THE CANCER LETTER

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PO Box 9905 Washington DC 20016 Telephone 202-362-1809

In Vote Against Tarceva As Maintenance, ODAC Seeks Stronger Survival Benefit

By Paul Goldberg

In a recommendation that will likely have broad implications for FDA approval of "maintenance" therapies for advanced cancer, the FDA Oncologic Drugs Advisory Committee voted 12-1 against approval of Tarceva (erlotinib) as maintenance in the treatment of non-small cell lung cancer.

Maintenance therapy is given after patients receive front-line treatment—in this case four cycles of platinum-containing doublet therapy—and attain either a response or stable disease.

The vote at the Dec. 16 meeting is significant for two reasons:

• ODAC said that approval should hinge on the magnitude of survival benefit.

• In discussion, the committee agreed with FDA that clinical trials of

(Continued to page 2)

In the Cancer Centers:

Vanderbilt-Ingram Wins $1.7 Million In Grants For Cancer Studies Led By David Carbone

VANDERBILT-INGRAM CANCER CENTER professor **David Carbone** was awarded nearly $1 million in federal stimulus funds to study polymorphisms or genetic variations among minorities with non-small cell lung cancer. Carbone and his colleagues plan to use the two-year NIH Challenge Grant grant to focus on African Americans diagnosed with lung cancer. Carbone, a professor of medicine, cell and developmental biology and cancer biology, will serve as principal investigator. **Velmalia Matthews-Smith**, the first official Vanderbilt University-Meharry Medical College Fellow in the Division of Oncology, helped spearhead the application. She joins **Steven Wolff** and **Billy Ray Ballard**, both of Meharry, and several VICC researchers as co-investigators. The joint investigation is made possible through the Meharry-Vanderbilt Alliance.

Also, a supplemental grant of more than $700,000 was awarded to the Lung Strategic Partnering to Evaluate Cancer Signatures grant that Carbone leads at Vanderbilt-Ingram. The grant will be used by Carbone and **Pierre Massion**, associate professor of medicine and cancer biology, to measure over 100 proteins in the blood of cancer patients and non-cancer patients to determine if they might be useful as molecular biomarkers to diagnose lung cancer.

UNIVERSITY OF COLORADO CANCER CENTER said **Dan Theodorescu**, a cancer researcher and urologic surgeon, was named director

(Continued to page 6)

FDA Maintenance Trial Design: Drug Earlier Vs. Drug Later

(Continued from page 1)

maintenance therapies should compare overall survival in two groups: those who receive the drug immediately after front-line therapy versus those who receive the same therapy after progression.

By definition, such studies can be conducted for supplemental New Drug Applications, only after the drug in question has been approved.

This was not the trial design used by OSI Pharmaceuticals Inc., the sponsor of Tarceva, or, for that matter, the sponsor of another drug approved for a related indication, Eli Lilly's Alimta (pemetrexed).

Instead of comparing Tarceva before progression vs. Tarceva after progression, the registration trial compared maintenance Tarceva against placebo. The pivotal trial was called Sequential Tarceva in Unresectable NSCLC, and abbreviated as SATURN. Lilly followed the same design in its successful Alimta application.

"We need to empower people to be able to make wise choices," said Thomas Fleming, a temporary member of ODAC and professor of biostatistics at the University of Washington. "But it comes down to having an evidence-based justification to make informed choices. This study is not adequate. Additional studies that could provide clarifications could, in fact, allow us to be able to say, 'Yes, there is evidence.' But based on the current evidence, it's not possible to make an informed choice whether patients would be better served starting at maintenance rather than second-line."

Paul Bunn, the Dudley Professor at the University of Colorado Cancer Center, who spoke on behalf of OSI, said the drug is needed in the clinic and physicians would know how to use it.

"I use pemetrexed and I use this drug," Bunn said at the ODAC meeting. "And there are patients who do better on pemetrexed, and ones who do better on this. Not having this available, especially for mutated patients, is going to be a sad day in our history." Tarceva is an approved drug, which can be prescribed off-label.

ODAC's recommendation came as a surprise to many pharmaceutical industry insiders, who believed that the company's reliance on the Special Protocol Assessment process, combined with FDA's approval of a similar drug, based on the same trial design for a similar indication guaranteed success. OSI markets Tarceva in partnership with the Swiss drug maker Roche.

