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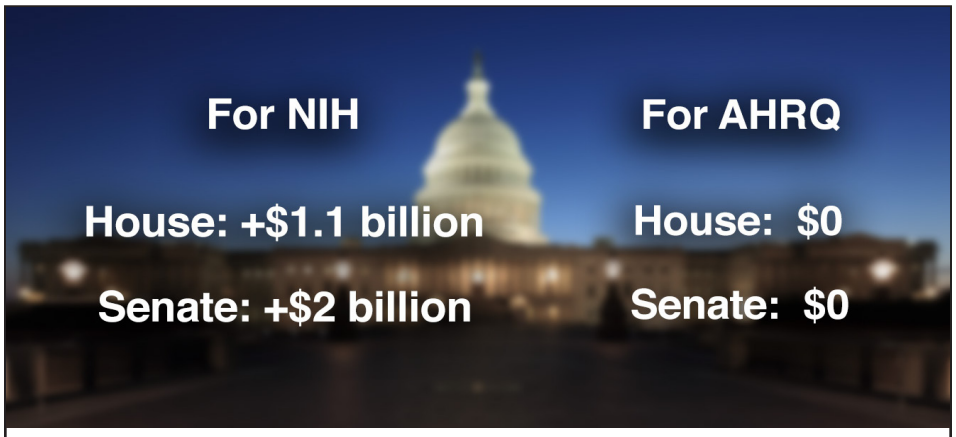

NIH Receives Glimmer of Hope As AHRQ Inches Closer to Elimination

By Nick Crispino

The House and Senate appropriations committees earlier this week passed parallel spending bills that would boost NIH budgets while eliminating the Agency for Healthcare Research Quality, a $465 million agency that plays a central role in the implementation of President Barack Obama's health care law.

After more than a decade of flat funding and budget cuts, both bills provided aggressive increases for NIH:

• The House appropriations committee approved a proposed $1.1 billion increase on June 24.

• Senate subcommittee appropriators went even further, proposing a $2 billion increase during markup June 23.

(Continued to page 2)

ASCO Publishes Drug Value Assessment Tool

By Paul Goldberg

The American Society of Clinical Oncology earlier this week published a proposed framework for assessing the value of new cancer treatments.

The paper, published in the Journal of Clinical Oncology June 22, quantifies clinical benefit, side effects and cost as components of value.

ASCO's objective is to build a standardized tool that can be used as the basis of shared decision-making by oncologists and their patients.

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In Brief

Five Members Appointed to NCAB

PRESIDENT BARACK OBAMA appointed five members to the **National Cancer Advisory Board**.

(Continued to page 11)

Both Spending Bills Would Increase NIH's Budget, Ax AHRQ

(Continued from page 1)

The House committee approved the bill by a 30-21 vote, and the Senate subcommittee by 16-14. Voting along party lines, Congressional Republicans dealt their one-two punch to the Affordable Care Act on the eve of the Supreme Court's ruling June 25 in King v. Burwell, which upheld a key provision of the Affordable Care Act.

The justices voted 6-3 in the decision that affirmed an IRS ruling that authorized tax subsidies for eligible Americans who buy health insurance, regardless of whether they live in an area with state-based health insurance marketplace or in the 34 states with federal marketplaces.

The House and Senate appropriations bills, if passed by Congress, would halt implementation of the ACA by rescinding previously allocated funds and prohibiting the use of any additional money to implement the law (The Cancer Letter, June 19).

The Republicans' efforts to cripple the ACA are making the appropriations bills unacceptable to the White House, which makes it impossible to predict whether proposed increases for NIH would remain in the final version of the spending bill.

In his remarks to the joint session of the National Cancer Advisory Board and the Board of Scientific Advisors June 24, NCI Acting Director Douglas Lowy focused on the potential increases in appropriations:

"There may be some glimmer for FY16 and beyond that the freeze that we have had in the appropriations landscape may be undergoing a thaw," Lowy said. "Both the Senate, as well as the House, have essentially gone along with relatively large proposals—for example, our NCI proposal was for close to a 15 percent increase for FY16, and the president's budget for a little over 3 percent.

"But just because the committees are marking these up with positive results does not necessarily mean the budget is passed that it will be that way. But we can, perhaps, be cautiously optimistic, for perhaps the first time in a long time, that there might be some appropriations increases for the NIH, including NCI."

For cancer organizations, the twin bills create a heart-wrenching challenge of separating the good from the bad.

"Patients, survivors and their loved ones are applauding Members of Congress for placing high value on the fight to defeat cancer in this country," American Cancer Society Cancer Action Network President Chris Hansen said in a statement June 24.

"We are however disappointed that the House bill includes proposed funding cuts to the operating funds for health care exchanges, as well as cuts to funding for innovative demonstrations that are examining ways to provide better quality care to patients, as access to quality health care is critical to saving lives from cancer.

"As the FY 2016 budget process moves forward, we urge Congress to figure out a way to fund the nation's priorities and stop cutting programs that are critical to our nation's health.

"To truly impact the cancer burden, Congress must prioritize access to proven prevention and treatments and invest in research that promotes further discovery."

The Obama administration should not "crow" about its Supreme Court victory, Senate Majority leader Mitch McConnell said in a statement.

"Today's ruling won't change Obamacare's multitude of broken promises, including the one that resulted in millions—literally millions of Americans losing the coverage they had and wanted to keep," McConnell said. "Today's ruling won't change Obamacare's spectacular flops."

The House and Senate appropriations push to eliminate funding for the ACA via AHRQ isn't new.

Similar attempts to defund the 25-year-old federal agency, which funds patient-centered outcomes research and monitors the manner in which medicine is practiced in the U.S., were made in 2010 and 2012 (The Cancer Letter, July 20, 2012).

In a letter to the House committee, the White House said the bill "seeks to turn back the clock" on progress made in containing health care costs and

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improving quality.

"Recent years have seen exceptionally slow growth across a wide range of measures of health care costs," wrote Shaun Donovan, director Office of Management and Budget. "The ACA has contributed to these trends by reducing excessive Medicare payments to Medicare providers and private insurers and by supporting innovative new ways of paying for health care in Medicare and throughout our health care system that encourage lower-cost, higher-quality care.

"These effects will grow in the years ahead as successful delivery system reforms mature and are scaled up and additional innovative reforms are implemented, but this bill would block most of these innovations, including eliminating the Agency for Healthcare Research and Quality, which invests in health services research that forms the foundation for delivery system reform efforts aimed at reducing health care costs and improving quality system-wide."

At the House committee markup June 24, Rep. Lucille Roybal-Allard (D-Calif.) fought to restore AHRQ funding in the bill. However, her proposal failed on a voice vote.

"AHRQ is the only federal agency with the sole charge of researching and disseminating evidence base information to make our healthcare safer, of higher quality, more accessible, equitable, and more cost efficient," Roybal-Allard said.

"Unfortunately, the bill before us actually eliminates AHRQ. This is done, I believe, under the mistaken belief that its work is duplicative or can be performed by other agencies."

