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.

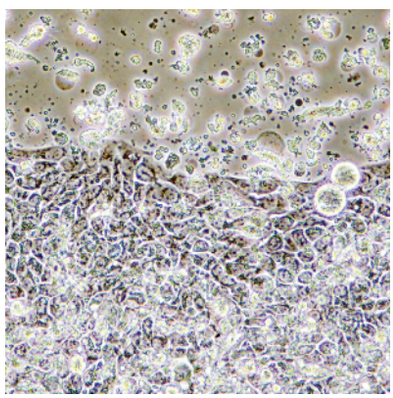
FDA approval was based on a single international trial of 760 patients previously treated for metastatic colorectal cancer. Researchers randomly assigned patients to receive either regorafenib or a placebo, in addition to supportive care. The patients continued treatment until they could no longer tolerate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

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- **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.

recalcitrant cancers. Pancreatic cancer has a 5-year relative survival rate of 6% and lung cancer, 16%. According to estimates, they will kill more than 37,000 and 160,000 people, respectively, this year.

"If the bill does nothing other than rivet our attention on these difficult malignancies, it will be great," says Margaret Tempero, MD, director of the University of California, San Francisco (UCSF), Pancreas Center at the UCSF Helen Diller Family Comprehensive Cancer Center, and a member of the scientific advisory board of the Pancreatic Cancer Action Network in Manhattan Beach, CA.

Creating a comprehensive plan—called a scientific framework in the bill—would help narrow survival gaps and address difficult issues, Tempero says. For example, surgical resection is often not an option for patients with pancreatic cancer because their tumors are too advanced by the time the disease is diagnosed. As a result, researchers lack the tissue they need to study the biology of the disease.

The scientific framework for each recalcitrant cancer, says Julie Fleshman, president and CEO of the Pancreatic Cancer Action Network, will summarize the current status of the disease, identify research questions that have not been adequately addressed, and make recommendations to advance research, such as coordinating various initiatives and setting benchmarks to measure progress.

First filed 5 years ago and named the Pancreatic Cancer Research and Education Act, the bill grew out of the Pancreatic Cancer Action Network's advocacy efforts. Attention to it swelled this past summer when the group released a report stating that pancreatic cancer is "anticipated to move from the fourth to the second leading cause of cancer death in the U.S. by 2020."

Although the bill initially had strong support from legislators, cancer researchers and others in the scientific community voiced considerable opposition to certain provisions. They expressed concern that the bill's authorization of additional funds solely for pancreatic cancer research would pull money away from other worthy projects. Many also feared that a mandated 13-member advisory panel would usurp the authority of NCI's peer-review committees.

In response to the criticism, the bill's sponsors, advocates, and a bipartisan House subcommittee overhauled it, eliminating the advisory panel and the financial obligation, and changing the name to the Recalcitrant Cancer Research Act to allow for the inclusion of other types of cancers.

However, Senator Tom Coburn, MD, expressed opposition to the revised bill in a letter to the Senate's minority leader. "I do not believe there is any demonstrated need for Congress to micromanage NIH how to better perform, organize, and disseminate the work being done in these fields," he wrote. He also questioned taking "an outdated disease-by-disease approach" when cancer research now largely "focuses on broader, interdisciplinary questions."

If the bill doesn't pass the Senate by year's end, supporters must reintroduce it next year. ■

FDA Approves Ultrasound Tool

The U.S. Food and Drug Administration (FDA) has approved a new adjunct screening tool to be combined with mammography for asymptomatic women with dense breast tissue who have not had prior clinical breast intervention.

About 40% of women who are screened by mammography have dense breast tissue. These women have a higher proportion of dense fibroglandular tissue, which can obscure smaller tumors, and mammography fails to detect about 35% of their breast cancers. Although a recent paper (J Natl Cancer Inst 2012;104:1218–27) indicates that high breast density does not increase risk of death from breast cancer in women once diagnosed, it has been associated with an increased risk of developing the disease.

The somo-v Automated Breast Ultrasound System (ABUS) from U-Systems of Sunnyvale, CA, was initially approved in a premarket notification program in 2005 for adjunct diagnostic purposes, which involves the assessment of tumors already identified or suspected.

The FDA's new approval for its use as a screening tool was based on a clinical reader study in which radiologists looked at 200 cases of asymptomatic women with dense breast tissue from a prospective multicenter registry. The study found that using somo-v ABUS in addition to mammography improved the detection of cancerous tumors by about 30% compared to mammography alone.

"What was very exciting in this reader study was that a majority of the cancers, which had not been seen on the screening mammograms during the prospective registry study, were invasive cancers that had not spread to the lymph nodes," says Maryellen Giger, PhD, principal investigator of the study and professor of radiology at the University of Chicago. "If we were to wait for these to grow and become visible on a mammogram, there's the chance the cancers would become lymph node positive." ■

CORRECTION NOTE: In "Focusing on Recalcitrant Cancers," 2 sentences in the second paragraph have been changed from the OnlineFirst version published October 4, 2012. The October 4, 2012, version included the following sentences: "The bill defines recalcitrant cancers as those 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 fit this definition of recalcitrant cancers." These sentences have been replaced with the following: "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 recalcitrant cancers." A correction has been issued for the OnlineFirst version. The publisher regrets the error.

For more news on cancer research, visit *Cancer Discovery* online at http://CDnews.aacrjournals.org.