The sponsor, too, seemed surprised. As biostatistician Fleming grilled the OSI presenters, they at times appeared to have been knocked out of balance by aggressive questioning and didn't have a biostatistics heavyweight to respond with precision and gravitas.

In the morning of Dec. 16, at the time the ODAC meeting started, OSI stock was trading at $35.34 per share. Stock price kept slipping and closed at $31.35 when trading ended on Dec. 17.

The Alimta Question

FDA didn't consult ODAC before approving Alimta as a single agent for the treatment of patients with locally advanced or metastatic nonsquamous non-small cell lung cancer after prior chemotherapy. The approval was granted last July.

Why did Alimta get the supplemental NDA while Tarceva is almost certainly heading for defeat?

The answer seems to be a matter of robustness of survival results and the sponsor's ability to pinpoint the subset of patients most likely to benefit:

• Overall, Alimta was statistically superior to placebo in terms of overall survival (median 13.4 months versus 10.6 months, HR=0.79 (95% CI: 0.65-0.95), p-value=0.012) and PFS (median 4 months versus 2 months, HR=0.60 (95% CI: 0.49-0.73), p-value<0.00001). For patients with nonsquamous NSCLC, Alimta had a 5.2-month survival advantage over placebo (median 15.5 months versus 10.3 months, HR=0.70 (95% CI: 0.56-0.88)) and PFS (median 4.4 months versus 1.8 months, HR=0.47 (95% CI: 0.37-0.60)). Survival was the primary endpoint in that trial.

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Editor: Paul Goldberg

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• For Tarceva, the results of the SATURN trial produced the median PFS advantage of 0.2 months (HR=0.71 (95% CI: 0.62-0.82), p-value==0.0001. Overall survival advantage was a month (HR=0.81 (95% CI: 0.70-0.95), p-value=0.0088. FDA said there was no clear way to pinpoint a subgroup of patients who would be more likely to benefit from Tarceva.

SATURN's co-primary endpoints were overall PFS and PFS in patients who were positive for the epidermal growth factor receptor, as measured by the immunohistochemistry assay.

Though SATURN has technically met the efficacy objectives, the value of meeting this endpoint in the IHC-positive subgroup has become uncertain. Over the four years since the trial began, EGFR mutation has become the biomarker of choice for drugs in Tarceva's class.

The number of EGFR mutation-positive patients in SATURN was insufficient to produce a meaningful result. More importantly, in an exploratory analysis of patients whose tumors had EGFR mutations, a large PFS effect didn't translate into an overall survival benefit, thereby raising questions about the value of PFS as a surrogate endpoint in this setting, FDA reviewers said.

In exchanges with ODAC members, Richard Pazdur, director of the FDA Office of Oncology Drug Products, said the agency was concerned about foregoing a more robust survival advantage of Alimta by approving Tarceva, based on data from SATURN.

"Should we be considering other available drugs on the market as part of our calculus for recommending that the drug be approved?" asked ODAC member Mikkael Sekeres, an associate professor of medicine at Cleveland Clinic Taussig Cancer Institute.

"I think that's why we are asking the question," Pazdur replied. "Because that is what we are grappling with. You do have other drugs, other treatment options. That's one issue. The other issue is, 'Is it a benefit to expose these people to this therapy, or is it better to wait till progression, and has that been shown?'"

SEKERES: "I am always careful in trying to paraphrase you, but in trying to paraphrase you, can I say that we should definitely be considering other available therapies?"

PAZDUR: "We do not have a comparative efficacy standard. However, one would not want to be giving up potential gains in survival."

Tarceva's toxicity profile should not be regarded as a factor in making the approval recommendation, Pazdur said.

"We frequently have this discussion," he said. "There are hard-fought battles to improve survival. And generally we don't want to just say, 'We'll forego an improvement in overall survival, because we will have less toxicity.'

"That's something that is a very slippery slope. Because once you go on that slope, why not just give half-dose chemotherapy? One-fourth dose chemotherapy? That probably would have less toxicity, but probably less efficacy."

Trial Design and SPA Disagreement

Agency officials said Alimta was approved because of a robust overall survival result, even though the trial was not structured in a way the agency now regards as optimal for maintenance therapy.

"I'd like to comment regarding the Alimta application," Pazdur said. "We internally had the same discussions regarding the appropriateness of design here. What drove the approval of Alimta was the magnitude of effect. We thought the magnitude of effect in that subgroup [nonsquamous NSCLC] warrants approval. If we were seeing a similar magnitude, we would not be bringing this application to ODAC."