Subcommittee Chairman Tom Cole (R-Okla.) said during markup that the legislation is an opportunity to reduce duplication and save costs.

"There are ample opportunities here to salvage what is appropriate and to get rid of some duplication," Cole said. "We're in a long process here and we haven't heard from the Senate yet. We'll certainly have an opportunity to revisit this issue.

"But for now, because there's no offset to [Roybal-Allard's] amendment, I will be forced to oppose it simply because it will put us over our allocation."

According to Roybal-Allard, AHRQ's budget is only 0.01 percent of all federal health care spending.

"The payback is many times more than that with better care, smarter spending, and healthier Americans," Roybal-Allard said. "Between 2010 and 2013, applications in AHRQ research resulted in a 17 percent reduction in hospital infections that saved 50,000 lives and $12 billion in health care spending," said Roybal-Allard.

"Even if there was money, no other HHS agency has the capacity or the proficiency to direct health services research to identify the most cost effective ways to organize, manage, finance, and delivery high quality care, reduce medical errors and improve patient safety," Roybal-Allard said.

A proposal to shift AHRQ to the National Coordinator for Health Information Technology would be detrimental because the appropriations bill does not provide additional resources, DeLauro said.

"AHRQ is the smallest of seven agencies that make up the Department of Health and Human Services," Rep. Rosa DeLauro (D-Conn.) said. "But it plays an important and a unique role that needs to be continued."

The American Society of Clinical Oncology said it will be reviewing the SCOTUS decision for cancer care implications of the ACA.

"ASCO is pleased that the provisions in the ACA that have significant impact for cancer patients and survivors—2.1 million of whom are Medicaid enrollees—will continue," ASCO said in a statement June 25. "These provisions include the requirement that private insurers and health plans cover the routine patient costs associated with participation in a clinical trial, the ban on lifetime limits and pre-existing condition, and the elimination of co-pays for preventative services like cancer screening.

"ASCO is concerned, however, about network adequacy for vulnerable populations who may need care outside of their network. ASCO will continue working with lawmakers to protect and retain critically important policies related to cancer treatments and screenings, and will work to eliminate healthcare disparities for patients with cancer. These core patient safeguards are critical to individuals who have cancer or who are at risk for cancer as the debate over ACA implementation continues."

House Appropriations Committee Publishes Report

The text of the House Appropriations Committee report for NCI follows:

Mission—NCI conducts and supports basic and applied cancer research in early detection, diagnosis, prevention, treatment, and rehabilitation. NCI provides training support for research scientists, clinicians and educators, and maintains a national network of cancer centers, clinical cooperative groups, and community clinical oncology programs, along with cancer prevention and control initiatives and outreach programs to rapidly translate basic research findings into clinical practice. The Committee expects the Institute to

systematically coordinate through other HHS agencies to share new scientific information to ensure it reaches the community and providers through various other HHS outreach programs.

The Committee modifies the bill language, as requested by the Administration, to allow NCI to use up to $16,000,000 for repairs and improvements at the NCI Frederick Federally Funded Research and Development Center in Frederick, MD due to the increasing maintenance backlog of this site.

Breast Cancer—The Committee is aware of recent news coverage highlighting studies about mammography screening for breast cancer that questions the use and validity of screening for discovering cancers. Although the majority of scientific studies have corroborated the value of early detection of breast cancers through screening, other studies have concluded that screening sometimes results in false positives and over treatment. This has created a less clear picture of the benefits of screening and may lead women to avoid periodic mammography, an experience some women already view as uncomfortable. From 1990 to 2010, deaths from breast cancer decreased by 34%. This drop in breast cancer mortality has been attributed to both improvements in treatment and earlier detection of cancers. However, in 2013, 230,000 new cases of breast cancer were diagnosed in the United States and almost 40,000 women died from breast cancer.

Given the current controversies over screening and the need to validate new screening technologies versus existing technologies, it is clear that a new, comprehensive study of these issues is warranted. The Committee encourages NCI to support research to address these issues and to hopefully provide women and physicians with a clearer, more informed picture of how breast cancer imaging should be considered as part of the overall women's health care environment and urges the Secretary not to implement changes to the breast cancer screening recommendations until this research is completed.

Cancer Disparities—The Committee requests NCI and the National Institute on Minority Health and Health Disparities (NIMHD) to prepare a joint update for the fiscal year 2017 budget request on efforts underway and planned to end this disparity, including activities to focus on research, prevention, and treatment of cancer in minority communities.

Colorectal Cancer—The Committee encourages support of meritorious scientific research on colorectal cancer to better understand the biology of young-onset colorectal cancer. Specifically, the Committee requests an update in the fiscal year 2017 budget request related to research activity on the biology of young-onset colorectal cancer in adults under the age of 50.

Gastrointestinal Cancer—The Committee continues to be concerned about gastric cancer, particularly among young adults and supports gastric cancer being studied in The Cancer Genome Atlas (TCGA). The Committee notes that research on gastric cancer is less advanced than that of many other cancers. The Committee therefore encourages NCI to consider requesting applications for gastric cancer research that leverages the use of genomic data from the TCGA.

Heavy Ion Cancer Therapy and Research—The Committee understands NCI recently issued a planning grant for a Heavy Ion Therapy and Research. The Committee encourages NCI to coordinate with other federal agencies on the need and potential funding sources in determining the scientific justification to move forward or retrofit any existing facilities.

Liver Cancer—The Committee continues to be concerned with the lack of a focused liver cancer research program. The NCI is urged to support a Specialized Program of Research Excellence on liver cancer, as well as liver cancer program projects. The Committee encourages more focus on the development of biomarkers to serve as early detection markers of cancer to therefore offer the prospect of improved outcomes.

Melanoma—The Committee encourages NCI to develop a 5-year plan across NCI's divisions, and coordinate with other federal agencies and advocates to align melanoma research resources. The Committee understands the NCI MATCH Trial and Exceptional Responders Initiative may provide valuable insight to benefit melanoma subpopulations knowledge and encourages use of these mechanisms.

The Committee requests an update in the fiscal year 2017 budget request on these efforts.

NCI Designated Cancer Centers.—The Committee requests an update in the fiscal year 2017 request on

how NCI supports or plans to support Institutional Development Award programs in states to broaden the NCI designated cancer center representation within these states.

NCI Precision Medicine Initiative (PMI).—The Committee provides the requested funds to support the five-year NCI PMI plan that will support activities such as the pediatric MATCH trial, clinical trials for five major cancer types based on genomic driven data, liquid biopsies, new models of cancer diagnostics, test targeted agents for clinical trials, and the related informatics infrastructure.

The Committee understands the NCI PMI is a one-time increase of $70,000,000 for five years. The Committee requests NCI to provide a breakout in the fiscal year 2017 budget request and future years with the specific science and funding details with these and NCI funds already supporting the PMI activity. The details should include long-term goals, milestones, and annual progress. The Committee encourages NCI, as scientifically feasible, to support existing research networks, especially collaborative efforts among NCI supported cancer centers and institutions serving historically underserved populations as they have certain attributes of cancer genomic data sharing that may be particularly effective.

