THE CANCER LETTER

Vol. 32 No. 34
Sept. 29, 2006

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Advocates Ask Genentech To Release FDA Letter On Avastin For Breast Cancer

By Paul Goldberg

Companies that receive FDA requests for additional data rarely talk back.

Yet, earlier this month, Genentech Inc. took a less-traveled path and complained publicly that the agency's demands are depriving patients of Avastin for front-line treatment of metastatic breast cancer.

Now, patient groups are urging Genentech to release the agency's "complete response letter" in order to ascertain whether FDA is indeed

(Continued to page 2)

Capitol Hill:

COA's Attack On Republican Leadership Prompts Others To Declare: We Aren't COA

By Paul Goldberg

As Congress was winding down its work before the Sept. 29 recess, the Community Oncology Alliance sent out an urgent email to oncologists and administrators:

The "subject" line declared: "Republican Leadership Not Supporting Cancer Care."

"By and large, the Republican House and Senate leadership have turned a deaf ear to the crisis facing cancer patients in this country, as has CMS," Steve Coplon, COA executive director, wrote in an email broadcast at 7:33 p.m. on Sept. 19. "We need congressional leadership that will not sit idly by as CMS dismantles the cancer care delivery system in this country."

Though COA has a relatively small number of members, its emails reach a much larger audience, and in a matter of minutes, Washington lobbyists for several cancer groups were staring at Coplon's fiery epistle.

By the morning, these lobbyists placed urgent calls to the White House and the Republican Congressional leaders. They did so not because they agreed with Coplon's message, but out of fear that the leaders of the majority party might confuse them with COA, a group funded by community oncologists and pharmaceutical companies.

"We had to get some differentiation out there," said a lobbyist who placed one such call. "I am sure they heard from several lobbyists at about the same time."

The American Cancer Society had a particularly urgent need to show that it had no relationship with COA. That's because Coplon's email appeared to suggest that an ACS event that taking place on the Mall directly in front of

(Continued to page 6)

Drug Development:
NBCC's Visco:
"The Goal Is Not
To Rush Drugs Out
To The Public"
. . . Page 2

In the Cancer Centers:
Young To Step Down
As Fox Chase President
. . . Page 4

Starr Foundation Gives
$100 Million To Form
Cancer Consortium
. . . Page 5

NCI Awards Grants
For Proteomic Tech
. . . Page 5

Funding Opportunities:
RFA, RFP Available
. . . Page 7

Company Declines To Release FDA Letter Seeking More Data

(Continued from page 1)

making frivolous demands. Earlier this week, advocates representing three groups that coincide with the likely markets for Avastin posed a series of questions to Genentech, NCI, FDA, and the Eastern Cooperative Oncology Group.

"Why is this FDA letter to Genentech not publicly available when the information used by Genentech to file their application was derived—at least partially if not substantially—from tax supported NCI clinical trials?" the advocates said in a letter dated Sept. 28.

Of all the recipients of the letter, only Genentech is in a position to release the FDA document. The company has shared the document with a small number of people. For example, Kathy Miller, the principal investigator of the ECOG trial and an oncologist at the University of Indiana School of Medicine, said she has not seen the document.

Though advocates who signed the letter represent relatively small groups, all of them have had long-standing working relationships with Genentech, FDA, and NCI, as well as expertise in trial design and design of expanded access programs. They are:

—Robert Erwin, president of the Marti Nelson Cancer Foundation, who played a role in setting up expanded access programs for Herceptin, Erbitux and Avastin.

—Nancy Roach, president of Colorectal Cancer Coalition, who took part in Erbitux and Avastin discussions between sponsors and FDA, and

—Jane Reese-Coulbourne, an advocate and consultant who serves on the board of the Lung Cancer Alliance. Reese-Coulbourne has been involved in expanded access programs for Herceptin, Eloxatin, Velcade, and Iressa.

The three advocates aren't alone. Fran Visco, president of the National Breast Cancer Coalition, didn't sign the letter, but said in an interview that Genentech should release the FDA document.

"The goal is not to rush drugs out to the public," Visco said. "The goal is to save lives, and if we are going to start approving drugs and making them available on intermediate endpoints—not survival—then we better have a much higher level of evidence in order to do that.

"I don't know if what FDA is requesting is reasonable, because I don't know what the letter says. So it's pretty difficult for advocates to demand that FDA do something differently when we don't know what they are doing in the first place."

Ellen Stovall, president and CEO of the National Coalition for Cancer Survivorship, agrees that the FDA document should be released. "

"Many of us in the community view Genentech's history of working with groups like NBCC and others in designing some of their breast cancer trials as a good model for how to work with informed advocates in the drug development process," Stovall said. "We now look to them to continue that behavior by being forthcoming with any information that patients need to assess this situation."

Erwin said the public has financed the ECOG trial and therefore is entitled to know what FDA has to say about it.

"Transparency in the operations of government agencies is a good thing, and it should not be a mystery to the public how decisions are made, policies established, and tax money allocated by the FDA and the NCI," Erwin said in an interview. "It is obvious to me that Genentech should just release the letter from FDA to remove any uncertainty about the quality of their product and to replace speculation with facts that can be examined in the open.

"We believe that these issues are broader than any one product, company or clinical trial, and open and thorough discussion can be a good thing for cancer patients," Erwin said.

Asked by The Cancer Letter to release the document, Genentech declined.

THE CANCER LETTER

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Founded Dec. 21, 1973, by Jerry D. Boyd.

"We are not releasing the Complete Response Letter at this time," Megan Pace, a company spokesman, said in an email to The Cancer Letter. "We are in discussions with the FDA and ECOG about the requests to determine next steps in the process. We have long-standing and productive relationships with patient advocates and value their feedback.

"We are working on a response to the questions we can address."

Genentech developed its portfolio with unprecedented help from patient groups, particularly NBCC. The coalition helped re-design Genentech's clinical trials of Herceptin and accelerated accrual in trials of that drug for the metastatic breast cancer indication. Advocates and industry insiders say that now that Genentech's biologics are both high-priced and widely used, the company can't afford to alienate them.

"Genentech has done a lot of things right, which is why advocates are so willing to work with them," Erwin said. "Now they must continue to do things right if they want to maintain this relationship."

Gentech Statement "Started This Whole Thing"

Industry insiders say the content of the FDA letter is important because it would likely shed light on the agency's thinking about trials that measure delays in progression of disease.

Also, it's likely that the document also contains information related to the agency's decision to tighten requirements for trials conducted by clinical trials cooperative groups. In the past, trials conducted by commercial sponsors had to have central review of patients' scans, while group-sponsored trials didn't.

Agency officials said that this double standard was tolerable when the agency relied on trials that measured survival. However, as the agency switches to time to progression as an approval criterion in some indications, a more rigorous, uniform review of scans is required (The Cancer Letter, Sept. 15). However, central review is expensive, and clinical trialists wonder how the financially starved system would pay for such review.