"I think we are going to be seeing more maintenance therapies," said ODAC member Wyndham Wilson, chief of the NCI Lymphoma Therapeutics Section, who chaired the committee meeting.

PAZDUR: "I think this is one of the reasons that we brought this to the committee. We are not going to be only seeing it in lung cancer, we could be seeing it in lymphoma application, and in other diseases, and where do we go from here regarding these sorts of applications?"

WILSON: "Let me put forward the question on the broader scale as to how you design studies like this. I think survival benefits may be a little easier to handle. At least in the world of lymphoma, a doctor named [John] Hainsworth [now of Nashville-based Sarah Cannon Research Institute] years ago, looking at maintenance, did the very study FDA has discussed here, which is, he looked at maintenance Rituxan vs. Rituxan at progression. And that was done many, many years ago."

The Alimta study in the maintenance indication was intended as a post-approval commitment for converting an accelerated approval into a regular approval. Though Tarceva at the time had a regular approval, SATURN, too, was a post-approval commitment.

During the ODAC presentation, OSI said FDA had "accepted" its decision to pursue the two PFS primary endpoints during the Special Protocol Assessment

process. However, the agency disagreed, stating that it had sought overall survival data from the outset.

"There obviously was not an agreement in terms of the study endpoints," said Martin Cohen, an FDA medical reviewer who worked on the clinical component of the application. "The FDA strongly recognized that overall survival was the endpoint. The sponsor chose PFS as the endpoint."

John Johnson, who led the FDA clinical review team on the application, confirmed that the SPA meeting in April 2005 failed to produce an agreement on endpoints.

"With respect to requirement for overall survival, FDA sent them a letter in 2005, after our meeting, and I quote from the letter—I think it's unequivocal—'To demonstrate the valuate of maintenance targeted therapy, superiority of survival will have to be demonstrated,'" Johnson said at the ODAC meeting.

Asked by the committee to describe how maintenance Tarceva is used in the clinic, Bunn described the drug as a "huge advance" in treatment.

"There are patients who have an outstanding response to their induction treatment, and they are asymptomatic," Bunn said. "For them, not getting any maintenance is not a bad idea--and that happens.

"The patient I saw last week, whom I will see again tomorrow, had started on pemetrexed and carboplatin as initial treatment. She presented with a pleural effusion. I suggested that she have EGFR testing, which she did. And after three weeks, when she was evaluated, she had a large pleural effusion and was symptomatic.

"The ability to give her Tarceva was a huge advance," Bunn said. "Giving her two more cycles of pemetrexed would not have been a good thing. And that's not to say that there aren't other patients, who are stable, who have adenocarcinoma, and sometimes it's most appropriate to offer them maintenance pemetrexed.

"So, no maintenance for some patients is reasonable. Pemetrexed for some patients is reasonable. And erlotnib for some patients is reasonable. I personally don't know the difference in magnitude between pemetrexed benefit and erlotinib benefit in any setting. And I don't know how people are arguing for that. Hazard ratio of 0.8 and HR of 0.79 is the same."

Biostatistician Fleming disagreed.

"The design of the trial was declaring positivity, i.e. statistical significance, for what would have been a 10-14 day overall improvement on a surrogate endpoint of PFS," Fleming said. "[This is] a single-trial application. How is that statistically persuasive evidence of clinically compelling effects? In context, a number of us could argue that you could use a PFS measure, but the multitude of effects would have to be large, and the statistical persuasiveness would have to be compelling for a single trial."

ODAC member Margaret Tempero, deputy director of the University of California, San Francisco, Helen Diller Family Comprehensive Cancer Center, was the only committee member to vote for approval. She gave the following justification for her vote:

"Although maybe this trial wasn't the one that this committee's members wanted to see, it was a trial that asked a reasonable question. It was done in full consultation with the FDA, and it met the endpoint that the sponsors accepted to meet, and which the FDA asked for.

"So overall survival benefit was met. When you see a group benefit—even when it's small—it means that some individuals have important benefits. We don't quite know from the biomarker studies done in this trial who these individuals were, and that troubles us all, and we wish that was different.

"But I know that clinicians are not robots. Clinicians take a careful assessment of the patient in front of them, including the smoking status, and whatever molecular data is available to them, and they try to make a wise choice for the patients.