Office of Cancer Survivorship—The Committee requests a report in the fiscal year 2017 budget request on actions planned or ongoing to focus resources and attention to the youngest of cancer survivors.

Pancreatic Cancer—The Committee encourages NCI to prioritize support for meritorious research for pancreatic cancer generally and specifically related to early detection of pancreatic cancer. The Committee encourages a focus on promising research to test members of high-risk pancreatic cancer families, including non-invasive screening methods. The Committee requests an update in the fiscal year 2017 budget request on these efforts.

Pediatric Low Grade Astrocytoma Research (PLGA)—The Committee encourages continued research efforts toward the identification of new therapies for PLGA patients, to include clinical trials. The Committee urges NCI and NIH to seek public/private partnerships opportunities on PLGA research. The Committee requests an update in the fiscal year 2017 budget request on on-going and planned activities across NIH.

ASCO Publishes Tool for Assessing Drug Value

(Continued from page 1)

The society proposes juxtaposing cost against the "net health benefit" metric, or NHB. The NHB is defined as the added benefit patients can expect to receive from the new therapy, versus the current standard of care.

The metric is calculated based on improvement in overall or progression-free survival, and on the number and severity of toxicities.

The paper shows how, for patients with advanced cancer, a higher NHB is awarded for regimens that also offer relief from cancer-related symptoms or allow patients a treatment-free period.

The NHB can be considered together with the patient's expected out-of-pocket costs for the regimens being compared, as well as the overall drug acquisition cost.

In the JCO paper, the NHB is derived from randomized clinical trials directly comparing chemotherapy regimens.

However, "one could envision an NHB calculated by measurement of patient OS, PFS, RR, and toxicities, derived from collation of data from real-world patient experiences, with these parameters measured in absolute values and not relative to a comparator arm (e.g., SEER program)," the article states.

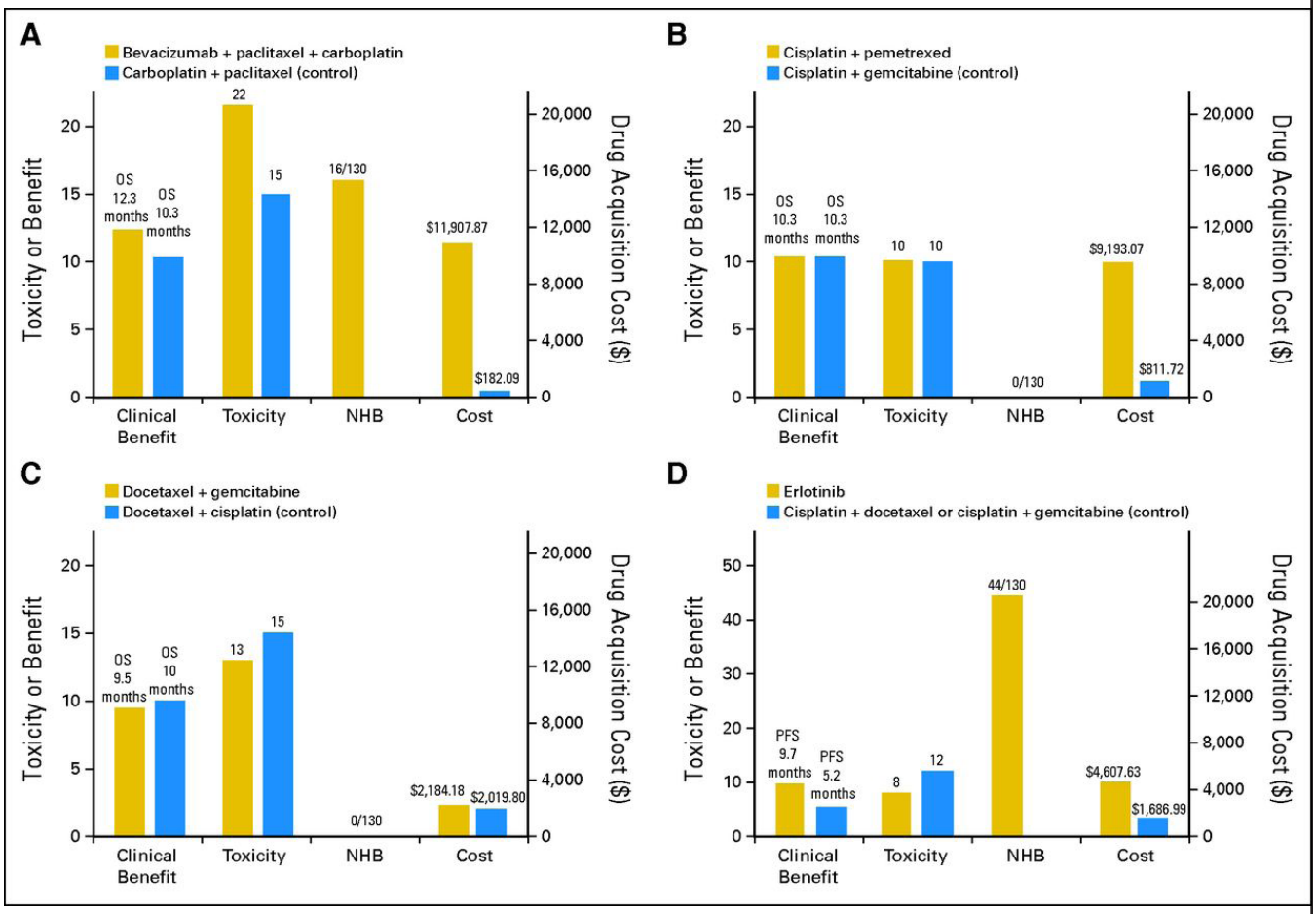
"Assuming a large-enough database, patients could also search to match their characteristics to those of other patients as a way of predicting their personal NHB with a specific therapy. Such a model will require maintaining a large database of medical records of patients with cancer, with advanced search capability, such as that being developed for the ASCO CancerLinQ, a rapid learning system for oncology."

Value Measured in Four Scenarios

Metrics proposed by the Institute of Medicine in 2013 call for using six metrics for assessment of value. In addition to clinical benefit, toxicity and cost—the three metrics that form the basis of ASCO's approach—IOM proposes including patient-centeredness, timeliness of therapy, and equity.

The latter three elements aren't easily quantified, ASCO concluded in preparation of its framework.

The ASCO paper goes through clinical scenarios that include first-line treatment of metastatic non-small cell lung cancer, advanced multiple myeloma, metastatic prostate cancer, and adjuvant therapy for HER2-positive breast cancer.



Clinical benefit, toxicity, net health benefit, and cost of four regimens when compared with standard-of-care used in clinical trials for first-line treatment of metastatic non–small-cell lung cancer. ASCO published similar graphs for treatments of multiple myeloma, prostate cancer and breast cancer. Source: JCO

For example, in the case of NSCLC, clinical benefit, toxicity, net health benefit, and cost are presented for four regimens:

• Bevacizumab, paclitaxel, and carboplatin versus carboplatin plus paclitaxel (control),

• Cisplatin plus pemetrexed versus cisplatin plus gemcitabine (control),

• Docetaxel plus gemcitabine versus docetaxel plus cisplatin (control),

• Erlotinib versus cisplatin plus docetaxel or cisplatin plus gemcitabine (control) in patients with *EGFR* mutation-positive advanced NSCLC.

