PEOPLE

Robert Carlson, MD, a medical oncologist specializing in breast cancer, has been appointed CEO of the National Comprehensive Cancer Network (NCCN), effective January 2, 2013. NCCN is a not-for-profit alliance of 21 leading American cancer centers dedicated to improving the quality and effectiveness of care for people with cancer.

Carlson is a professor of medicine in the division of oncology at Stanford University Medical Center in Palo Alto, CA, having joined the faculty in 1983. He serves as the medical director of inpatient oncology and hematology at Stanford Cancer Institute, an NCCN member. He has held several leadership roles at NCCN since the organization was founded in 1995.

AstraZeneca

Pascal Soriot, MBA, started his role as CEO of AstraZeneca and joined the company's board as executive director on October 1. He joins AstraZeneca from Roche AG, where he served as chief operating officer of the company's pharmaceuticals division since 2010. Prior to that, Soriot was CEO of Genentech and led the merger of the San Francisco-based biologics business with Roche.

Adam Donohue

Colleen Lawton, MD, a professor of radiation oncology at the Medical College of Wisconsin in Milwaukee, began her 1-year term as president of the American Society for Radiation Oncology at the end of October. She succeeds Michael Steinberg, MD.

Lawton's research focuses on the role of total body irradiation in stem cell transplantation. She has also worked extensively with the Radiation Therapy Oncology Group on several prostate cancer studies, examining nodal radiation and brachytherapy.

Varmus Highlights Funding Challenges

If sequestration, the automatic federal spending cuts triggered by the Budget Control Act of 2011, does kick in next January, National Cancer Institute (NCI) funding of new grant applications may drop by as much as 40%, estimates NCI Director Harold Varmus, MD.

Speaking at a press conference in Washington, DC, in September, Varmus explained that although sequestration would lower NCI (and overall NIH) budgets by only around 8%, new grant approvals may suffer a dramatic drop because most of NCI's $5-billion budget is committed to current investigations and personnel. "I have a lot of checks to write before I can start to write checks for new investigations," he said.

Sequestration "would be very damaging to biomedical research," he added. "I don't like it and I assume it won't happen," as Congress works to find a budget compromise by year's end that would prevent the automatic spending ax.

Varmus noted that NCI's effective buying power already has dropped by one fifth since 2003, and the success rate for grant applications has fallen to an all-time low of 14%.

"The pace of research is slower than it could be and should be, mostly because we are unable to fund all the people who have good ideas," the NCI director remarked. "It's always hard to predict what ideas will bear fruit."

With more stable funding for biomedical research available in other countries, "we are running the risk of losing leadership to Europe and parts of Asia," warned Varmus, who headed the NIH from 1993 to 1999.

One consequence of the ongoing budget crunch is "an inherent aversion to risk by grant applicants and peer review panels," he said. "There's a tendency to support safe science rather than revolutionary science."

Another byproduct is that researchers experience "severe feelings of competition and stress, feelings that transmit "unfortunately" to young trainees or foreigners who might want to come here and settle," Varmus said. He added, however, that he strongly encourages young cancer researchers to stick with the field, because "things will get better and the science is so good and so exciting." ■

Moores Pushes Clinical Sequencing

In the quest to provide personalized cancer treatment, the Moores Cancer Center at the University of California, San Diego (UCSD), is launching "My Answer to Cancer," a program that intertwines clinical care and research.

The initial goal of the program is in-depth targeted sequencing to examine tumor biopsies from 1,000 patients for mutations in hundreds of known cancer genes. If the analysis reveals a known mutation or other aberration that can be treated with an approved or experimental drug, the patient will be treated with that drug, explains Scott M. Lippman, MD, director of Moores, a National Cancer Institute–designated Comprehensive Cancer Center.

The analysis will be done with equipment and facilities that meet Clinical Laboratory Improvement Amendments (CLIA) standards, so the results can be used to direct patient care. The intent is to exploit the best technology available in the CLIA setting and to continually adopt newer technologies as they emerge, Lippman emphasizes.

If no known "actionable" mutations or other molecular aberrations are found in the CLIA setting, a subsequent more intensive evaluation may be done, including full genomic sequencing as well as proteomic and RNA analysis, where appropriate, to reach a better understanding of the underlying defects that drive the tumor's growth. The latter will initially be done in a research setting, and patterns noted and correlated with responses will inform further development of molecular tests to be applied in the clinical setting under stringent CLIA conditions.

"UCSD's new, cutting-edge Center for Advanced Laboratory Medicine will work to customize testing that is best coordinated with clinical studies at Moores," Lippman adds. There will be close synchronization between multiple specialists, including pathologists, surgeons, medical oncologists, and other clinicians, as well as bioinformatics

experts, so that tissue is properly collected and handled, complicated information is swiftly analyzed, and timelines are streamlined, he notes.

"The idea is to quickly and continually incorporate innovations from the preclinical research setting into the clinical trial and treatment setting," says Lippman.