Genentech's press release Sept. 11 and its subsequent conference call with patient advocates did little more than tease the information-hungry oncology insiders.

"The FDA has communicated to Genentech that they now expect the information from this cooperative group trial to be audited and summarized in a manner typically used for a company-sponsored trial," the company said in a statement announcing the FDA response to the supplemental Biologics License Application.

"This expectation is different from the understanding that Genentech had when the sBLA was submitted and will require the re-collection of information from ECOG study sites."

The statement quotes Hal Barron, Genentech's chief medical officer and senior vice president, stating that the agency's action "will cause a delay in the review of our application, as there is a great unmet medical need for women with metastatic breast cancer."

"Genentech really started this whole thing," said Reese-Coulbourne. "We were concerned that if somebody didn't say something, it would just get swept under the rug, and I think that there are some policies people may want to think about changing, like why would this letter be a secret? I don't get how this would be a real problem. It doesn't contain secrets. It's no different than if you had an [Oncologic Drugs Advisory Committee meeting]. This way, if the company wants to make claims about how they have been wronged, we could be the judge of that. Because we'd have data. But now we don't have any information."

Reese-Coulbourne said she called several of her industry contacts before signing the advocates' letter.

"I said, 'So, what do you think?' And one person hesitated and said, 'If it were our company, we would just go give the money to a cooperative group to gather the rest of the data and be done with it,'" Reese-Coulbourne said.

Genentech's claim that it has been given a different "understanding" in pre-approval meetings with FDA isn't unusual. Sponsors who fail to get what they want from FDA frequently claim to have been misinformed by the agency.

In this case, any such understanding by Genentech had to have been based on non-binding advice from the agency. Only applications that go through Special Protocol Assessment at the end of phase II testing get to sign a binding agreement with FDA. The Avastin breast cancer study wasn't designed to support registration. There was no "end of phase II meeting," no Special Protocol Assessment.

Nonetheless, the data were good enough to trigger a standing ovation at the 2005 annual meeting of the American Society of Clinical Oncology and to convince Genentech to support an NCI study and file an sBLA for the indication.

Sources familiar with the data said the findings are unusually robust, but no new data have been released to the public since the 2005 ASCO.

In May, the USPDI Compendium listed Avastin for the treatment of HER2 negative metastatic breast cancer in combination with paclitaxel. The listing supports Medicare reimbursement and helps facilitate reimbursement with private payers.

Without an approved sBLA, the company is precluded from marketing the drug for breast cancer, and, some doctors say, CMS carriers and private insurers in some cases have to be challenged before they pay for the drug.

The monthly wholesale acquisition price of Avastin for the approved indication of first-line metastatic colorectal cancer is about $4,400.

The company said it is yet to set the price of the drug for metastatic breast cancer, but based on the per-month dose used in the E2100 study (10mg/kg every two weeks), the WAC of Avastin for metastatic breast cancer is approximately $7,700.

The advocates' letter is posted at www.cancerletter.com.

In the Cancer Centers:

Young Plans To Step Down As Fox Chase President

By Kirsten Boyd Goldberg

Robert Young, president and CEO of Fox Chase Cancer Center since 1988, said he plans to step down next year following a search for his successor.

Young, 66, said it was time for the center to recruit new leadership. He began succession planning discussions with the Board of Directors last year, following renewal of the center's NCI core grant.

"I want to make sure that the institution is optimally positioned for the next 20 years of its growth," Young said to The Cancer Letter. "Although I have plenty of energy, [reviewers] keep writing in our pink sheets that they want to know what the next leadership of the place is going to be. That's understandable.

"I also have a personal philosophy that more institutions get screwed up by people staying too long than people leaving too early," Young said. "It's time for somebody to come in and take a fresh look."

Board Chairman William Avery is head of the search committee. "The Board of Directors is committed to a search process that ensures success for the next president and this institute," Avery said. "Bob is completely devoted to Fox Chase. We are most pleased he has agreed to stay on until the new president is recruited and in place. We may well utilize him in a continuing role at Fox Chase in a capacity to be decided at a later date depending on the needs of the center."

Between 1988 and 2006, the number of Fox Chase employees increased 77 percent, from 1,300 to 2,300. The budget increased 300 percent, from $75 million to $300 million. The number of new patients increased 442 percent, from 1,200 to 6,500. The center's NCI core grant went up 235 percent, from $17 million to $57 million (in 2004).

The center developed a 25-year expansion plan that calls for tripling the size of the institution, and recently received final approval for construction of a 125,000-square-foot Cancer Research Pavilion. A fundraising campaign for $100 million is halfway to its goal, having raised $52 million.

"It's really a perfect time to create the transition," Young said. "Our desire is to have somebody recruited and in place with enough time to get settled before they have to turn around and present a new core grant in 2009."

The target date for the recruitment is next July, but Young said he hasn't made any plans and will remain on the job until the president is hired. "I've not accepted some new job somewhere," Young said. "In fact, the interesting thing for me personally is, what am I going to do next? I'm not going to retire. I've got a lot of energy, and I think I've got a lot of things I'd like to do and say."

Following the successful recruitment, Young plans to take a six-month sabbatical "to get out of the new person's hair" and consider his options, he said.

The presidency of Fox Chase "is a great job," Young said. "It's probably a position that offers somebody more control over the destiny of the institution than any other one I know of in the country. All of the space, all of the recruitment, all of the appointments, are essentially under the control of the president and CEO. It provides enormous flexibility for a leader."

With the building plans and city approvals finalized, the next president "will just be faced with the challenge of building it, filling it, and creating the next phase of Fox Chase history."

The board plans a national and international search. "There has been a long history in this institution of going outside for new leadership," Young said. "While there are some very credible internal candidates, I think the history has generally been to look outside, and given the duration of the leadership internally, that's probably even a stronger reason to look outside. But they will look for the best possible person, no matter where they come from."

Young has been a fixture as an advisor to NCI,

the American Society of Clinical Oncology, and other organizations. He has served continuously on the NCI Board of Scientific Advisors since its inception in 1996. His term as BSA chairman is scheduled to end in July.

Young said he's optimistic about the future of federal funding of biomedical research. "We're in a sort of trough here," he said. "I feel, based on no data, but just having hung around in this business a long time, that the FY07 budget will be the low-water mark for the time being.

"I see a lot of evidence [for future budget increases]," he said. "It's not just Sen. Arlen Specter and Sen. Tom Harkin [advocating for NIH], but also Mike Castle on the House side, pushing for a restoration of budget increases that would at least maintain the impact of the NIH budget doubling and allow for the biomedical research inflation index to continue to play a role. I think that concept is going to get more and more traction.

"I think that [NIH Director] Elias Zerhouni is trying to make the case to the public about impact of NIH biomedical research in general, and I think he's doing a good job," Young said. "The NIH reauthorization bill, although it's not perfect in everybody's mind, defines a little bit more clearly the relationship between the various institutes and the NIH in general. I view the change in that legislation to increase the support for the NIH common fund, but only in the context of the increase in the NIH budget in general, to be an extremely positive change. I think that reflects the growing realization that we're going to have to continue to invest in biomedical research."