The paper shows that in some clinical scenarios, a newer, more expensive regimen had a much larger NHB than the previous standard. In other scenarios, the newer regimen showed little or no net health benefit.

"Value and cost are among the biggest issues in healthcare today, but there are few tools to help doctors and patients objectively assess benefits, side effects and costs," ASCO President Julie Vose said in a statement. "Our goal is to help oncologists and their patients weigh potential treatment options based on high-quality scientific evidence and a thoughtful assessment of each patient's needs and goals. In publishing this initial version of the framework, just the beginning of the process, we hope to drive discussion and debate about a critically important issue.

"This framework is about weighing the options, not limiting them. It should not be used to replace physician judgment or patient preference."

ASCO is inviting comments on the framework.

Bach: ASCO's Stance Signals "Paradigm Shift"

"Even well-insured patients are often unprepared for the high out-of-pocket cost of some cancer therapies. Too often, that leads to severe financial strain and even bankruptcy," Lowell Schnipper, chair of ASCO's Value in Cancer Care Task Force, said in a statement.

The average price of new cancer drugs is $10,000 per month, and some cost as much as $30,000 per month.

"It's critical to distinguish between value and cost," said Schnipper. "Sometimes the more valuable treatment will be the more expensive one and sometimes it won't be. Ultimately, the definition of 'value' will be highly personalized for each patient, taking into account an individual's own preferences and circumstances. For example, in the setting of advanced cancer, is length of life the most important goal or is quality of life? Is the proposed treatment affordable? That's why we're proposing to provide information on net health benefit and cost side-by-side."

Last week, Peter Bach, a researcher at Memorial Sloan-Kettering Cancer Center, proposed DrugAbacus, a tool for measuring value of new cancer therapies (The Cancer Letter, June 19).

"There are technical differences between the DrugAbacus and the ASCO value paper, but they are minor," Bach, who is not involved in the ASCO initiative, said to The Cancer Letter. "ASCO, the largest organization of oncologists in the world, is calling for a framework by which we can evaluate cancer treatments with respect to their costs. That is an important paradigm shift by a highly respected organization that has always been closely intertwined with drug development and pharmaceutical education dollars. It is a sea change, necessitated by the reality that high prices are harming the patients the system is supposed to be helping.

"ASCO also is calling on all of us, including those designing clinical trials, to expand the way we think about value to the patient. They propose explicitly including a score for treatments that achieve palliative objectives, including giving patients longer intervals off of treatment entirely. If that kind of concept could be formalized, we will hopefully get more research about the impact of new treatments on these endpoints—as ASCO notes the data on many treatments is thin or absent in these domains."

MD Anderson Team Says Blood Cancer Drugs Not Cost-Effective

In a related development, the journal Cancer published a paper that concludes that the majority of existing treatments for hematologic, or blood, cancers are currently priced too high to be considered cost-effective in the U.S.

Their findings were published online in the journal Cancer June 23.

The text of the abstract follows:

"In the past 15 years, treatment outcomes for hematologic malignancies have improved substantially. However, drug prices have also increased drastically. This commentary examines the value of the treatment of hematologic malignancies at current prices in the United States through a reanalysis of a systematic review evaluating 29 studies of 9 treatments for 4 hematologic malignancies. Incremental cost-effectiveness ratios (ICERs) were calculated on the basis of drug prices in the United States in 2014. Sixty-three percent of the studies (15 of 24) had ICERs higher than $50,000 per quality-adjusted life-year (QALY), the benchmark widely used by health economists to define cost-effectiveness. In studies evaluating the current standard-of-care treatments for chronic myeloid leukemia, the ICERs for tyrosine kinase inhibitors versus hydroxyurea or interferon ranged from $210,000 to $426,000/QALY. The lower ICER values were mostly obtained from 11 studies evaluating rituximab, which was approved by the Food and Drug Administration in 1997 (ICER range, $37,000-$69,000/QALY). In conclusion, the costs of the majority of new treatments for hematologic cancers are too high to be deemed cost-effective in the United States."

The paper directly counters an analysis published in the journal Blood earlier this year. That paper, by Saret et al., of Tufts Medical Center, concluded that drugs for hematologic malignancies are cost-effective (The Cancer Letter, Feb. 13).

Jagpreet Chhatwal, assistant professor of health services research at MD Anderson Cancer Center and Hagop Kantarjian, chair of the Department of Leukemia at the cancer center, said that cost-effectiveness calculations by the Tufts group were performed using drug prices at the time of the original studies, and often included prices from countries outside of the U.S.

Therefore, Chhatwal and Kantarjian performed a critical re-analysis.

"We found that, in a majority of the studies, the incremental cost-effectiveness ratios (ICERs) were substantially higher than the previously reported values," said Chhatwal, the study's lead author. "This led us to the conclusion that current prices are too high to say that the drugs provide a good value for the money."

OHSU Reaches $1 Billion Goal, Begins Recruiting Scientists

Oregon Health & Science University met the challenge posed by Nike co-founder Phil Knight and his wife Penny by raising $500 million in less than two years, earning the Knights' matching gift and setting a $1 billion fundraising record. The announcement was made June 25.

The $1 billion will support the first large-scale program dedicated to early detection of lethal cancers. OHSU Knight Cancer Institute will now begin rapid recruitment of about 25 of top-tier researchers.

These recruits will, in turn, hire an additional 225 to 275 scientists and physicians, forming a team focused on the detection of cancer, including the early biological changes in the body that signal a lethal cancer is beginning to develop. These scientists will be given substantial financial support, so they can focus on discovery instead of spending time securing grants.

OHSU will also move forward with construction of two buildings: a cancer research facility designed from the ground up to support a new model of combining scientific disciplines to speed progress, and new cancer care clinics for expanded clinical trials that will translate the scientific discoveries made by the team into next-generation detection tests, tools and treatments.

"While cancer treatment has evolved to become more precise and less toxic, the tests and tools used for cancer detection have not changed in decades. Without better, earlier detection, and a full understanding of cancer's origins in the body, the promise of precision cancer medicine cannot be realized," said Brian Druker, director of the OHSU Knight Cancer Institute.

Druker conducted the research that led to the development of Gleevec (imatinib) for chronic myeloid leukemia.

"Penny and I have total confidence in Brian Druker and the entire OHSU Knight Cancer Institute team to put a stop to a disease that touches each of our lives," said Knight. "These last 22 months have shown what is possible when people of vision focus on a single goal. We are more convinced than ever that cancer will meet its match at OHSU, and we are proud to play a role in this history in the making."

In the past few weeks, more than $20 million in donations came in to support the campaign, including significant gifts from Cambia Health Foundation; Pat and Stephanie Kilkenny of San Diego; Mark Wolfson and Jasper Ridge Partners; Intel Corp.; Wayne D. Kuni and Joan E. Kuni Foundation; the Blumenfeld family of New York; the Wendt family of Klamath Falls, Ore.; and Consumer Cellular.

