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.

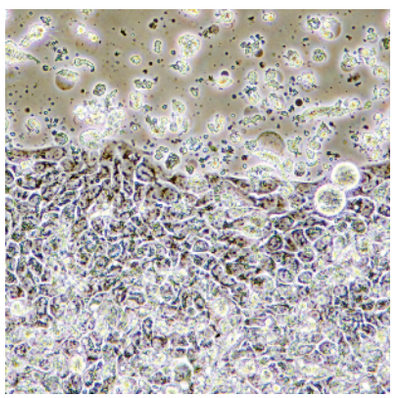
FDA approval was based on a single international trial of 760 patients previously treated for metastatic colorectal cancer. Researchers randomly assigned patients to receive either regorafenib or a placebo, in addition to supportive care. The patients continued treatment until they could no longer tolerate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