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PAGE 1 OF 6

Avastin's Breast Cancer Bid Set Back One Year By FDA

By Randall Osborne
West Coast Editor

As Genentech Inc. hinted earlier, marketing clearance of Avastin for breast cancer has been pushed back by the FDA's request for an independent review of patient scans from the pivotal trial, and satisfying the agency could take longer than analysts expected.

"They didn't give us any specifics [earlier], but we didn't know it would be a year," said Christopher Raymond, analyst with Robert Baird & Co. in Chicago.

The South San Francisco-based firm's stock (NYSE:DNA) dipped on the news, closing Monday at $78.33, down $3.74, possibly because investors grew jittery about Avastin's chances at the FDA against non-small-cell lung cancer as well.

Genentech expects word in October about Avastin for

See Avastin, Page 3

FDA Advisors Meet On Factive's Rash Risks

By Aaron Lorenzo
Washington Editor

The FDA on Monday publicized side-effect concerns around Factive (gemifloxacin mesylate), Oscient Pharmaceuticals Corp.'s drug that is being reviewed by an advisory committee today.

The anti-infective already is approved for acute bacterial exacerbations of chronic bronchitis and community-acquired pneumonia (CAP) over a seven-day treatment course. Waltham, Mass.-based Oscient has applied for a broader label to treat both acute bacterial sinusitis and CAP over five days.

The FDA is scheduled to act on the supplemental new drug application for CAP by Sept. 21, but this gathering of the Anti-Infective Drugs Advisory Committee is solely related to the sinusitis submission.

See Oscient, Page 4

Making An Omelet Without A Hammer

Turning P53 On, Off Could Avoid Radiation's Damage

By Anette Breindl
Science Editor

One of the ironies of cancer is that patients generally feel worse after treatment than before; radiation and chemotherapy induce widespread cell death, by activating the DNA damage response via p53.

P53's claim to fame is that it is a tumor suppressor, and so conventional wisdom holds that you can't make an omelet without breaking eggs: Chemotherapy's and radiation's side effects are "generally deemed an unfortunate but unavoidable consequence of the role p53 has in tumor suppression," a research team from the University of California at San Francisco wrote in the Sept. 7, 2006, issue of *Nature.*

But in its paper, the team presented data that suggested

See Radiation, Page 5

Metastatix Targeting CXCR4 Receptors In Cancer, HIV

By Jennifer Boggs
Staff Writer

With the recent completion of a $3.6 million Series A round, start-up firm Metastatix Inc. is ready to move toward the clinic with its first program, a chemokine inhibitor designed to prevent tumor growth and cancer metastasis by blocking the CXCR4 receptor.

The financing, led by Atlanta-based H.I.G. Ventures, is expected to "take us up to filing an investigational new drug application," said Metastatix President and CEO Tony Shuker, who, along with Dennis Liotta, Mike Natchus, Jim Snyder and Hyansuk Shim, founded the company last year as a spin-out of Emory University in Atlanta.

Emory licensed to Metastatix the initial technology to develop compounds targeting CXCR4, a cell surface receptor that the founding scientists had been investigating for

See Metastatix, Page 6

INSIDE:

CLINIC ROUNDUP

• **Acuity Pharmaceuticals Inc.**, of Philadelphia, disclosed positive data from its Phase II CARE trial for bevasiranib sodium (formerly Cand5), Acuity's lead compound for the treatment of wet age-related macular degeneration. Bevasiranib is a first-in-class small interfering RNA therapeutic designed to silence the genes that produce vascular endothelial growth factor. Though the study included no placebo arm, bevasiranib patients demonstrated stronger measures of visual acuity than predicted by the comparative placebo analysis The results with three doses in 129 patients were presented at the 24th Annual Meeting of the American Society of Retina Specialists in Cannes, France.

• **Can-Fite BioPharma Ltd.**, of Petach Tikva, Israel, plans to start a Phase II trial with CF101 for psoriasis. This adds to the other indications currently in various trial phases, including rheumatoid arthritis and dry eye syndrome. CF101 is a targeted therapy directed at cell surfaces.