The largest gift received since the campaign launched in 2013 was from the state of Oregon, which invested $200 million for the needed research and clinical facilities.

The largest gift from an individual, $100 million, came from Columbia Sportswear Chairman Gert Boyle.

In all, more than 10,000 donors participated and, of these, more than half were first-time donors to OHSU.

Donations were received from every state in the nation and five countries.

The Knights made their challenge pledge in September 2013 after being inspired by the OHSU Knight Cancer Institute's goal to revolutionize how cancer is detected. The challenge pledge follows their $100 million gift to OHSU in 2008 to support Druker's work.

According to researchers with the Indiana University Lilly Family School of Philanthropy, meeting the Knights' $500 million fundraising challenge marks the largest documented challenge pledge to succeed.

Appropriations Bill Seeks to Preempt FDA Efforts to Broaden Tobacco Regulation

By Nick Crispino

A $20.65 billion agriculture appropriations bill, which cleared a House subcommittee June 18, seeks to limit FDA's ability to review electronic cigarettes, cigars and other tobacco products already on the market.

The legislation—which was approved by the House Appropriations Subcommittee on Rural Development, Food and Drug Administration and Related Agencies—would prevent the FDA Center for Tobacco Products from requiring products already on the market to go through the Premarket Tobacco Review application process under the Federal Food, Drug and Cosmetic Act.

The bill's exemption of existing tobacco products from potential FDA review appears to have been created in response to FDA's April 24 proposal to extend the agency's tobacco authority to cover additional products, including e-cigarettes.

Under the FDA proposal, manufacturers of tobacco products—including currently unregulated marketed products—are subject to the agency's regulation. FDA currently regulates cigarettes, cigarette tobacco, roll-your-own tobacco and smokeless tobacco.

Products that would be deemed subject to FDA regulation are those that meet the statutory definition of a tobacco product, including currently unregulated marketed products such as e-cigarettes, cigars, pipe tobacco, nicotine gels, waterpipe (or hookah) tobacco, and dissolvables not already under the FDA's authority.

Manufacturers of these products would be required to:

• Register with FDA and report product and ingredient listings,

• Only market new tobacco products after FDA review,

• Only make direct and implied claims of reduced risk if FDA confirms that scientific evidence supports the claim and that marketing the product will benefit public health as a whole, and

• Not distribute free samples.

The House bill would exempt any tobacco products that are already on the market from being reviewed when FDA issues its final rule, which is expected later this year. A vote by the full House committee, initially scheduled for June 25, has been delayed.

A coalition of public health groups—including the Campaign for Tobacco-Free Kids, American Cancer Society Cancer Action Network, American Heart Association and American Lung Association—is urging Congress to reject the language in the bill.

"Our organizations urge rejection of language included in a U.S. House appropriations bill that would significantly limit the Food and Drug Administration's ability to protect our nation's children from flavored cigars and e-cigarettes now on the market, including e-cigarettes with flavors such as gummy bear and cotton candy," the groups said in a joint statement.

"The appropriations language would undermine a key provision of the landmark 2009 law giving the FDA authority over tobacco products and weaken the FDA's proposed regulation of e-cigarettes, cigars and other tobacco products.

"Rarely has Congress so blatantly put the special interests of the tobacco industry above the health of America's kids."

The American Vaping Association—an advocate for the benefits of vapor products such as electronic cigarettes—praised the bill:

"Without action by Congress, the FDA's proposed regulations threaten to ban 99 percent of vapor products currently available on the market," Gregory Conley, president of the American Vaping Association, said in a statement. "This would be a disaster not only for thousands of small businesses."

"Anyone who claims that this bill would somehow render the FDA toothless is either not familiar with the law or not being forthright.

"We are thrilled to see movement on this issue. It is unconscionable to effectively ban the sale of tens of thousands of vapor products while leaving combustible cigarettes freely available."

Anti-tobacco advocates highlight a recent CDC survey, which found that youth e-cigarette use tripled from 2013 to 2014—increasing from 4.5 percent to 13.4 percent among high school students—and now exceeds youth use of regular cigarettes.

High school boys now smoke cigars at about the same rate as cigarettes—10.8 percent for cigars and 10.6 percent for cigarettes. Cigars are the most commonly used tobacco products among African American high school students, who smoke cigars at nearly twice the rate of cigarettes, according to the CDC.

"Over the last several years, tobacco manufactures have introduced flavored cigars to get around the ban on flavored cigarettes that appeal to kids, and e-cigarette manufacturers have introduced thousands of flavored products that appeal to kids," the Campaign for Tobacco-Free Kids coalition said in its statement. "Congress should not interfere with the FDA's ability to regulate these products to protect our nation's kids and health."

Study: Widespread Overtreatment Of Benign Lung Nodules in Community Oncology Practices

Thousands of U.S. patients may be undergoing unnecessary lung biopsies and surgeries annually due to overtreatment of benign lung nodules, according to a study published in the journal CHEST.

The study—funded by Integrated Diagnostics, or Indi—examined how community pulmonologists treated and managed the care of 377 patients with indeterminate (medium-sized) lung nodules. The paper is titled "Management of Pulmonary Nodules by Community Pulmonologists: A Multicenter Observational Study."

Findings showed a relatively low overall rate of cancer, 25 percent, but a significantly higher rate of invasive procedures.

Thirty-five percent of the patients in the retrospective review who underwent surgery turned out to have benign nodules. Forty-four percent of patients initially deemed at low risk by some models for malignancy nevertheless underwent an invasive procedure.

"[This suggests] that some pulmonologists may not be adhering to existing guidelines for managing nodules," Indi officials said in a statement. "American College of Clinical Pharmacy guidelines suggest CT surveillance for patients deemed have less than 5 percent risk of cancer.

"Estimates of number of patients with pulmonary nodules range from 150,000 to one million per year in the U.S.—most of which turn out to be benign. The incidence of these nodules is likely to rise given the recent recommendation by the US Preventive Services Task Force to screen high risk smokers and former smokers with annual CT scans."

Indeterminate lung nodules—between 8 and 20 mm—are difficult to diagnose, said Gerard Silvestri, Hillenbrand Professor of thoracic oncology, Medical University of South Carolina, one of the principal investigators of the study.

"Typically, nodules smaller than those are treated conservatively, while larger ones are treated more aggressively. This is the first study of its kind to focus on this middle group," Silvestri said. "The results indicate there is significant variation in how lung nodules are managed.

"Further, when we went back and calculated the patients risk of having lung cancer at presentation, those in the low risk group had similar rates of surgery as those in high risk groups. We concluded that some patients with indeterminate lung nodules may be too aggressively treated."

According to Indi, conservative management of lung nodules—sometimes referred to as "watchful waiting"—involves repeated CT scans over a two-year period to monitor the progress of patients whose nodules are initially deemed likely to be benign.

If the clinician's initial assessment of the patient's lung nodule is later found to be incorrect, then the cancers are usually discovered early in the follow up period and remain at an early enough stage for therapeutic intervention.

