Arcalyst (rilonacept), an interleukin-1 blocker approved for cryopyrin-associated period syndromes. The firm reported a net loss of \$14.9 million, or 19 cents per share, a narrower loss than the 25 cents per share that analysts had estimated. Analyst Joe Pantginis, of Merriman Curhan Ford, called it a "vanilla quarter" in a research note, but maintained a "buy" rating ahead of data coming out in 2010. Arcalyst is being tested in a Phase III program in gout, and Regeneron and partner **Sanofi-Aventis Group**, of Paris, are well into Phase III with aflibercept (VEGF Trap) in combination with chemotherapy regimens in metastatic colorectal, pancreatic, non-small-cell lung and prostate cancers. As of June 30, the company had \$466.4 million in cash, restricted cash and marketable securities.

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