Young is first vice president and a director-at-large of the American Cancer Society's national board. He is chairman of the board of the National Comprehensive Cancer Network. He was a president of ASCO and the International Gynecologic Cancer Society.

Born in Columbus, Ohio, Young received a B.Sc. degree in zoology in 1960 from Ohio State University and an M.D. in 1965 from Cornell University Medical College. Following an internship at New York Hospital, he completed residency at NCI and Yale-New Haven Medical Center.

Young came to Fox Chase from NCI, where he was associate director of the centers and community oncology program. He served as chief of the NCI Medicine Branch for 14 years.

* * *

STARR FOUNDATION announced a $100-million grant to create a cancer consortium to coordinate the efforts of five research institutions: **The Broad Institute** of MIT and Harvard, **Cold Spring Harbor Laboratory**, **Memorial Sloan-Kettering Cancer Center**, **The Rockefeller University**, and **Weill Cornell Medical College**.

The five will collaborate on research to understand cancer at its most fundamental levels and develop new approaches to prevention, diagnosis, and treatment. The program will be called the Starr Cancer Consortium

"The opening years of the 21st century have brought dramatic advances in understanding cancer and in putting new discoveries to work for the people who need it most," said **Maurice Greenberg**, chairman of The Starr Foundation. "Our goal in launching the Starr Cancer Consortium is to bring these exceptional institutions together in a manner that assures maximum efficiency and the greatest firepower in targeting cancer. This will enable us to achieve tangible results more quickly and decisively than any one or two members of the consortium could accomplish working alone."

The funding will be earmarked specifically for joint projects involving two or more institutions, including initiatives currently underway. Key areas of focus will include:

—Creation or accelerated development of powerful technology platforms designed to unravel the genetic and molecular basis of cancers

—Application of these technologies in joint projects aimed at developing new and highly effective approaches to diagnosis and treatment

—Support for basic biological research to provide insights into the fundamental molecular and cellular processes underlying cancer

Activities selected for funding through the Starr Cancer Consortium will be determined by an executive committee including leaders of the five institutions: **Eric Lander** of the Broad Institute, **Bruce Stillman** of CSHL, **Harold Varmus** of MSKCC, **Paul Nurse** of Rockefeller and **Antonio Gotto Jr**., of WCMC.

* * *

NCI announced funding for a major component of its $104 million, five-year Clinical Proteomic Technologies Initiative for Cancer. Awards totaling $35.5 million over five years will establish a collaborative network of five Clinical Proteomic Technology Assessment for Cancer teams.

Awardees and PIs are: Broad Institute of MIT and Harvard, **Steven Carr**; University of California, San Francisco/Lawrence Berkeley National Laboratory, **Susan Fisher**; Vanderbilt University School of Medicine, **Daniel Liebler**; Purdue University, **Fred Regnier**; and Memorial Sloan-Kettering Cancer Center, **Paul Tempst**.

COA Says GOP Leadership Doesn't Support Cancer Care

(Continued from page 1)

the U.S. Capitol was connected with COA's agenda.

"On Wednesday, September 20th, representatives from community cancer care will be delivering a message to the Congress that the Republican leadership has not delivered on its promise to support cancer care in this country," Coplon wrote.

"Against this backdrop, over 10,000 cancer patients and survivors will be in Washington, D.C., rallying for cancer care. In the coming weeks before the election, COA will be providing community cancer clinics with letters and materials to engage their patients, caregivers, survivors, and staff to only vote for those Members of Congress supporting cancer care."

In a flurry of public statements and private communications, ACS, the American Society of Clinical Oncology, the Oncology Nursing Society, and US Oncology declared that they were committed to working with both parties and that they should not be confused with COA.

"ASCO is committed to working in good faith—and in an effective manner—with both parties and their leadership in both Houses of Congress, as well as CMS and other responsible cancer community advocates on behalf of cancer patients throughout the country," wrote Joseph Bailes, the society's interim executive vice president and CEO.

Bailes's email, sent out at 9:11 a.m. on Sept. 20, included the text of Coplon's letter. "In no way whatsoever does ASCO support or endorse the views expressed below," Bailes wrote.

In an email sent out two and a half hours later, ACS established that the 10,000 cancer survivors were there for a society function and artfully avoided mentioning COA by name.

"A number of cancer groups are carrying messages to Congress today," ACS said in a statement. "We would like you know that the 10,000 American Cancer Society Cancer Action Network (ACS CAN) volunteers gathered on the Mall today for Celebration on the Hill 2006 are meeting with their Members of Congress to make only three requests.

"Support the National Breast and Cervical Cancer Early Detection Program Reauthorization Act (S. 1867/ H.R. 5742) to reauthorize and provide more funding for this important program at the Centers for Disease Control and Prevention.

"Support at least a 5% funding increase for the National Cancer Institute to ensure continued progress in life-saving cancer research.

"Sign the Congressional Cancer Promise to support key steps that Congress can take in the short term to accelerate the fight against Americans most feared disease…These are the only issues on the ACS CAN legislative agenda."

US Oncology described Coplon's letter as "an unfortunate and unhelpful declaration" and broadcast it to its entire staff and affiliated practices.

"We have been working for several months with the Congressional Leadership and the broad cancer care community to structure and attach legislation related to ASP Prompt Pay Discounts, 2Q Lag issues and the deep reductions in Imaging payments to "must pass" legislation in this year," wrote Dan Cohen, US Oncology senior vice president, government relations and public policy.

"Ideally, our efforts would be included in legislation passed prior to the Sept. 29 Congressional recess. As we have communicated in the past, this year is challenging.

"Still, we have been making significant progress and have reasonable hopes of some successes this year. With immediate intervention, meetings scheduled for this week with Congressional healthcare leaders remain in place and we will continue to work with ALL Members of Congress in the coming days.

"Now is not the time to keep score or to accuse anyone of bad faith," Cohen wrote. "The COA communication has put community oncology's agenda at risk during these final days of Session."

The Oncology Nursing Society urged both the Republican and the Democratic leadership not to confuse it with COA.

"We are writing to express our deep disappointment regarding a statement issued by the Community Oncology Alliance," the ONS letter said. "Please know that ONS is in no way affiliated with COA and does not subscribe, endorse, or in any way support the COA communique."

Strategic considerations aside, COA can likely support one party over another. The group is organized under section 501(c) (6) of the federal tax code, which makes it similar to a chamber of commerce. COA members can't deduct their contributions to the group, but are allowed to claim a portion of dues as a write-off. Also, COA operated a political action committee.

According to information on its Web site (http://communityoncology.org), COA members pay $2,000 a year in dues and another $500 a year in contributions

to a political action committee. Also, the group has five corporate sponsors, who pay $75,000 to $250,000 a year each.