The retrospective study was funded by Indi, the maker of Xpresys Lung, a non-invasive, clinical laboratory-based, molecular blood test service designed to help physicians identify benign lung nodules with high probability. A separate, recent clinical validation study of the laboratory-developed test showed when the test indicates a nodule is likely benign, the result is correct between 84 and 98 percent of the time—with each nodule receiving an individual score based on its molecular signature.

Xpresys Lung is supported by a landmark clinical validation study published in The Journal of Thoracic Oncology in January 2015 and two studies published in Science Translational Medicine in October 2013.

"The chart review study suggests many more patients should be put into 'watchful waiting'," said Indi CEO Albert Luderer. "Xpresys Lung is designed specifically to help pulmonologists evaluate whether to put more of their patients into watchful waiting with confidence. We believe doing so will reduce over-treatment, lower costs and risks, and lessen patient anxiety. Our hope is the use of Xpresys Lung will make it easier for pulmonologists to follow established clinical guidelines."

The chart review study is a multicenter, community-based chart review of patients age 40 to 89 years with indeterminate pulmonary nodules presenting to 18 geographically representative outpatient pulmonary clinics across the U.S. Nodule size was restricted to 8 to 20 mm because management decisions in this size range are the most challenging.

"In the coming years, we are likely to see a significant rise in the number of indeterminate lung nodules due to new recommendations from the USPSTF to screen high risk individuals with annual low dose CT scans," said lead author Nichole Tanner, assistant professor at the Medical University of South Carolina. "My hope is this study will play an important role in raising awareness of the importance of managing these patients and those with incidentally detected nodules in closer accordance with established guidelines and ensure that only those patients with concerning findings are subjected to the risks associated with invasive procedures."

Funding Opportunity

AACR Launches Grant Program For Young Investigators

The American Association for Cancer Research has launched the AACR NextGen Grants for Transformative Cancer Research, a funding initiative to stimulate innovative research from young investigators.

The grant mechanism is intended to promote and support creative, paradigm-shifting cancer research that, because of its very nature, may not otherwise be funded through existing channels.

The grants will provide a total of $450,000 over three years, beginning July 1, 2016. The recipients will formally accept the grants at the AACR's 2016 Annual Meeting, held April 16-20 in New Orleans.

Eligibility will be limited to junior faculty who, at the start of the grant term, have held a full-time, tenure-track appointment as an assistant professor for no more than three years. The proposed research must represent a highly innovative approach to a major contemporary challenge in cancer research.

Funded projects must have the potential to lead to groundbreaking discoveries in the field, and transform the understanding of the tumorigenesis process or the ability to treat, detect or prevent cancer, according to AACR. The research can be in any area of basic, translational, or clinical science.

"The AACR NextGen Grants for Transformative Cancer Research represent an exciting new initiative to provide funding to young investigators who are working on projects that have the potential to lead to major breakthroughs in the field of cancer research," Carlos Arteaga, AACR immediate past-president, and the Donna Hall chair in breast cancer research and director of the Center for Cancer Targeted Therapies at Vanderbilt-Ingram Cancer Center, said in a statement.

Further details are available online. Letters of intent must be submitted by noon ET, Aug. 10, using the proposalCENTRALwebsite. Additional inquiries may be directed to Ashley Jones at grants@aacr.org.

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In Brief

Five NCAB Members Appointed

(Continued from page 1)

The five NCAB members are:

• **PETER ADAMSON** is attending physician in the Division of Oncology at the Children's Hospital of Philadelphia, a position he has held since 1999. Adamson has been chair of the Children's Oncology Group since 2010.

He was chief of the Division of Clinical Pharmacology and Therapeutics at CHOP from 1999 to 2014, and also served as director of the office of Clinical and Translational Research from 2005 to 2011. He served as professor of Pediatrics and Pharmacology and associate professor of Pediatrics and Pharmacology at the University of Pennsylvania from 1999 to 2006.

He was an investigator in the Pediatric Oncology Branch of NCI from 1995 to 1999, and he served in the United States Public Health Service from 1994 to 1997. Adamson was the Children's Cancer Foundation research scholar from 1992 to 1994.

He was a biotechnology fellow from 1990 to 1992 and a pediatric hematology/oncology fellow at NCI from 1987 to 1990.

He began his pediatric career as a resident at CHOP from 1984 to 1987. Adamson received a B.A. from Wesleyan University and an M.D. from Cornell University.

• **DEBORAH BRUNER** is currently the Robert W. Woodruff Professor of Nursing at the Nell Hodgson Woodruff School of Nursing, professor of Radiation Oncology, and associate director for outcomes research at the Winship Cancer Institute of Emory University, positions she has held since 2011.

Before joining Emory University, Bruner served at the University of Pennsylvania as professor of Nursing and Radiation Oncology from 2006 to 2011 and as co-leader of the Cancer Prevention and Control Program at the Abramson Cancer Center from 2008 to 2011.

From 1989 to 2006, she held various positions at the Fox Chase Cancer Center, including nurse manager/clinical specialist in the Department of Radiation Oncology, director of the Prostate Cancer Risk Assessment Program, and director of the Symptoms and Outcomes Research Program.

From 1986 to 1989, Bruner was a gyn-oncology clinical nurse specialist/program coordinator at the Albert Einstein Medical Center. She served as research nurse for Burns and Trauma at Crozer-Chester Medical

Center from 1985 to 1986.

Bruner began her career as a staff nurse at the Crozer-Chester Medical Center from 1978 to 1985. She received a B.S.N. from West Chester University, an M.S.N. in Oncology and an M.S.N. in Administration from Widener University, and a Ph.D. from the University of Pennsylvania.

• **YUAN CHAN** is a professor of pathology at the University of Pittsburgh, a position she has held since 2002. Chang has been a distinguished professor of pathology since 2012, and is the University of Pittsburgh Cancer Institute chair of cancer virology.

She served in a few positions at the Columbia University College of Physicians and Surgery during her tenure, first as assistant professor of pathology from 1993 to 1997, associate professor of pathology from 1997 to 2000, and then as professor of pathology from 2000 to 2002.

From 1991 to 1992, Chang was clinical instructor in the Department of Pathology at Stanford University Medical Center. She has also held a number of clinical assignments, including assistant attending pathologist at Columbia Presbyterian Hospital from 1993 to 1997, associate attending pathologist from 1997 to 2000, and attending pathologist from 2000 to 2001.

She is a member of the National Academy of Sciences. Chang received a B.S. from Stanford University and an M.D. from the University of Utah College of Medicine.

• **TIMOTHY LEY** is director of the stem cell biology section in the Division of Oncology at Washington University School of Medicine, a position he has held since 2000.

Ley has also served as the associate director for cancer genomics at the Genome Institute at Washington University since 2008. He has held various faculty positions at Washington University since 1986, including professor of medicine and genetics, director of the Hematopoiesis Research Center, and director for basic science at the Alvin J. Siteman Cancer Center.