• **Iomai Corp.**, of Gaithersburg, Md., received clearance from the FDA to launch a head-to-head trial comparing its needle-free, patch-based influenza vaccine with the traditional vaccine, delivered via intramuscular injection. The study will enroll up to 300 patients and begin later this month. The randomized, double-blind Phase I study will track the safety of the vaccinations and measure the immune response to both forms of the vaccine in healthy adults.

• **NitroMed Inc.**, of Lexington, Mass., said five presentations highlighted new findings related to BiDil (isosorbide dinitrate/hydralazine hydrochloride) at the 10th Annual Meeting of the Heart Failure Society of America in Seattle. BiDil, which was approved in June 2005 to treat African Americans with heart failure, demonstrated longer-term compliance with the fixed-dose combination drug, as well as continued efficacy, safety and tolerability. It also showed positive results in a particular genotype of the G protein beta 3-subunit, a survival benefit among post-menopausal women, and a significant decrease in cardiac death in the moderately severe heart failure population. A fifth presentation suggested there is a further benefit in patients treated with BiDil and beta blockers than those treated without beta blockers.

• **Peregrine Pharmaceuticals Inc.**, of Tustin, Calif., is completing plans to start a clinical trial in India of bavituximab in combination with chemotherapy. The trial is primarily designed to test the safety and tolerability of bavituximab with several standard chemotherapy regimens commonly used for treating major cancer types, including breast, lung and pancreatic cancers. The company is collaborating with an Indian contract research organization with recent success in managing a registration clinical trial for a novel monoclonal antibody therapeutic. Peregrine expects that results from this study, along with data from its ongoing U.S. Phase I cancers trial, will help support advancing bavituximab into Phase II cancer trials in 2007.

• **Pharmacopeia Inc.**, of Princeton, N.J., said **Schering-Plough Corp.**, of Kenilworth, N.J., initiated a Phase I clinical trial in the U.S. with a new compound identified through their collaboration. Pharmacopeia will receive a cash milestone payment from Schering-Plough as a result. (See *BioWorld Today*, Sept. 8, 2003.)

• **Synta Pharmaceuticals Corp.**, of Lexington, Mass., disclosed positive data from a Phase IIb study in metastatic melanoma for STA-4783, a first-in-class heat shock protein 70 inducer that activates natural killer cell-mediated tumor killing. In the double-blind, randomized, controlled trial in patients with Stage IV disease, STA-4783 plus paclitaxel doubled progression-free survival, the prospectively defined primary study endpoint, compared to paclitaxel alone.

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Brady Huggett, **(404) 262-5408**
Aaron Lorenzo, **(202) 719-7816**
Jennifer Boggs, **(404) 262-5427**
Kay Torrance, **(404) 262-5454**
Fax: **(404) 814-0759**
Randall Osborne, **(415) 384-0872**
Anette Breindl, **(304) 296-1160**

VP/Group Publisher
Donald R. Johnston, **(404) 262-5439**

Internet: http://www.bioworld.com

Avastin

Continued from page 1

NSCLC, which could add another $1 billion yearly to the bottom line.

Monday's sell-off aside, trouble from the FDA seems less likely in this indication, since the NSCLC application is based on the more solid endpoint of overall survival rate, rather than progression-free survival (PFS), as in the breast-cancer trial.

"Lung cancer [approval] is a very real possibility," said Raymond, who put Avastin's odds at 80 percent or greater in that indication. Raymond's rating on Genentech is "neutral," with a price target of $94.

Already approved for colorectal tumors, anti-VEGF Avastin (bevacizumab) sold $423 million in the U.S. during the second quarter, a 72 percent jump over the same period last year. (See *BioWorld Today*, July 13, 2006.)

Wall Street, though, had expected $15 million more from Avastin for the quarter, and Genentech needs the broadened label in order to hit the higher targets, especially with consumer groups pressuring the company about pricing. Avastin sold $1.1 billion last year, and many analysts believe the breast cancer indication will add at least another $1 billion, and possibly much more.