The group's Web site identifies these corporate sponsors: Bayer Oncology, Genomic Health, Onyx Pharmaceuticals, Oncology Therapeutics Network, and International Oncology Network.

Washington insiders noted that the bulk of COA's Washington lobbying is done by Harold Ford Sr., formerly a Tennessee Democratic House member, whose son, Harold Ford Jr., a current House member, is running for a Tennessee Senate seat. Calls to Harold Ford Sr.'s Memphis office weren't returned.

COA is also represented by the Livingston Group, a lobbying firm established by former Louisiana Republican House Member Bob Livingston.

Coplon, the CEO of the West Clinic of Memphis, couldn't be reached for comment. COA's tax filings aren't posted on publicly available databases.

The text of Coplon's Sept. 19 email follows:

In its four years of existence, the Community Oncology Alliance (COA) has not supported a political party. Rather, COA has supported those Members of Congress who have supported community cancer care. COA is about protecting patients' rights, not about partisan politics.

However, it is now obvious that the Republican leadership in the Congress is not supporting community cancer care. Instead, they have sat idly by while the Centers for Medicare & Medicaid Services (CMS) continues to ratchet down Medicare funding for cancer care. Community cancer clinics report to us virtually every day on the increasing disruptions to cancer care in this country. This situation will be a true crisis next year as an additional $400-500 million will be cut from Medicare funding for cancer care.

On Wednesday, September 20th, representatives from community cancer care will be delivering a message to the Congress that the Republican leadership has not delivered on its promise to support cancer care in this country.

Against this backdrop, over 10,000 cancer patients and survivors will be in Washington, DC rallying for cancer care. In the coming weeks before the election, COA will be providing community cancer clinics with letters and materials to engage their patients, caregivers, survivors, and staff to only vote for those Members of Congress supporting cancer care.

With an estimated average of 30,000 patients, survivors, and professional staff per congressional district, the voice of community cancer care will be heard on Election Day.

We do appreciate the Herculean efforts of certain Members in leadership positions in the Congress. Most notably, Representatives Nancy Johnson, Jim Ramstad, and Charlie Norwood have been vocal supporters of cancer care, as have many of the Republican and Democratic Members of the House of Representatives. In the Senate, Senator Arlen Specter, himself a cancer survivor, has stood up for cancer care. However, by and large, the Republican House and Senate leadership have turned a deaf ear to the crisis facing cancer patients in this country, as has CMS. Cancer patients in this country are increasingly facing delays in treatment, receiving disjointed cancer care, and deciding to forego treatment.

COA will be sending out materials for you to distribute to your patients, caregivers, survivors, and staff about supporting only those candidates who support cancer care. We need congressional leadership that will not sit idly by as CMS dismantles the cancer care delivery system in this country.

If the congressional leadership does not act before the elections, it is time for a change!

Funding Opportunities:

RFA, RFP Available

RFA-CA-07-502: Pediatric Phase 1/Pilot Consortium. U01. Letters of Intent Receipt Date: Oct. 30. Application Receipt Date: Nov. 30. Full text: http://grants.nih.gov/grants/guide/rfa-files/RFA-CA-07-502.html. Inquiries: Malcolm Smith, 301-496-2522; smithm@ctep.nci.nih.gov.

RFP N02-CM-77000-16: Support Services for the Pharmaceutical Management Branch, CTEP. Response Due Date: Nov. 2. Full text: http://www.fbodaily.com/archive/2006/09-September/20-Sep-2006/FBO-01146627.htm. Inquiries: Annmarie Keane keanea@mail.nih.gov.

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- Multidisciplinary Approaches to the Treatment of Head & Neck Cancer
- New Therapies for Renal Cancer
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- Roundtable: Cancer Care in the 21st Century – Reality and Promise
- Roundtable: Oncology Practice Today – Quality Evaluation, Coverage, and Reimbursement

NCCN Regional Guidelines Symposia

- NCCN Clinical Practice Guidelines in Oncology™ Breast Cancer
- NCCN Clinical Practice Guidelines in Oncology™ Colorectal Cancers
- NCCN Clinical Practice Guidelines in Oncology™ Non-Small Cell Lung Cancer
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WEB-N-0126-0906

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THE CANCER LETTER

Vol. 21 No. 8
Sept. 2006

Business & Regulatory Report

Product Approvals & Applications:

FDA Approves Amgen's Panitumumab For EGFr Metastatic Colorectal Cancer

Amgen (NASDAQ: AMGN) said FDA approved Vectibix (panitumumab), the first entirely human monoclonal antibody for the treatment of patients with epidermal growth factor receptor-expressing metastatic colorectal cancer after disease progression on, or following fluoropyrimidine-, oxaliplatin-, and irinotecan- containing chemotherapy regimens.

The FDA approval of Vectibix was based on a progression-free survival endpoint. Vectibix is the first anti-EGFr antibody shown to significantly

(Continued to page 2)

Oncology Management:

US Oncology, MPII To Form Tissue Bank To Handle Biospecimen Collection

US Oncology of Houston said it has entered into a venture with the **Molecular Profiling Institute Inc.** of Phoenix to create the Tissue Banking and Analysis Center Inc.

While serving research, pharmaceutical and diagnostic clients, TBAC would handle the large volume of biospecimen collection and analytical services for US Oncology, the company said.

TBAC, in collaboration with US Oncology and AmeriPath, a network of pathologists in cancer diagnosis, would provide tissue samples, clinical trial design, biomarker development and esoteric testing under the guidance of scientists from government and industry.

"The tools exist to target the treatment approach that works best for the genetic makeup of individual patient tumors, but those tools aren't currently available in many community care settings," said Daniel Von Hoff, clinical director of the Translational Genomics Research Institute, who also plays a role in developing TBAC.

"Nor do individual academic medical centers have the volume of patients of a national network like US Oncology," Von Hoff said. "This is a relationship that benefits both sides of the equation, enabling more personalized oncology treatment. This is the kind of approach that may lead to the identification of specific therapeutic fits for the most aggressive kind of cancers."

In another development, **US Oncology** said it has begun OncologyRx Care Advantage, an oncology specialty pharmacy in Texas, Washington,

(Continued to page 8)

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Product Approvals:
GSK Sumbits NDA For Tykerb For HER2 Metastatic Breast Ca
. . . Page 2

Clinical Trials:
Allos Begins Phase II For Antifolate PDX In T-Cell Lymphoma
. . . Page 3

Deals & Collaborations:
MedImmune, Infinity Agree To Develop HSP90 Drugs
. . . Page 6

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Amgen Says It Will Expand Patient Assistance Program

(Continued from page 1)

improve progression-free survival in patients with metastatic colorectal cancer. Currently no data are available that demonstrate an improvement in disease-related symptoms or increased survival with Vectibix. Vectibix can be administered intravenously once every two weeks.

Vectibix is expected to be commercially available in early-to-mid October and will be priced at approximately 20 percent less than the other anti-EGFr antibody currently on the market, the company said.