From 1984 to 1986, Ley was senior investigator for the National Heart, Lung, and Blood Institute, where he previously served as clinical associate from 1980 to 1983. From 1983 to 1984, he was a hematology-oncology fellow at Washington University Medical Center.

He completed his residency at Massachusetts General Hospital from 1979 to 1980, and he served as a commissioned officer with the United States Public Health Service from 1980 to 1986.

He is a past president of the American Society for Clinical Investigation and was chair of the board of scientific counselors for the National Human Genome Research Institute from 2009 to 2013. He is also an elected member of the Institute of Medicine and of the American Academy of Arts and Sciences. Ley received a B.A. from Drake University and an M.D. from Washington University School of Medicine.

•**MAX WICHA** is the Madeline and Sidney Forbes professor of oncology at the University of Michigan Comprehensive Cancer Center, a position he has held since April 2015.

Wicha has served as attending physician for Medical Oncology In-Patient and Consultation Services for the University of Michigan Health System since 1980.

In 1986, he founded the University of Michigan Comprehensive Cancer Center and served as its director since its inception until 2015. Wicha has held various positions at the University of Michigan Medical School since 1980, including assistant professor, associate professor, chief of the division of hematology/oncology, director of the Simpson Memorial Research Institute, and distinguished professor of Oncology.

From 1977 to 1980, he served in several capacities at NCI including research associate, investigator in the Laboratory of Pathophysiology, and then as a clinical oncology fellow. Wicha served as a commissioned officer in the United States Public Health Service from 1977 to 1980 and completed his residency at the University of Chicago Hospitals and Clinics from 1975 to 1977.

He is a past president of the American Association of Cancer Institutes and a fellow of the American Academy of Arts and Sciences. Wicha received a B.S. from the State University of New York at Stony Brook and an M.D. from Stanford University School of Medicine.

Five members are rotating off **THE NCI BOARD OF SCIENTIFIC ADVISORS.** They are:

• **Todd Golub**, (chair), chief scientific officer at the Broad Institute of Massachusetts Institute of Technology and Harvard University.

• **Curt Civin**, director of the Center for Stem Cell Biology and a regenerative medicine professor of pediatrics and physiology associate dean for research at the University of Maryland School of Medicine.

• **Betty Ferrell**, director and professor of Nursing Research and Education, as well as associate director for nursing research, at the City of Hope Comprehensive Cancer Center.

• **Bruce Stillman**, president and CEO of Cold Spring Harbor Laboratory.

• **Irving Weissman**, director of the Institute of Stem Cell Biology and Regenerative Medicine at Stanford University.

MAURIZIO D'INCALCI will receive an award in recognition of his scientific career at the Special Conference on Anticancer Drug Action and Drug Resistance: from Cancer Biology to the Clinic, organized by the **European Association of Cancer Research**, the **American Association of Cancer Research** and the **Italian Cancer Society** and that will be held in Florence, Italy, June 20-23.

D'Incalci will receive the first Pezcoller-Prodi Award in Scientific Career in recognition of his work in translational cancer research and his contribution to the advancement of new avenues in therapeutic oncology.

The award lecture will focus on the importance of translational research for the successful development of innovative drugs, using trabectedin as an example of a new class of drugs that target both cancer cells and the tumor microenvironment.

D'Incalci is the Head of the Department of Oncology at the IRCCS Institute for Pharmacological Research 'Mario Negri' in Milan, Italy. His lecture on "From seabed to the bedside: lessons learnt from the marine-derived anticancer drug trabectedin." will take place June 23.

Identified from an extract of a small marine macroorganism called Ectenascidia turbinata or sea squirt found in the Caribbean Sea, trabectedin has been developed into an anticancer drug approved in Europe and many other countries for the treatment of soft tissue sarcoma and ovarian cancer.

THE CONQUER CANCER FOUNDATION of the American Society of Clinical Oncology honored six oncology practices from throughout the U.S. with its 2015 Clinical Trials Participation Awards during the ASCO Annual Meeting in Chicago.

The CTPA was first awarded in 2003 to recognize community-based practices for excellence in implementing high-quality clinical trials programs and to also increase awareness and participation in clinical trials among physicians.

"The Clinical Trials Participation Awards are particularly special because they provide the Conquer Cancer Foundation with an opportunity to recognize the leaders in community oncology practices that contribute greatly to clinical advancements through involvement in cancer research," said W. Charles Penley, chair of the Conquer Cancer Foundation Board of Directors. "We are pleased to recognize these practices for their commitment to scientific innovation, and for their efforts to bring therapeutic breakthroughs to patients within their communities."

The 2015 CTPA recipients are:

● **Blue Ridge Cancer Care**, Roanoke, Va.

● **Cancer Care Specialists of Central Illinois**, Decatur, Ill.

● **Cone Health Cancer Center**, Greensboro, N.C.

● **Oncology Hematology Care Inc**., of Cincinnati

● **Scottsdale Healthcare**, Scottsdale, Ariz.

● **The Division of Gynecologic Oncology at St. Joseph's Hospital and Medical Center**, of Phoenix

THE BROAD INSTITUTE of MIT and Harvard University will work with **Google** to explore technical barriers that hinder biomedical research by addressing the need for computing infrastructure to store and process enormous datasets, and by creating tools to analyze such data.

The institute's Genome Analysis Toolkit will be offered as a service on Google Cloud Platform, as part of Google Genomics. The goal is to enable any genomic researcher to upload, store, and analyze data in a cloud-based environment. An initial alpha release of the GATK service will be made available to a limited set of users.

GATK is a software package developed at the Broad Institute to analyze high-throughput genomic sequencing data. GATK offers a variety of analysis tools, with a primary focus on genetic variant discovery and genotyping.

The institute plans to continue to support and upgrade GATK for all users, both on site and on the cloud, and will continue to offer the software directly. Academic and non-profit users will continue to have free access to GATK. By offering GATK on Google Cloud Platform, users will have another option that could eliminate the need for labs to develop additional computing infrastructure on site, according to MIT.

GUARDANT HEALTH has partnered with **SWOG** on a study to use cell-free DNA testing to identify mechanisms of resistance and future treatment options in non-small cell lung cancer.

SWOG chose Guardant360 as the blood test for a tumor genomic profiling study of approximately 600 lung cancer patients. The study will test patients at the time of enrollment and upon progression with

cell-free DNA. The test will be used to adjust therapy as appropriate for those patients progressing after first line treatment.

"Using blood to test changes in the genomic makeup of cancer allows us to obtain multiple specimens over time, something that is challenging to do with tissue biopsy," said David Gandara, chair of the SWOG Lung Cancer Committee. "NSCLC is an ideal tumor type to test this novel technology due to the known genomic complexity and evolution of this genomic landscape after therapy. In the case of patients with EGFR-mutated lung cancer, patients may fail first-line treatment due to the emergence of the T790M resistance mutation, which is one of the targets that Guardant360 will be used to detect."

The trial, known as SWOG-1403, will examine the potential that combination EGFR blockade, with cetuximab and afatinib, will be superior to afatinib alone as a frontline treatment for 600 patients with newly diagnosed EGFR-mutant non-small cell lung cancer. During the trial, blood samples will be taken at the time of enrollment and upon progression.