The My Answer to Cancer program was kick-started with $500,000 in support from the UCSD Clinical and Translational Research Institute. The Institute is also providing matching funds for individual "investments," which Moores hopes will cover most of the remaining cost, estimated at $5 million in the initial phase. ■

Regorafenib Okayed for Colorectal Cancer

The U.S. Food and Drug Administration (FDA) has given a green light to Bayer to market the oral drug regorafenib (Stivarga) for the treatment of metastatic colorectal cancer that progresses in spite of other therapies. An inhibitor of multiple kinases that promote cancer growth, including vascular endothelial growth factor receptors 1, 2, and 3, regorafenib received an expedited review because patients with the disease have few treatment options.

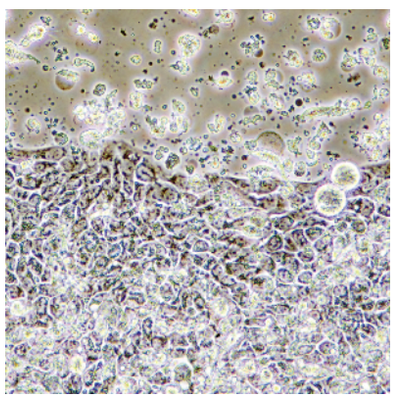
FDA approval was based on a single international trial of 760 patients previously treated for metastatic colorectal cancer. Researchers randomly assigned patients to receive either regorafenib or a placebo, in addition to supportive care. The patients continued treatment until they could no longer tolerate it or their disease progressed.

Patients who were treated with regorafenib lived a median of 6.4 months compared with 5 months in patients who received the placebo. Patients taking the drug also experienced a median delay in tumor growth of 2 months compared with 1.7 months in those taking the placebo. Other drugs aren't much more effective. Approved by the FDA in August, the colorectal cancer drug ziv-aflibercept (Zaltrap; Sanofi/Regeneron) improved overall survival by just 1.5 months compared with placebo.

"The impact has been incremental, and we all wish that the benefit of these therapies would be greater," says Charles Fuchs, MD, MPH, director of the gastrointestinal cancer center at Dana-Farber Cancer Institute in Boston, who was not an investigator for the trials of either drug. "But these studies were done in patients who had already failed multiple therapies."

"It's incumbent upon us to come up with a much better strategy to develop and test drugs," he adds.

For example, clinical trials of both drugs assessed safety and efficacy in heterogeneous patient cohorts. If researchers could find biomarkers that define patient populations more likely to respond to these agents, overall survival for those particular subgroups might be higher. ■



Metastatic colorectal cancer gained another treatment option with regorafenib's approval.

Focusing on Recalcitrant Cancers

In late September, the U.S. House of Representatives unanimously passed the Recalcitrant Cancer Research Act of 2012, which would require the National Cancer Institute (NCI) to create long-term plans to accelerate research on at least 2 recalcitrant cancers. The fate of the bill remains uncertain in the Senate, however.

While the bill defines recalcitrant cancers as those having a 5-year relative survival rate of less than 50%, it directs the NCI to initially develop a scientific framework for 2 or more cancers having a 5-year relative survival rate of less than 20% and estimated to kill at least 30,000 Americans a year. Supporters hope it will raise public awareness of particularly intractable malignancies, notably pancreatic and lung cancers, the only 2 diseases that currently meet this more limited definition of

NOTED

- **Findings were reported from a study that claims to be the first large-scale trial of whole-genome cancer testing** at the European Society for Medical Oncology 2012 Congress in Vienna in October. In the SAFIR01 trial, researchers at the Institute Gustave Roussy in Villejuif, France, developed a program in which the entire genome from a biopsy of a metastatic lesion was analyzed prospectively for 248 individual patients with metastatic breast cancer.
- In a comprehensive study of samples from 825 patients, **The Cancer Genome Atlas has confirmed and greatly broadened the understanding of the 4 major subtypes of breast cancer**: HER2-enriched, luminal A, luminal B, and basal-like (Nature 2012;490:61–70). Among results, the work uncovered marked genomic similarities between the basal-like subtype and high-grade serous ovarian cancer.
- **The University of Texas MD Anderson Cancer Center launched its Moon Shots Program,** which will bring together sizable multidisciplinary groups of its researchers and clinicians to accelerate cancer research. The 6 initial Moon Shot teams will target acute myeloid leukemia/myelodysplastic syndrome, chronic lymphocytic leukemia, melanoma, lung cancer, prostate cancer, and triple-negative breast and ovarian cancers.
- **BGI-Shenzhen of Shenzhen, China, is acquiring Complete Genomics** of Mountain View, CA, for approximately $117.6 million. Complete Genomics, which offers whole-genome sequencing services and its own sequencing technologies, will continue operating as a separate company. BGI is the world's largest sequencing organization.
- **The American Association for Cancer Research released its Cancer Progress Report 2012**, which highlights the need for strong funding for cancer science. "Any further reduction in funding for cancer research and biomedical science would result in a major setback in our ability to develop even more effective interventions and save lives from cancer," said AACR President Frank McCormick, PhD, director of the UCSF Helen Diller Family Comprehensive Cancer Center.