Marketing applications were simultaneously submitted to the European Medicines Agency in April and Health Canada, Australia, and Switzerland in May. Vectibix is being evaluated in clinical trials as both a monotherapy and in combination with other agents for the treatment of various types of cancer.

Amgen has expanded its patient assistance program. Patients who are uninsured, underinsured, or unable to afford their insurance co-payments can receive financial support for Amgen's cancer medicines, including Vectibix. The Amgen Oncology Assistance program will be available for U.S. cancer patients and will launch in October, the company said.

* * *

AMDL Inc. (AMEX:ADL) of Tustin, Calif., said **Jade Pharmaceutical Inc**., the registration agent in China for AMDL, has submitted an application with the China State FDA for marketing approval of its AMDL DR-70 cancer test.

The SDFA has begun the approval process and DR-70 is undergoing standard product review by the Beijing Institute of Medical Device Quality Supervision and Inspection Center, the company said.

* * *

Callisto Pharmaceuticals Inc. (AMEX:KAL) of New York said FDA has granted orphan drug designation to Atiprimod for carcinoid tumors.

Atiprimod, a small molecule antiangiogenic drug, also is being developed for relapsed multiple myeloma, the company said. Callisto said it would begin a phase II trial for advanced carcinoid cancer soon.

* * *

Cephalon Inc. (NASDAQ:CEPH) of Frazer, Pa., said it has received approval from FDA to market Fentora (fentanyl buccal tablet) [C-II] for breakthrough cancer pain in patients already receiving and are tolerant to opioid therapy.

Cephalon said it would market the agent in five dosage strengths: 100, 200, 400, 600, and 800 micrograms.

* * *

GlaxoSmithKline plc (NYSE:GSK) of Philadelphia and London said it has completed the submission of a New Drug Application to market Tykerb (lapatinib ditosylate), in combination with Xeloda (capecitabine), for advanced or metastatic HER2 positive breast cancer in patients with prior therapy, including Herceptin (trastuzumab).

The compound has been granted Fast-Track status by FDA in that patient population, the company said. Tykerb is a small molecule dual kinase inhibitor developed by GSK as an oral therapy.

A planned interim analysis of the phase III international, multicenter, open-label trial randomized 324 women who had advanced or metastatic breast cancer with documented HER2 overexpression and whose disease progressed following treatment with Herceptin and other cancer therapies, to Tykerb and Xeloda or Xeloda alone, the company said. The combination of Tykerb and Xeloda versus Xeloda alone nearly doubled median time to progression (36.7 weeks [8.5 months] in the combination arm versus 19.1 weeks [4.4 months] with Xeloda alone, p=0.00008).

The most common adverse events (>25 percent) during therapy with Tykerb plus Xeloda were gastrointestinal or dermatologic, the company said.. The majority of adverse events and laboratory abnormalities

THE CANCER LETTER

Member, Newsletter and Electronic Publishers Association

World Wide Web: http://www.cancerletter.com

Business & Regulatory Report
Publisher: Kirsten Boyd Goldberg
Editor: Paul Goldberg
Editorial Assistant: Shelley Whitmore Wolfe

Editorial: 202-362-1809 Fax: 202-318-4030
PO Box 9905, Washington DC 20016

Customer Service: 800-513-7042
PO Box 40724, Nashville TN 37204-0724

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were mild to moderate in severity.

The principal investigator is Charles Geyer, director of breast medical oncology at Allegheny General Hospital, Pittsburgh.

In March 2006, an IDMC made a unanimous recommendation to stop enrollment of the study based on the early success of the trial, the company said. The study met its primary endpoint of time to disease progression, and exceeded the predetermined stopping criteria outlined in the committee charter. GSK stopped enrollment in April.

* * *

Millennium Pharmaceuticals Inc. (NASDAQ: MLNM) of Cambridge, Mass., said FDA granted Priority Review designation to its supplemental new drug application for Velcade for relapsed mantle cell lymphoma.

The submission was based on final phase II data from the PINNACLE study, a multi-center studies in relapsed MCL, which showed a 33 percent overall response rate and an 8 percent complete response rate, the company said. The median duration of response was 9.2 months, and 13.5 months for those who achieved a complete response. The results are similar to those of four investigator initiated phase II trials where overall response rates of 30 to 40 percent with single-agent Velcade were established, the company said.

Velcade is approved for multiple myeloma patients who have received at least one prior therapy.

In another development, Millennium said it has entered into an agreement to acquire **AnorMED Inc.** (Nasdaq: ANOR; TSX: AOM) of Canada.

Under the agreement approved by the boards of directors of both companies and the largest shareholder of AnorMED, Millennium said it would tender a cash offer to acquire the shares of AnorMED stock at a price of U.S. $12.00 per outstanding share, for a total purchase price of $515 million.

Clinical Trials:

Allos Begins Phase II Trial Of Antifolate For Lymphoma

Allos Therapeutics Inc. (NASDAQ:ALTH) of Westminster, Colo., said it has begun PROPEL, a phase II study of the antifolate PDX (pralatrexate) with vitamin B12 and folic acid supplementation for relapsed or refractory peripheral T-cell lymphoma.

PROPEL, or Pralatrexate in Patients with Relapsed Or Refractory PEripheral T-cell Lymphoma, is an international, multi-center, open-label, single-arm 100 patient study, that would treat with 30 mg/m^2 of PDX once every week for six weeks followed by one week of rest per cycle, the company said. The primary endpoint is objective response rate. Secondary endpoints include duration of response, progression-free survival, and overall survival.

In August, Allos said it reached agreement with FDA under the Special Protocol Assessment process on the trial design.

The study would take place at 35 centers in the U.S., Canada, and Europe, and would take 18 to 24 months to complete, the company said.

"To date pralatrexate has achieved a high complete response rate that has proven very durable among PTCL patients with a historically very poor prognosis," said Owen O'Connor, international study chairman and head of laboratory of experimental therapeutics for lymphoproliferative malignancies, lymphoma and development chemotherapy services, Memorial Sloan-Kettering Cancer Center.

Interim results from a phase I/II study at Memorial of PDX relapsed or refractory non-Hodgkin's lymphoma and Hodgkin's disease demonstrated preliminary evidence of activity for subtypes of aggressive and chemotherapy resistant T-cell lymphoma, the company said. Four of seven evaluable patients with T-cell lymphoma achieved a complete response following treatment with PDX, despite having failed multiple prior therapies. The addition of vitamins to the treatment regimen appeared to successfully mitigate the previously established dose limiting toxicity of stomatitis.

* * *

Astex Therapeutics of Cambridge, England, said it had begun dosing in a phase I/IIa trial for AT9283, an inhibitor of Aurora kinases.

The trial, conducted at M.D. Anderson Cancer Center, would assess safety and tolerability and efficacy for hematological malignancies, the company said. Astex said it would initiate additional clinical studies in North America and Europe within the next six months.