"I had hoped that we could make sure that erlotinib was available to more patients at an earlier stage, when it seemed to be clinically important for that patient."

Research Funding:

Obama Signs Spending Bill Giving NCI $5.1 Billion Budget

President Obama Dec. 16 signed an omnibus spending bill for the fiscal year 2010, giving NCI a 2.8 percent ($139 million) increase.

The institute's appropriation stands at $5.1 billion.

NIH gets a 2.3 percent ($691 million) increase, which pushed its total appropriation to $31.008 billion.

Cancer programs of Centers for Disease Control and Prevention are getting an 8.8 percent increase over their current level of $340.3 million.

The bill also gives FDA additional $310 million, a 15.2 percent increase, which boosts the agency's appropriation to $2.35 billion.

The text of the bill is posted at http://thomas.loc.gov/home/approp/app10.html.

In Brief:

Thorson Is ACS President, Partridge Is President-Elect

AMERICAN CANCER SOCIETY elected 11 new officers to its volunteer 2009-2010 National Board of Directors during its annual meeting in Los Angeles.

Leading the National Assembly will be the newly elected President Alan Thorson, a clinical professor of surgery at Creighton University and the University of Nebraska. George Atkins, recently retired from Wachovia Bank, will serve as chairman of the board.

Other officers elected were Edward Partridge, of Birmingham, Ala., president-elect; Stephen Swanson, of Allison Park, Penn., chair-elect; Cynthia LeBlanc, of Richmond, Cal., vice chair; Daniel Heist, of State College, Penn., treasurer; Lila Johnson, of Honolulu, secretary; W. Phil Evans, III, of Dallas, first vice president; Vincent DeVita, Jr., of New Haven, second vice president; Elizabeth Fontham, of New Orleans, immediate past president; and Van Velsor Wolf, of Phoenix, immediate past chair.

The society also gave the following awards to honor volunteers:

Paul Engstrom, senior vice president, extramural research programs, and medical director, Fox Chase Cancer Center Partners, received the Distinguished Service Award for his major and unique contributions to cancer control through clinical practice, education, and administration.

Samuel LaMonte, a retired head and neck surgeon, received the National Volunteer Leadership Award for his dedicated service to the American Cancer Society since 1976.

Adnan Hammad, health director of the Arab Community Center for Economic and Social Services, received the Humanitarian Award for his critical role in the founding, growth and development of the ACCESS Community Health and Research Center.

ONCOLOGY NURSING SOCIETY FOUNDATION received a $1.54 million grant to develop, test, and evaluate quality-of-care measures for patient- and survivor-centered experiences of diverse populations of women with breast cancer.

The three-year grant is provided by the Breast Cancer Fund of National Philanthropic Trust.

The goals of the initiative are to develop a process for testing patient- and survivor-centered quality measures and to develop and disseminate education about the use of patient-centered breast cancer quality measures in ambulatory practices.

NIH News:

Guttmacher To Direct NICHD; AACR Honors NCI's Schiffman

ALAN GUTTMACHER was appointed acting director of the Eunice Kennedy Shriver National Institute of Child Health and Human Development at NIH.

Guttmacher replaces **Susan Shurin**, who left the NICHD to serve as acting director of the National Heart Lung and Blood Institute. Guttmacher's appointment was effective Dec. 1.

"Dr. Guttmacher brings a unique combination of expertise and experience to this new role," said NIH Director Francis Collins. "A highly regarded pediatrician and medical geneticist, he has served in a number of important leadership roles at the National Human Genome Research Institute since joining the Institute from the University of Vermont in 1999."

Guttmacher served as deputy director of NHGRI from 2002 to 2008, and then became acting director.

At University of Vermont, Guttmacher directed the Department of Pediatrics' Vermont Regional Genetics Center and Pregnancy Risk Information Service. He served as the medical director of the Vermont Newborn Screening Program, founded Vermont's only pediatric intensive care unit, and co-directed the Vermont Cancer Center's Familial Cancer Program.

MARK SCHIFFMAN, senior investigator of the hormonal and reproductive epidemiology branch at NCI, has been selected to receive the 2009 American Association for Cancer Research-Prevent Cancer Foundation Award for Excellence in Cancer Prevention Research.