THE BARBARA ANN KARMANOS Cancer Institute and the **Detroit Tigers** will host the fourth annual "Pink Out the Park" Sept. 18 at Comerica Park in Detroit, as the Tigers play the Kansas City Royals. The event helps raise funds for breast cancer research at the Karmanos Cancer Institute.

Delta Air Lines, the official airline of the Detroit Tigers, will serve as host sponsor for Pink Out the Park.

Delta will be providing a free Pink Infinity Scarf to the first 10,000 women in attendance. FOX Sports Detroit will again provide Cheer Cards for all fans to write the name of a loved one battling breast cancer or honor the memory of someone lost to the disease. Special messages of support can also be tweeted at #pinkout.

Special sales promotions will benefit breast cancer research underway at Karmanos, as will the proceeds from two 50/50 raffles at Comerica Park.

Drugs and Targets

FDA Grants Priority Review To MM-398 in Pancreatic Cancer

FDA granted Priority Review to MM-398 for the treatment of metastatic adenocarcinoma of the pancreas following a gemcitabine-based therapy.

The FDA has set a goal of October 24 to take action under the Prescription Drug User Fee Act.

Sponsored by Merrimack Pharmaceuticals Inc. and Baxalta Incorporated, the new drug application is based upon the results of an international phase III study, NAPOLI-1, conducted in patients with metastatic pancreatic cancer who previously received gemcitabine-based therapy. MM-398 in combination with 5-fluorouracil and leucovorin achieved its primary and secondary endpoints by demonstrating a statistically significant improvement in overall survival, progression free survival and overall response rate compared to the control group of patients who received a combination of 5-FU and leucovorin.

Data for the study were presented at the European Society for Medical Oncology World Congress on Gastrointestinal Cancer in June 2014 and the American Society of Clinical Oncology 2015 Gastrointestinal Cancers Symposium in January.

MM-398 (irinotecan liposome injection) is a novel encapsulation of irinotecan in a long-circulating liposomal formulation. The activated form of irinotecan is SN-38, which functions by inhibiting topoisomerase I and promoting cell death.

The European Medicines Agency has also accepted a Marketing Authorization Application for MM-398 for the treatment of patients with metastatic adenocarcinoma of the pancreas who have been previously treated with gemcitabine-based therapy. The acceptance of the MAA marks the beginning of the review process in the European Union for MM-398 in this indication.

The FDA and EMA have granted MM-398 orphan drug designation for patients with metastatic pancreatic cancer. MM-398 was granted Fast Track designation by the FDA in November 2014.

Merrimack and Baxalta have entered into an exclusive licensing agreement to develop and commercialize MM-398 outside of the United States.

Soligenix Inc. will collaborate with the National Organization for Rare Disorders and the Cutaneous Lymphoma Foundation to recruit patients for its phase

III clinical study of SGX301 (synthetic hypericin) in the treatment of cutaneous T-cell lymphoma.

SGX301 has previously been granted both orphan drug and fast track designations from FDA for the first-line treatment of CTCL.

SGX301 is a photodynamic therapy utilizing visible light for activation. The active ingredient, synthetic hypericin, is a potent photosensitizer which is topically applied to skin lesions and activated by visible fluorescent light. This treatment approach avoids the risk of secondary malignancies inherent with chemotherapeutic drugs and other photodynamic therapies that are dependent on ultraviolet A exposure, according to Soligenix.

In a phase II, placebo-controlled clinical study in CTCL patients, the drug was safe and well tolerated, with 58.3 percent of CTCL patients responding to SGX301 treatment compared to only 8.3 percent receiving placebo ($p <= 0.04$).

The upcoming phase III protocol will be a double-blind, randomized, placebo-controlled, multicenter trial and will seek to enroll approximately 120 subjects. The trial is anticipated to begin in the second half of 2015 with primary data available in the second half of 2016.

Advaxis Inc. submitted a Special Protocol Assessment request to the FDA to initiate detailed design discussions for a phase III clinical study of ADXS-HPV for the treatment of high-risk, locally advanced cervical cancer.

The trial is planned to be conducted in collaboration with the Gynecologic Oncology Group Foundation, Inc. and to be led by principal investigator Thomas Herzog, professor of obstetrics and gynecology and clinical director at the University of Cincinnati Cancer Institute.

Following receipt, the FDA will determine the appropriateness of the SPA request and may take up to 45 calendar days to provide comments to Advaxis. The nature and extent of comments received will determine the need for additional rounds of review and/or a formal meeting, according to Advaxis.

The proposed clinical trial (AIM2CERV) is designed as a double-blind, placebo-controlled multinational study of ADXS-HPV (ADXS11-001) administered in the adjuvant setting following concurrent chemoradiation given with curative intent in patients with HRLACC for whom recurrence has not yet occurred. Advaxis plans to initiate the trial by the end of this year.

ADXS-HPV is Advaxis's lead Lm-LLO immunotherapy product candidate for the treatment of HPV-associated cancers. It is currently under investigation in three HPV-associated cancers: invasive cervical cancer, head and neck cancer, and anal cancer.

FDA granted orphan drug designations for ADXS-HPV for the treatment of stage II-IV invasive cervical cancer, HPV-associated head and neck cancer, and for HPV-associated anal cancer.

Amgen and Roche announced they will collaborate on a phase Ib study to evaluate the safety and efficacy of talimogene laherparepvec, Amgen's investigational oncolytic immunotherapy, in combination with Roche's investigational anti-PDL1 therapy, atezolizumab (also known as MPDL3280A), in patients with triple-negative breast cancer and colorectal cancer with liver metastases.

Talimogene laherparepvec is an investigational oncolytic immunotherapy designed to selectively replicate in tumors and to initiate an immune response to target cancer cells. Atezolizumab is an investigational monoclonal antibody designed to interfere with the PD-L1 protein.

The rationale for combining these two investigational agents is to activate an anti-tumor immune response with talimogene laherparepvec and to block inhibitory T cell checkpoints with atezolizumab, to potentially increase the anti-tumor activity relative to each agent alone.

"We believe that talimogene laherparepvec has potential to help patients in several cancer types based on its mechanism of action to promote tumor antigen release and presentation, important steps in activating a systemic immune response," said Sean Harper, executive vice president of Research and Development at Amgen.

"Atezolizumab is our most advanced cancer immunotherapy with 10 ongoing phase III pivotal trials across lung, bladder, breast and kidney cancers," said Sandra Horning, chief medical officer and head of Global Product Development at Roche.

Cigna Corp. issued a positive coverage decision for VeriStrat serum proteomic testing developed by Biodesix Inc. Cigna published its position to extend coverage for the VeriStrat blood-based test, stating the test is "…medically necessary for an individual with advanced non-small cell lung cancer (NSCLC)…"

VeriStrat testing is considered standard of care by nationally recognized clinical guidelines, and is clinically proven for use in patients with NSCLC, according to Biodesix. The test now covered for more than 115 million people in the U.S.