In addition to its inhibition of Aurora kinases, AT9283 is highly active against the Gleevec resistant T315I abl mutation and could be beneficial when treatment with agents such as Gleevec and Sprycel has failed, the company said.

The inhibitor also works against JAK-2, and the present trial will assess its activity for myeloproliferative disorders associated with activating mutations of the protein, the company said.

* * *

EntreMed Inc. (NASDAQ:ENMD) of Rockville,

Md., said it has begun a phase I study of MKC-1 for hematological malignancies.

Francis Giles, professor in the Department of Leukemia at M.D. Anderson Cancer Center, will conduct the study, the company said. MKC-1 is also in a phase II study for metastatic breast cancer.

* * *

Exelixis Inc. (NASDAQ:EXEL) of South San Francisco said it had begun a phase II trial of XL647, an orally bioavailable small molecule inhibitor of the HER2, EGF, VEGF, and EphB4 receptor tyrosine kinases, for advanced non-small cell lung cancer that has not been treated with chemotherapy.

Although the individual RTKs are targets for approved therapies, XL647 inhibits all three targets simultaneously, the company said.

In the proof-of-concept trial, participants must meet at least two of the following criteria: Asian, female, non-smoker, or adenocarcinoma, the company said.

The multi-center, open-label study would be conducted in up to 15 clinical sites and would follow a two-stage enrollment strategy. The primary objectives are to determine the response rate of subjects with NSCLC treated with XL647 and to evaluate the safety and tolerability of the drug. Secondary objectives include assessment of progression-free survival, duration of response, and overall survival, and characterization of pharmacokinetic and pharmacodynamic parameters.

XL647 has exhibited favorable safety and tolerability profiles in a phase I trial in for advanced solid tumors, the company said. The data indicate that of 40 evaluable patients, one has had a partial response and 12 others have had prolonged stable disease (>3.5 months). The first two patients treated at the 7.0 mg/kg dose experienced dose-limiting toxicities of grade 3 diarrhea, which resolved upon a reduction in dose to 4.68 mg/kg. One serious adverse event of grade 4 pulmonary embolism was considered related to study treatment in a patient treated at the 0.28 mg/kg dose. One patient at the 3.12 mg/kg dose had an asymptomatic QTc prolongation on electrocardiogram. Expansion of the 4.68 mg/kg cohort to six patients occurred without further DLTs, and is considered the maximum tolerated dose, the company said.

* * *

Genmab A/S of Copenhagen said it has begun a phase III study with HuMax- EGFr (zalutumumab) for squamous cell carcinoma of the head and neck that is considered refractory to or intolerant to standard platinum-based chemotherapy.

Randomization would occur into two treatment groups: HuMax-EGFr in combination with best supportive care or best supportive care alone, the company said. Treatment with the drug in combination with best supportive care would receive an initial dose of 8mg/kg of HuMax-EGFr, followed by weekly infusions of a maintenance dose until disease progression. The maintenance dose would be adjusted as necessary a dose limiting skin rash develops, up to a maximum dose of 16 mg/kg of HuMax-EGFr. An MRI would assess disease status every 8 weeks according to RECIST criteria until disease progression, the company said.

The objective is to evaluate the efficacy of HuMax-EGFr in combination with best supportive care as compared to best supportive care alone in terms of overall survival. The primary endpoint in the study is overall survival from randomization until death.

* * *

Genzyme Corp. (NASDAQ:GENZ) of Cambridge, Mass., said treatment has begun in a phase III trial examining the safety and effectiveness of Clolar (clofarabine) in older patients with acute myelogenous leukemia.

This is the first clinical study of clofarabine in adult patients with AML, and is expected to provide support for expanding the current product label, the company said.

The trial, for adult AML patients aged 60 and older previously treated with at least one, but not more than two prior induction regimens, is a randomized, double-blind, controlled study that would compare the combination of Clolar and cytarabine (Ara-C) to cytarabine alone, the company said. The 376-patient study would take place at 100 medical centers in the U.S. and Canada.

"The trial is a natural and important extension of our experience with the clofarabine and cytarabine combination and would further determine the position of clofarabine combinations in the management of this population group," said Stefan Faderl, of M.D. Anderson Cancer Center and principal investigator of the study.

The trial would evaluate the effectiveness of one dose of 40 mg/m^2 per day of Clolar combined with 1 g/m^2 per day of Ara-C, compared with 1g/m^2 per day of Ara-C combined with placebo, the company said. The primary endpoint is improved overall survival. Other endpoints include overall remission rate, duration of remission, disease-free survival, event-free survival, and safety and tolerability. Patients would be followed for at least two years after their end of treatment visit.

Clolar is indicated for pediatric patients 1 to 21 years old with relapsed or refractory ALL after at least

two prior regimens, the company said. The use is based on the induction of complete responses. Randomized trials demonstrating increased survival or other clinical benefits have not been conducted, the company said.

Clolar has Orphan Drug designation for adult and pediatric ALL, and seven years of market exclusivity in the U.S. for relapsed/refractory pediatric ALL, the company said. FDA also granted six months of extended market exclusivity to the drug under the Best Pharmaceuticals for Children Act.

* * *

GPC Biotech AG (Frankfurt Stock Exchange: GPC; TecDAX index; Nasdaq: GPCB) of Martinsried and Munich said it has begun a randomized phase II trial evaluating satraplatin, in combination with Tarceva (erlotinib) as a first-line therapy in patients with inoperable advanced non-small cell lung cancer 70 years of age and older. The phase II 120-patient study, which would take place at 20 centers in the U.S. and Europe, would evaluate progression-free survival as the primary objective, the company said. The study would also examine overall survival, response rates and safety.

Randomization would involve treatment with satraplatin plus Tarceva or Tarceva alone, the company said. A sequential dosing regimen would be used in the satraplatin arm. The treatment cycle for both arms is 28 days. Stratification would be according to smoking history and gender, the company said.

A phase III registrational trial of satraplatin in combination with prednisone as a second-line chemotherapy treatment for hormone-refractory prostate cancer has completed enrollment, the company said.

* * *

Maxygen Inc. (NASDAQ:MAXY) of Redwood City, Calif., said it has begun a phase I trial in the U.S. to evaluate the safety, tolerability, pharmacokinetic and pharmacodynamic profile of Maxy-G34, a Granulocyte Colony Stimulating Factor for chemotherapy-induced neutropenia.

The trial is a double-blind placebo controlled dose escalation study in healthy male and female volunteers, the company said. The drug is a PEGylated proprietary G-CSF variant to be administered as a single subcutaneous injection once per chemotherapy cycle.

* * *

MDS Nordion of Ottawa said it has received approval from FDA to begin the first clinical trial for TheraSphere.

The study will enroll 150 patients with secondary liver cancer from five TheraSphere treatment centers in the U.S., the company said.

With the treatment, tiny radioactive glass beads attack tumors in the liver, while minimizing the impact on healthy tissues, the company said. Unlike chemotherapy, it has few side effects; extreme fatigue, nausea and vomiting usually associated with high-dose, systemic chemotherapies are rarely experienced. The therapy can be administered on an outpatient basis.