Schiffman is being honored for his research on the mechanisms of cervical carcinogenesis based on a model of infection with HPV. Schiffman has led efforts to understand cervical cancer etiology and natural history, spurring novel prevention strategies such as molecular diagnostics and prophylactic vaccines. Among his achievements, Schiffman's seminal work in HPV DNA testing as a more sensitive and reliable screening test than cervical cytology helped lead to FDA approval of a commercial HPV test.

In the 1990s, Schiffman first proposed that cervical cancer does not progress along a pathology model of stepwise progression from CIN1 to CIN2 to CIN3 to cancer, but rather along a simple, causal schema composed of four reliably measured stages: HPV acquisition, HPV persistence (vs. clearance),

progression to precancer and invasion. This conceptual model, radical at the time, has gained firm empirical support and is now widely accepted.

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES awarded nearly $9.7 million over five years to the Radiation Effects Research Foundation, Japan, to study the effects of atomic bomb radiation and aging on the human immune system.

For the first time, experts in both the U.S. and Japan will systematically analyze biological samples from the unique population of elderly Japanese atomic bomb survivors to better understand the health consequences of exposure to ionizing radiation on the natural aging process.

Investigators will analyze blood samples from survivors to determine how radiation exposure alters the normal age-related decline of the immune system and identify the cellular and molecular changes that occur. They also will determine how the observed immune changes are related to disease and infection. One goal is to understand how exposure to ionizing radiation and aging affect a person's ability to respond to vaccination.

Yoichiro Kosunoki, Kei Nakachi, and Tomonori Hayashi, of the Department of Radiobiology/Molecular Epidemiology at RERF, will lead a team of nine experts in Japan and in the U.S. RERF, formerly known as the Atomic Bomb Casualty Commission, is a cooperative Japan-U.S. scientific organization based in Hiroshima and Nagasaki.

In the Cancer Centers:

Theodorescu Leaving UVA To Lead Colorado Center

(Continued from page 1)

of the cancer center effective July 1. Theodorescu is leaving his post as director of the Mellon Urologic Cancer Institute at the University of Virginia after six years. He succeeds interim director **Tim Byers**, associate dean of the Colorado School of Public Health, and will hold the $2 million Paul Bunn Chair in Cancer Research, named after the lung cancer researcher who founded UCCC in 1988.

UNIVERSITY OF ALABAMA AT BIRMINGHAM Comprehensive Cancer Center said **Mary-Ann Bjornsti**, chair of the UAB Department of Pharmacology and Toxicology, has been appointed associate director for translational research at the cancer center. Bjornsti is the program co-leader for UAB's cancer cell-biology program. She holds the Newman H. Waters Chair of Clinical Pharmacology at UAB. In her new role, Bjornsti has responsibility for linking all the cancer center's basic science and experimental therapeutics programs to a translational and interdisciplinary approach. She also will provide direction for UAB's Specialized Program of Research Excellence teams funded by NCI. Bjornsti came to UAB in 2009 from St. Jude Children's Research Hospital.

DANA-FARBER/HARVARD CANCER CENTER co-leader in gynecologic oncology **Stephen Cannistra** was named editor-in-chief of the Journal of Clinical Oncology effective May 2011. Cannistra is professor of medicine at Harvard Medical School and director of Gynecologic Medical Oncology at Beth Israel-Deaconess Medical Center. Cannistra has served JCO in various capacities, including reviewer, associate editor, consultant editor and editorial board member since 1989. He will replace **Daniel Haller**, who will complete his second term as editor-in-chief in May 2011.

ARIZONA CANCER CENTER announced plans to develop a full service outpatient cancer treatment clinic and research facility in downtown Phoenix. By 2013, plans call for the Arizona Cancer Center facility to be operational at the Phoenix Biomedical Campus. Clinical operations will start in leased space, also in downtown Phoenix, by mid-2010, said **Thomas Brown**, the cancer center's chief operating officer.

Locating in the state's population center will enable the Arizona Cancer Center to have access to the patients the institution is dedicated to serve and to professional talent, institutional collaborators and philanthropic support, Brown told the Board of Regents on Dec. 4. Plans call for a 250,000-square-foot clinic with multidisciplinary services including the range of physician specialties. The estimated total cost of the project is less than $140 million. Brown said projected revenues from the clinic will cover the construction, finance and clinical program development costs.