In breast cancer, at issue for the FDA are data from the E2100 trial, done by a network of researchers led by the Eastern Cooperative Oncology Group, which stopped the 685-patient study early because Genentech's antibody worked so well. The PFS in metastatic breast cancer patients given Avastin plus paclitaxel hit 11 months, compared to six months with paclitaxel alone.

But regulators, in their complete response letter to Genentech, want E2100's results audited as they would be if the company had sponsored the study – a demand Genentech didn't expect, although the firm's "language [two months ago] was hinting at a delay" and listeners might more wisely have expected something substantial, Raymond said.

During a July conference call related to second quarter earnings, Susan Desmond-Hellman, Genentech's president of product development, told investors that the company had not "established exactly what the [necessary] documentation will be, but in the middle of those negotiations [with the FDA], we became concerned about the timing."

Now, Genentech estimates the resubmission of its supplemental new drug application will not happen until the middle of next year. Then the six-month approval countdown will begin, which means the label expansion will take until at least the end of 2007.

E2100 tested patients who had either HER2-negative disease, or were HER2-positive and had either been previously treated with Genentech's breast-cancer therapy Herceptin (trastuzumab) or were deemed unsuitable for Herceptin, which sold $747.2 million last year, beating 2004 by 56 percent.

Herceptin is among the drugs that have been approved on the basis of unblinded PFS trials. Another is Taxol (paclitaxel), from Bristol-Myers Squibb Co., of New York. "Breast cancer has the bigger opportunity" of Avastin's two pending cancer indications, Raymond said.

Avastin, first approved in 2004 for colorectal cancer, has gained drug compendia listings for breast and lung cancers (in May 2006 and September 2005, respectively), which means insurance companies and Medicare will reimburse for them. The drug is widely used off label, but Genentech needs formal FDA clearance to rev sales more powerfully in those indications.

Analyst Bret Holley, with CIBC World Markets in New York, predicted Avastin's approval at the end of 2007 or the start of 2008, and deemed Genentech a "sector outperformer," though he reduced his price target to $96 from $98 on news of the delay and estimated U.S. sales of Avastin for breast cancer, if approved, could reach $800 million-plus by 2010.

Avastin is partnered with Basel, Switzerland-based F. Hoffmann-La Roche Ltd., which owns a majority of Genentech. ■

OTHER NEWS TO NOTE

• **Affinergy Inc.**, of Research Triangle Park, N.C., entered a multiyear development and license agreement with Synthes GmbH, of Solothurn, Switzerland. Affinergy will apply its site-specific biological delivery system in the exclusive arrangement on multiple product applications across the spine, trauma and craniomaxillofacial markets. Financial terms were not disclosed.

Oscient

Continued from page 1

Reviewers at the FDA are worried about Factive's association with serious skin rashes in treating sinusitis. There were 24 cases found in a recent analysis of the Adverse Event Reporting System, including serious allergic reactions and others requiring hospital treatment. They suspect that some of those cases might be Stevens-Johnson syndrome, a particularly serious rash, although no such definitive diagnoses were made.

In its briefing document to its advisory committee members, the agency concluded that the company has not demonstrated that Factive's benefit in sinusitis outweighs the "disproportionately higher risk of rash" and concern regarding severe cutaneous reactions that may occur in those patients.

Company representatives could not be reached for comment, but the supplemental new drug application for sinusitis includes data from five Phase III trials involving more than 1,800 patients who received Factive, 1,100 of whom took the drug for five days. In those trials, conducted by Factive's former owner, London-based GlaxoSmithKline plc, a 320-mg daily dose produced high clinical and bacteriologic response rates and met all predefined endpoints for non-inferiority.

In addition, the filing included a proposal for a post-approval epidemiological study to address safety concerns, but the FDA recommended that this study be completed prior to approval for sinusitis. When Oscient rejected that suggestion, the FDA first refused to accept the submission but eventually accepted it under protest.

The agency's briefing document suggested that any benefit Factive provides to sinusitis sufferers should be more clearly defined to weigh the magnitude of the product's risks. In its text, the FDA noted that its recommendations regarding Factive use for sinusitis "have been consistent across several submissions for this indication," and there remains concern that the incidence of skin reactions "is greater than comparator therapy" based on clinical trial findings and post-approval data.