* * *

Pharmion Corp. (NASDAQ:PHRM) of Boulder said along with its partner **MethylGene Inc**. (TSX: MYG), it has begun a phase II trial of MGCD0103, its histone deacetylase inhibitor product candidate for relapsed or refractory B-cell lymphomas.

Patient populations include those with diffuse large B-cell lymphoma and follicular lymphoma, two tumor types that are classified as non-Hodgkin's lymphomas, the company said. The first patient was enrolled at M.D. Anderson Cancer Center, where Anas Younes is principal investigator.

The open-label, single-agent study, Trial 008, would enroll up to 82 patients at cancer centers in North America, the company said. The product would be given orally, three times per week without interruption at a flat dose of 110 mg. The dose was determined based on safety and efficacy data from the phase I hematologic malignancy study, Trial 003. Objectives include determining the effectiveness of MGCD0103 as a treatment option. Secondary objectives include safety profile, as well as assessing biomarkers and predictive markers for the agent. The trial is expected to last up to 24 months, the company said.

"HDAC inhibition represents a novel mechanism for treatment of non-Hodgkin's lymphoma since key targets such as BCL-2 and BCL-6 have been shown to be regulated by HDAC," said Michael Crump, associate professor of medicine, University of Toronto lymphoma site leader at Princess Margaret Hospital and a principal investigator for the trial.

* * *

PTC Therapeutics Inc. of South Plainfield, N.J., said it has received a three-year, $2.2 million grant from the Department of Defense for preclinical and clinical development of PTC299 for breast cancer.

The product is an orally-administered small molecule that inhibits the production of vascular endothelial growth factor, or VEGF. The product is in phase I trials in healthy volunteers, the company said.

PTC said it is collaborating with researchers at the New York University Medical Center.

"The collaboration combines the preclinical and clinical development expertise of an experienced

biopharmaceutical company and a DoD Breast Cancer Center of Excellence," said Robert Schneider, director of Translational Cancer Research, co-director of the Breast Cancer Research Program and an associate director of the NYU Cancer Institute and co-principal investigator for the DoD award.

* * *

SGX Pharmaceuticals Inc. (NASDAQ:SGXP) of San Diego said it has discontinued the phase II/III trial of Troxatyl as a third-line treatment for acute myelogenous leukemia, based upon the recommendation of the independent data and safety monitoring board.

The DSMB found the study response rates were unlikely to provide evidence of a treatment benefit as a third-line treatment for AML, the company said. The recommendation to discontinue the clinical trial was not made due to safety concerns.

* * *

Threshold Pharmaceuticals Inc. (NASDAQ: THLD) of Redwood City, Calif., said it has completed enrollment in a phase III trial evaluating glufosfamide for second-line treatment for pancreatic cancer and a phase II trial evaluating glufosfamide in combination with gemcitabine for first-line treatment of pancreatic cancer.

Deals & Collaborations:

MedImmune, Infinity Agree To Develop HSP90 Drugs

MedImmune Inc. (NASDAQ:MEDI) of Gaithersburgh, Md., and **Infinity Pharmaceuticals Inc.** of Cambridge, Mass., said they have entered into an agreement to develop and commercialize small molecule cancer drugs targeting Heat Shock Protein 90 and the Hedgehog cell-signaling pathway.

In preclinical studies, Hsp90 and the Hedgehog pathway are implicated in the growth and survival of blood-related and solid tumor types, the company said. IPI-504, the most advanced of the drug candidates included in the agreement, is an Hsp90 inhibitor that has been studied in two disease-focused phase I trials.

Under the agreement, the companies would share costs and profits from the development and commercialization of any future products. MedImmune would provide Infinity a one-time upfront payment of $70 million for co-exclusive, shared rights to the Hsp90 and Hedgehog pathway product development programs. In addition, Infinity could receive up to an additional $430 million in milestone payments if late-stage clinical development and sales targets for any future products resulting from the collaboration are achieved.

For each of the Hsp90 and Hedgehog pathway programs, Infinity said it would retain primary responsibility for discovery, preclinical development and translational clinical development of products through proof-of-concept in humans. MedImmune and Infinity would jointly conduct clinical development through first product approval. MedImmune would lead worldwide regulatory strategy as well as sales and marketing of resulting products; Infinity retains an option to co-promote any future products in the U.S., contributing up to 35 percent of the total promotional effort, the companies said.

* * *

AnorMED Inc. (NASDAQ:ANOR; TSX:AOM) of Vancouver said it would receive $10 million cash for amending the license agreement for its proprietary anti-cancer drug picoplatin, NX473, to expand the licensed territories worldwide, forego future development milestones, and reduce royalty payments.

AnorMED said it licensed picoplatin to Poniard Pharmaceuticals Inc. (NASDAQ:PARD), formerly NeoRx Corp., in 2004.

Under the new amendment, AnorMED said it would receive a cash payment of $5 million by Oct.16, and an additional cash payment of $5 million by March. AnorMED said it would continue to be eligible to receive a reduced partnership revenue stream from Poniard within the first year of the amendment and single digit royalty payments on product sales, assuming future marketing approval. AnorMED said it retains rights to a total of $5 million in commercialization milestone payments if sales targets are achieved. The amendment expands the Poniard licensed rights to picoplatin to include Japan.

Poniard completed enrollment in a phase II trial of picoplatin for small cell lung cancer. Poniard also is evaluating the drug in phase II trials for colorectal and prostate cancer.

* * *

Ariadne Genomics Inc. of Rockville, Md, said it has licensed Pathway Studio and its Enterprise installation, PathwayExpert software, to NCI for pathway and microarray data analysis with integrated literature mining.

Pathway Studio automatically updates the database, keeping the NCI users up to date while the flexible user interface allows for expansion of known pathways and new regulatory networks reconstruction focused on specific research tasks, said Ilya Mazo, president of Ariadne.

The software enables scientists to identify relationships among proteins, small molecules, cell processes, and treatments, and extract relevant biological interactions from the scientific literature.

* * *

Array BioPharma Inc. (NASDAQ:ARRY) of Boulder said it received a $3 million payment from **AstraZeneca** (NYSE:AZN) for achieving a phase II milestone for AZD6244, a selective MEK inhibitor that was in-licensed by AstraZeneca from Array in 2003.

The randomized 180-patient study would compare the drug to temozolomide in stage III/IV melanoma, the company said.

Results from the phase Ib study, which recently completed recruitment, and which included patients with melanoma and other solid tumors, demonstrated that AZD6244 inhibits MEK and associated downstream markers in tumors at doses deemed well tolerated, the company said.

* * *

Genstar Capital LLC of San Francisco said it has acquired **OnCURE Medical Corp**. of Newport Beach, Calif.

OnCURE Medical and its physician partners provide radiation therapy services in 33 free-standing treatment centers in California and Florida.

Genstar is a private equity firm.