M.D. ANDERSON CANCER CENTER associate professor **Shiaw-Yih Lin**, in the Department of Systems Biology, received an Era of Hope Scholar Award from the U.S. Department of Defense. The award, one of only three given nationally, provides $3.5 million over five years to study early defects that lead to breast cancer. The grant funds will be used to explore a crucial component of that process called replication stress response.

ROSWELL PARK CANCER INSTITUTE appointed **Thomas Schwaab** as staff physician and

assistant professor of oncology in the Departments of Urology and Immunology. He comes to RPCI from the Center for Urologic Care, Concord Hospital, N.H. He also served as an adjunct assistant professor of medicine in the Immunologic Therapy Program, Norris Cotton Cancer Center, Dartmouth Medical School, and an adjunct assistant professor of surgery at the Dartmouth Hitchcock Medical Center.

UNIVERSITY OF WARWICK, in Coventry, U.K., has formed a Centre for Mechanochemical Cell Biology with four research teams that moved from the Marie Curie Research Institute.

Following the decision of Marie Curie Cancer Care to focus more on its palliative care research, the University of Warwick agreed to the transfer of groups working on molecular motors (**Robert Cross**), DNA replication (**Jacob Dalgaard**), chromosome segregation (**Andrew McAinsh**) and cytoskeletal organization (**Anne Straube**). MCCC will support the groups with transitional program funding for three years, as well as allowing the transfer of laboratory equipment.

Mechanochemical cell biology focuses on understanding the principles and mechanisms by which cells organize their contents in space and time. It is an emerging area of interdisciplinary research at the interface between biomedicine, physics, chemistry, engineering, computing and mathematics.

"Our goal is to make Warwick Medical School the international destination of choice for ambitious scientists wishing to make rapid progress on these technically demanding problems," said John Davey, associate dean for biomedical research. "It will affirm Warwick's position as an international leader in biomedical research."

UNC LINEBERGER COMPREHENSIVE CANCER CENTER an associate professor **Charles Perou** was named by American Association for Cancer Research as the 2009 Outstanding Investigator Award for Breast Cancer Research, funded by Susan G. Komen for the Cure. Perou's work sets the stage to redefine breast cancer into multiple subtypes of disease, AACR said.

MAYO CLINIC CANCER CENTER neuro-oncology genetics researcher **Robert Jenkins** received an American Recovery and Reinvestment Act Challenge Grant to identify germ line alterations that are involved in the pathogenesis and biology of high grade gliomas. The grant provides $983,862 of funding over two years to define alterations near CDKN2a/CDKN2B on chromosome 9p, and RTEL1 on 20q. MCCC scientists brought in more than $14.5 million in 44 grant awards supported by ARRA funding.

MOORES UCSD CANCER CENTER Director **Dennis Carson**, professor of medicine, and **Catriona Jamieson**, assistant professor of medicine and director of the Cancer Stem Cell Research Program, were awarded $20 million over four years to lead a research team to develop novel drugs against leukemia stem cells. The grant is from the California Institute for Regenerative Medicine. The researchers will develop six existing candidate molecules targeting leukemia stem cells and these will be tested against both chronic and acute forms of leukemia. The Moores group will collaborate with a Canadian research team led by **John Dick**, of the University of Toronto. Also at UCSD, professor of medicine **Webster Cavenee** is co-principal investigator of a $19.2 million grant to UC San Francisco for a six-institution study of the effectiveness of using neural stem cell-based gene therapy to fight brain tumors. The disease team, led by principal investigator **Mitchel Berger** of UCSF, includes researchers from UCLA, the Salk Research Institute, LICR, and the Burnham Institute.

Moores researchers also received a $6 million, five-year contract from the National Institute of Allergy and Infectious Diseases to identify and characterize novel adjuvants, substances that can be added to vaccines to enhance the protective immune response they induce.

VIRGINIA COMMONWEALTH UNIVERSITY Massey Cancer Center received nearly $4 million in federal stimulus funds from NIH for 13 research projects. The grants range in size from $99,993 to $591,990 for a variety of projects ranging from clinical trials for leukemia to pre-clinical studies on a gene therapy for pancreatic cancer. "We can attest that the stimulus funding we've received is doing exactly what it was designed to—help us advance our research mission and create and retain jobs that stimulate the economy," said **Gordon Ginder**, cancer center director. "The funding has a ripple effect beyond our laboratories. For example, it supports biomedical supply companies, transportation businesses that deliver these supplies to our labs, and even the vendors on campus who sell lunch to our staff."