According to Oscient's website, drug-related rash was reported in 2.8 percent of Factive patients in one trial of five-day sinusitis treatment and was more commonly observed in those younger than 40, especially females. In addition, the rate of rash increased with treatment longer than the maximum-labeled duration of 7 days.

Despite the FDA's negativity, Oscient's stock (NASDAQ:OSCI) gained 5 cents on Monday to close at $1.14.

A broader Factive label clearly could boost sales, said Hamed Khorsand, a senior research analyst with BWS Financial in Los Angeles. He said an expanded label encompassing the sinusitis and five-day CAP indications would add between $100 million and $150 million in revenue over the next five years. The product produced $2.6 million in sales in the last quarter and $11.9 million over the first six months of this year, reflecting its heavier seasonal use in the cooler months.

Khorsand said the rash frequency is "not a big deal," but he expressed concern over Oscient's protest to secure the meeting. His firm assigned no value to the advisory committee meeting, he said, adding that if it produces a negative outcome, the stock might see a reversal in today's gains, if that much. "I don't think the market should put any value on this meeting" until the outcome is known, Khorsand said.

He noted that the FDA's coming decision on the five-day CAP application, about which he's optimistic, represents a stronger catalyst for the stock.

Absent any new indications, Khorsand forecasted Factive sales of $100 million next year, well ahead of this year's probable $40 million to $45 million this year, as physicians become more and more comfortable with prescribing it. Oscient employs a 200-person sales force to market the drug.

The FDA is scheduled to complete its review for sinusitis by Dec. 15. ■

OTHER NEWS TO NOTE

• **Amphora Discovery Corp.**, of Research Triangle Park, N.C., formed two stand-alone business units to leverage its intellectual property and expertise. The first unit, Amphora Pharmaceuticals, is based in Los Altos, Calif., and will focus on the company's drug candidates and on creating partnerships. The second unit, Amphora Discovery, will work out of Durham, N.C., to use the company's drug discovery expertise through a contract research offering.

• **Atrium Biotechnologies Inc.**, of Quebec, acquired the assets of **Douglas Laboratories Canada**, of London, Ontario, which has annual revenues of about $5 million. Financial terms were not disclosed. Atrium markets active ingredients, specialty chemicals and health and nutrition products.

• **Codexis Inc.**, of Redwood City, Calif., achieved a development milestone under a research agreement with **Schering-Plough Corp.**, of Kenilworth, N.J. The collaboration is aimed at generating a new biocatalytic process to produce a key intermediate for an undisclosed human therapeutics compound, a program based on Codexis' MolecularBreeding pharmaceutical process re-engineering platform. It is expected to reduce manufacturing costs and environmental waste in the final production process.

• **Cortex Pharmaceuticals Inc.**, of Irvine, Calif., submitted a complete response to the FDA for each of the agency's points regarding certain toxicology issues on its lead Ampakine compound CX717, which is under a clinical hold. Prior to the freeze, the company had reported positive Phase IIa results in adult attention deficit hyperactivity disorder. The FDA is required to respond within 30 days as to whether it will remove or maintain the clinical hold.

Radiation

Continued from page 1

it might be possible to separate the baby from the bathwater, preventing radiation-induced p53 activation from bumping off cells left and right in response to DNA damage while preserving the protein's cancer-suppressing ability.

The scientists suspected that p53's tumor suppression might not be dependent on the DNA damage response because most DNA damage does not, in fact, cause cancer; senior author Gerard Evan likened using the DNA damage response for tumor suppression to "using a hammer to crack eggs."

Mice lacking p53 take months to develop tumors, despite not having a DNA damage response. And when they do, the tumors arise from a single cell, out of the millions that have had DNA damage in the interim. So "almost every cell that gets damaged does *not* form a tumor," Evan told *BioWorld Today*.