* * *

Genstruct Inc. of Cambridge, Mass., said it would begin the second phase of a multi-phase agreement with **GlaxoSmithKline plc** (NYSE:GSK) to investigate compound mechanisms in oncology and to identify biomarkers for patient stratification and drug response.

Under the agreement, GSK said it has paid an upfront fee pursuant to an agreement signed in 2005 and would continue to fund research projects for the term of the agreement.

* * *

GTx Inc. (NASDAQ:GTXI) of Memphis said the **Men's Health Biotech Co**., and **Ipsen** of Paris, France, have entered into a definitive agreement under which Ipsen would have an exclusive license to develop and market the GTx Acapodene (toremifene citrate) in all indications except breast cancer in Europe.

The agent is in separate phase III trials for two indications. The first indication is the multiple side effects of androgen deprivation therapy for advanced prostate cancer (80 mg dose). The second indication is for the prevention of prostate cancer with high grade prostatic intraepithelial neoplasia (20 mg dose). GTx said it would conduct an interim efficacy analysis between the second half of 2007 and first quarter of 2008 for the HGPIN indication.

Under the agreement, Ipsen would pay GTx $30 million. GTx also would receive milestone payments from Ipsen of $50 million for Acapodene, depending on the successful development and European launch of the agent. Ipsen would pay all clinical development, regulatory and launch expenses to commercialize the drug in Europe.

* * *

Inex Pharmaceuticals Corp. (TSX: IEX) of Vancouver said its partner **Hana Biosciences** (NASDAQ:HNAB) has begun enrollment in a phase I trial evaluating the safety, tolerability and preliminary efficacy of INX-0125 (sphingosomal vinorelbine) for advanced solid tumors.

Commencement of patient dosing triggers a $1million milestone payment from Hana to Inex.

* * *

Infinity Pharmaceuticals Inc. of Cambridge, Mass., said the Securities and Exchange Commission has declared effective the Form S-4 Registration Statement of **Discovery Partners International Inc.** (NASDAQ:DPII), or DPI, relating to the proposed merger between DPI and Infinity.

Assuming stockholder approval of the merger and the other matters, DPI would change its name to Infinity Pharmaceuticals Inc. and the common stock of the new company would trade on the NASDAQ National Market under the symbol INFI.

* * *

Rigel Pharmaceuticals Inc. (NASDAQ:RIGL) of South San Francisco said **Serono,** its partner, has begun enrollment in a phase I study on the safety and tolerability of R763, an orally available multi-Aurora kinase inhibitor, for refractory solid tumors.

Serono said it licensed development and commercialization rights to the inhibitor program, including R763 for cancer, in 2005. Rigel said it would receive a $3 million milestone payment from Serono triggered by the initiation of the study.

The multi-center, U.S. study would enroll 60 to 80 patients with refractory tumors.

* * *

Schering AG Germany (FSE: SCH, NYSE: SHR) of Berlin and **AstraZeneca** formed an alliance to develop and commercialize the Schering AG selective estrogen receptor downregulator for breast cancer.

Under the agreement, AstraZeneca would lead clinical development and Schering would

lead the non-clinical and process development as well as manufacturing activities. The companies would co-promote the product. All development and commercialization costs and global profits would be shared equally.

The Shering SERD, which is in preclinical development, is a new class of compounds with a mechanism of action that increases the rate at which the ER protein is degraded, the companies said. That in turn, reduces the amount of ER available to interact with other intracellular signaling pathways known to be involved in resistance to hormone treatment. The SERDs could be used as monotherapy for treatment of all stages of hormone-sensitive breast cancer or in combination with other targeted agents for the prevention and/or treatment of hormone resistant disease, the companies said.

* * *

Spectrum Pharmaceuticals Inc. (NASDAQ: SPPI) of Irvine, Calif., said its licensor for ozarelix, **AEterna Zentaris**, has entered into a licensing and collaboration agreement with **Nippon Kayaku** of Japan for the fourth generation luteinizing hormone-releasing hormone antagonist, ozarelix.

Under the agreement, Nippon Kayaku has an exclusive license to develop and market the hormone antagonist for oncological indications in Japan, the company said. The licensor would receive an upfront payment upon signature, and would receive payments upon achievement of development and regulatory milestones, in addition to low double-digit royalties on net sales.

Ozarelix is being studied for hormone-dependent prostate cancer and benign prostatic hypertrophy.

In another development, Spectrum said it has data from its phase II trial with ozarelix for hormone-dependent prostate cancer.

In the open-label study, the drug was administered intramuscularly in 65, 100, or 130 mg dosing schedules and repeated for 3 cycles of 28 days. The total dose by patient during the study ranged from 230 mg to 390 mg. Treatment with doses of 130 mg per cycle of ozarelix have shown the greatest continuous suppression of testosterone, the primary endpoint, where patients remained suppressed to castration until at least day 85. In patients with continuous testosterone suppression, tumor response as measured by PSA levels, was 97 percent. Ozarelix was well tolerated at all dosages, the company said.

The trial primary endpoint is the most tolerable dosage regimen of ozarelix that would ensure continuous suppression of testosterone at castration levels (< 0.5 ng/mL) for a three-month test period, the company said. The trial is being conducted in Europe in collaboration with AEterna Zentaris, its partner, and has enrolled 64 patients.

Oncology Management:

OPR Selects OTN And Onmark To Provide Oncology Services

(Continued from page 1)

Oregon, and Virginia, with remaining states to be added as pharmacy licenses are secured.

OncologyRx Care Advantage provides home delivery of oral cancer care therapies, and 24-hour access to oncology-trained pharmacists and nurses, the company said. The pharmacists and nurses answer questions, monitor side effects and provide treatment recommendations for side effects, ensuring patient adherence to the prescribed therapy and providing support to the patient.

* * *

OTN of San Francisco and **Onmark**, an OTN company and group purchasing organization, said **Oncology Physician Resource** has selected them to provide oncology services to its members.

OPR, a physician member owned company that that strengthens oncology practices by improving operational efficiencies and purchasing power, has 42 practices at 77 sites, primarily in Michigan, representing 88 oncologists. The agreement, worth $250 million, covers drug distribution, technology and GPO services, the company said.

"Given the current environment, with skyrocketing healthcare costs, we believe that the use of the OTN technology would help our members run their practices more efficiently and better manage costs by providing them with critical financial and clinical information," said Philip Stella, president and CEO of OPR.

Under the agreement, members of OPR would have access to OTN offerings, including drug distribution; competitive pricing; the OTN full technology portfolio, including Lynx Station, Lynx Mobile and Lynx Practice Manager; comprehensive medical/surgical supplies; and practice management tools, including Lynx Practice Intelligence Reports, the company said.

Through Onmark, OPR members would have access to contracts for oncology drugs and supplies with 16 leading pharmaceutical manufacturers, exclusive discounts, practice optimization tools, including Onmark Regimen Profiler, and clinical and educational programs, the company said.