CLARIFICATION of a story in last week's issue of The Cancer Letter: **Peter Adamson** was elected group chair-elect of the Children's Oncology Group and will assume this position on Jan. 1. This will overlap the current COG chair, **Gregory Reaman**, by one year to ensure smooth transition. Adamson will assume the position of COG chair in 2011.

Funding Opportunities:

• The Dr. Paul Janssen Award for Biomedical Research has opened the 2010 call for nominations.

The $100,000 award recognizes individuals whose efforts have made significant transformational contributions towards the improvement of human health. Nomination forms are available at www.pauljanssenaward.com and will be accepted until Feb. 15. The winner is chosen by an independent committee, which includes three new members: Robert Langer, of Massachusetts Institute of Technology; past award winner Axel Ullrich, of the Max Planck Institute of Biochemistry; and Huda Zoghbi, of Baylor College of Medicine.

Established by Johnson & Johnson in 2004, the award is named for Paul Janssen, the founder of Janssen Pharmaceutica, N.V.

• Protect Your Lungs invites grant applications for its inaugural Request For Application distributing up to $1 million in early 2010 for the study of early detection and disease management of lung cancer.

Applications will be accepted from individual investigators or teams of up to three scientists. Grants will be awarded for a two-year period for a maximum amount of $100,000 per year per scientist.

Mandatory Letters of Intent are due by Dec. 22. Application deadline is March 15, and funding will commence May 2010. The projects are expected to have a direct impact on the early detection of lung cancer or to provide a clear conceptual or experimental foundation for the future development of methods for early detection.

Further information: www.protectyourlungs.org.

Note To Readers:

Final Cancer Letter For 2009

This issue of The Cancer Letter is the final issue of 2009, and the last one to be mailed to print subscribers.

Print subscribers who have not yet submitted their email addresses to switch to the online edition should contact The Cancer Letter staff as soon as possible to ensure the delivery of the next issue. Please contact Kirsten Goldberg, at 202-362-1809, or by email to kirsten@cancerletter.com, to provide your email address.

The next issue of The Cancer Letter is scheduled for Jan. 15, 2010.

MEN2 Thyroid Cancer Research Scholar, Mentored Research Scholar, and Postdoctoral Fellows:

A Request for Applications

Research Scholar Grant Eligibility Expanded to Include Independent Investigators at any Career Stage

Next Receipt Deadline: April 1, 2010

The American Cancer Society announces this revised **Request for Applications** for the **American Cancer Society MEN2 Thyroid Cancer Consortium.** ***Funds remain available*** for up to seven (7) **Research Scholar** and/or **Mentored Research Scholar** grants and up to five (5) **Postdoctoral Fellow** grants will be awarded. The Consortium will be led by a single renowned senior scientist who will be awarded the American Cancer Society MEN2 Thyroid Cancer Professorship and act as leader for the overall program (details at links below). Appropriate areas of investigation include, but are not limited to: understanding consequences of *RET* mutations, molecular ev
imaging approaches, and new pharmacologic and other strategies to blunt the effects of mutations in *RET* and other genes associated with medullary thyroid cancer.

Individuals applying for a **Research Scholar Grant** must have an independent research or faculty position *and can be at any stage of their career*. These grants will be awarded for up to $200,000 a year, direct costs, for 5 years. **Mentored Research Scholar Grants** will be a
Ph.D.) that
research experience immediately prior to their faculty appointment. The successful applicant is expected to transition into a career as an independent investigator. Awards are for up to five years and for up to $135,000 per year direct costs.

Applicants for **Postdoctoral Fellowships** must have obtained their doctoral degree prior to activation of the fellowship. Awards are for three years with progressive stipends of $44,000, $46,000, and $48,000 per year, plus a $4,000 per year institutional allowance. Indiv

Deadline: Complete applications are due by April 1, 2010. Funding will begin January 1, 2011. For information regarding funding policies or to obtain an application, go to https://proposalcentral.altum.com or refer to the ACS website at www.cancer.org/research: select *Funding Opportunities* followed by *Index of Grants*, scroll down to *Special Initiatives* and select the appropriate RFA for MEN2 Thyroid Cancer. For inquiries, contact Charles Saxe, PhD at (404) 929-6919 (charles.saxe@cancer.org).

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