"P53 clearly didn't evolve as a cancer suppressor," said Evan, who is a professor of cancer biology at UCSF. The protein appeared early in evolution, in organisms that had neither the size nor the longevity that make it possible to develop cancer in the first place; Evan said that during the course of evolution, p53 may have been hijacked from its original role, so that "our tumor-suppressor response and our DNA-damage response are now routed through the same engine. That's the way it is, but that's not the way it has to be."

To test whether P53's tumor-suppressor abilities could be separated from its DNA-damage response, the researchers irradiated three groups of mice, with a dose that Evans said was similar to that received by the victims of the Hiroshima and Nagasaki bombs. The animals were then checked for damage due to the irradiation, and for the occurrence of tumors down the road.

All animals had a mutated version of p53 that was not normally responsive to DNA damage signals but could be rendered responsive to normal by a drug, though the drug itself did not activate the p53. One group never had p53 function restored; another group had p53 function restored for six days immediately prior to and during the irradiation; and a third group had no p53 function during the irradiation, but had p53 function restored a week later.

Mice with no functional p53 at any time did not show radiation-induced sickness, but did start developing tumors by about 4 months of age; none of the animals survived beyond about 10 months of age. (The maximal lifespan of nonirradiated p53 knockouts is about 12 months.)

Mice whose p53 function was restored during irradiation were in the worst shape; they developed radiation sickness including damaged intestinal lining and low white blood cell count. But their brief spell of p53 did not protect them from cancer; they started developing tumors, and died from them, at a rate that was indistinguishable from the group with no active p53.

In contrast, mice with p53 function restored one week after irradiation were comparatively lucky: Not only did they not suffer radiation sickness, but they developed tumors, on the average, about 100 days later than their p53 knockout brethren.

To investigate exactly how delayed p53 activation protects mice from radiation-induced cancer, the researchers next created inducible p53 animals that also lacked P19ARF protein. P19ARF activity "only occurs in cells with oncogenic mutations due to DNA damage," Evans explained, making it a likely candidate to activate p53. And indeed, P19ARF-deficient animals did not benefit from delayed p53 restoration.

The data suggested that if timing issues can be worked out, it might be possible to make cancer treatment less of an ordeal by briefly inhibiting p53 during chemotherapy or radiation. Such inhibition is advocated by some physicians, but the concern has been that by inhibiting p53, "you may just be storing up cancer for the future," Evan said. "Eventually, all the mice came down with cancer. So we're not giving as good protection as if we were keeping [p53] on all the time." Wild-type mice will rarely develop tumors and will live for two to three years.

But given that six days of p53 activation led to a delay in tumor formation of more than three months, a brief inactivation is not outside the realm of possibilities.

On the futuristic side, turning the body's relationship to p53 into an on-again, off-again pattern might have other uses as well.

"You can have all the benefits of a p53-negative lifestyle. You can go to a nuclear reactor, you can go to Mars, you might even age more slowly," since p53 activation also plays a role in the aging process. "And as long as you restore p53 intermittently, you can clean out incipient cancers."

The latter possibilities are "very, very speculative," Evan cautioned. "But it's certainly not inconsistent with our data." ■

OTHER NEWS TO NOTE

• **Genesis Bioventures Inc.**, of New York, and **Prion Development Laboratories**, of Buffalo, N.Y., agreed to extend the non-binding acquisition letter of intent, initially signed July 24, for an additional 60 days. GBI holds about 44 percent equity interest in PDL and intends to establish the diagnostics business as a wholly owned subsidiary.

• **Industrial Biotechnology Corp.**, of Sarasota, Fla., said it gained a bio-repellant technology through the acquisition of **Advanced Pheromone Technologies Inc.**, of Pullman, Wash., which holds a license to patents developed at Washington State University relating to the isolation and bacterial expression of a sesquiterpene synthase that produces the aphid alarm pheromone (E)-B-Farnesene. That pheromone offers a means of controlling direct aphid damage and preventing aphid-vectored viral diseases. Terms of the acquisition were not disclosed.

Metastatix

Continued from page 1

a few months before deciding that it was "a fantastic jumping off point for a commercial operation," Shuker said.

One of the founders, Liotta, previously had success with another compound emerging from Emory. He and two colleagues discovered Emtriva (emtricitabine), which Foster City, Calif.-based Gilead Sciences Inc. markets individually and as part of its once-daily, triple-drug regimen for HIV patients. Last year, Gilead purchased Emtriva's royalty interest from Emory in exchange for $525 million in cash. (See *BioWorld Today*, July 20, 2005.)

"The actual origins of [Metastatix] really were based on the fact that Dennis had been extraordinarily successful in converting academic research into commercial opportunities," Shuker told *BioWorld Today*, combined with the potential of CXCR4 as a biological target.

Naturally present on cells such as stem cells and liver cells, CXCR4 normally functions in growth and recovery. But, in cancer cells, it's produced "in much greater levels," Shuker said, which allows the diseased cells to "recruit blood vessels and move around the body."

It's that metastatic process, rather than the initial tumor, that often leads to the patient's death, he added.

Metastatix is developing compounds aimed at blocking CXCR4 from receiving a signal from a chemokine, specifically the SDF-I chemokine that's found in areas such as the liver, lungs and bone marrow. The hope is that, by interrupting that signal, the compound could prevent the cancer from spreading and, possibly, from growing.

"We've been able to demonstrate in animal models that we can do both of those things successfully," Shuker said.

Unless a patient is in a diseased state, CXCR4 is expressed in very low levels, so Metastatix expects the oral, small-molecule drugs to be "extremely safe," he added.

A CXCR4 blocker likely would be administered in combination with another cancer therapy.

In addition to its cancer program, Metastatix is investigating the CXCR4 as an entry target in T-tropic HIV infection.

In that instance, the CXCR4 receptors are found on the surface of T-lymphocytes. The HIV viral particle "has a molecular probe that latches onto the CXCR4 receptor and uses that to trigger a cascade of molecular events that end up with the virus injecting its genetic information into the cell," Shuker said.

Metastatix is working on a compound to block that entry point. That program is in preclinical development.

Shuker said the company, currently staffed by seven employees, is focused on taking its molecules as far through development as possible before considering alternatives such as partnerships.

"We have a lot of confidence in this program," Shuker said, "and we hope that will give us some pretty attractive options."

To date, Metastatix has raised more than $4 million, including a research grant from the Georgia Research Alliance followed by a half-million dollar seed round from Atlanta-based Centrosome Ventures, Georgia Venture Partners, also of Atlanta, and the State of Georgia. Those existing investors also participated in the Series A.

Other Series A investors included: The Aurora Funds, of Durham, N.C.; CM Capital, of Brisbane, Australia; SR One, of West Conshohocken, Pa.; and MedImmune Ventures, of Gaithersburg, Md.

Bruce Robertson, of H.I.G. was named Metastatix chairman, and Doug Gooding, of Aurora; Ad Rawcliffe, of SR One; and Wayne Hockmeyer, of MedImmune, joined the company's board. ■

OTHER NEWS TO NOTE

• **Somaxon Pharmaceuticals Inc.**, of San Diego, completed genotoxicity studies requested by the FDA for Silenor (doxepin HCl), its lead candidate for insomnia. The studies consisted of an in vitro bacterial reverse mutation test, an in vitro mammalian chromosomal aberration test and an in vivo rodent micronucleus test to assess for chromosomal damage. The company did not observe a signal indicative of genotoxicity in any of the assays, and soon plans to submit the data and request that it be allowed to submit carcinogenicity data as a post-approval commitment. Somaxon plans to file a new drug application in about a year.

• **Valeant Pharmaceuticals International**, of Costa Mesa, Calif., said the SEC is conducting an informal inquiry regarding events and circumstances surrounding trading in the company's common stock and the public release of data from its first pivotal Phase III trial of Viramidine. In addition, the SEC requested data regarding stock option grants since Jan. 1, 2000, and information about its lawsuit to recover bonuses paid to its company's former chairman and CEO and others in connection with the initial public offering of **Ribapharm Inc.**, also of Costa Mesa. Valeant said it is cooperating with the SEC in those matters.

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