THE CANCER LETTER

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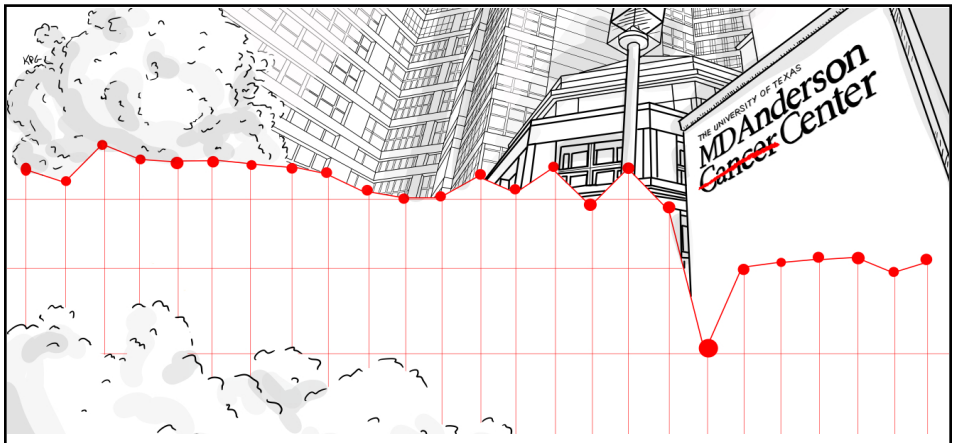

MD Anderson Projects $450 Million Loss in Fiscal 2017

By Paul Goldberg

MD Anderson Cancer Center lost $267.1 million on its operations in fiscal 2016. Now, a month into fiscal 2017, America's largest cancer center is on track to lose $400 million to $450 million.

In a confidential report intended for department chairs, MD Anderson's administration attributes the operating loss to four factors:

- Epic system (tools, reports, technology fixes);
- Providers – Capacity (Mondays & Fridays; weekends for select services; services at right location);
- Demand (wait times, rate of incoming calls/requests to set up appointments);
- Insurance coverage.

(Continued to page 2)

Cancer Moonshot Research Dollars Must Go to NCI—Not NIH—Groups Say

By Matthew Bin Han Ong

Nearly 50 cancer-related organizations urged Congressional leaders to ensure that funds slated for research in the National Cancer Moonshot Initiative go directly to NCI—as opposed to NIH or any other federal entity.

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A Countdown: Top 10 Problems With NCI-Designated Cancer Centers

By David Rubenson

For nearly a half century, much of the "war on cancer" has been fought at NCI-designated cancer centers, the 69 major medical schools and free-standing research institutes have this designation.

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MD Anderson Projects $450M Loss in Fiscal 2017

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Epic, an electronic medical record software, was deployed by MD Anderson in March. Though it's not clear precisely how this implementation affected the cancer center's finances, at other institutions, new EMR systems have been known to, at least initially, slow down the physicians' progress as they enter data from patient encounters, lowering the number of patients seen.

According to the document, the magnitude of the loss would be equal to the cost of maintaining 4,500 to 5,000 full time equivalent positions. The Houston institution, which is celebrating its 75th anniversary this year, employs about 20,000 people.

In 2015, the cancer center's total operating revenues were at $4.086 billion.

The confidential report shows that the operating margin rose from $95.4 million to $144.9 million between fiscal 2014 and 2015. However, it dropped precipitously in 2016, creating a $267.1 million loss.

MD Anderson's unfortunate 2016 fiscal year ended Aug. 31, but downward trends seem to continue. The center had a $41.5 million loss on its operating margins in September alone. It appears that September's losses were higher than the administration expected. According to the memo, losses were budgeted to be at $13.2 million, but, in fact, hit $41.5 million.

The report, dated Oct. 19, is posted here.

The Cancer Letter presented MD Anderson officials with a list of detailed questions.

How will the institution manage the projected $400 to $450 million operating loss coming on the heels of a 267.1 million loss? Is there indeed a plan to let go of as many as 5,000 FTEs, or roughly 25 percent of the labor force? Would someone elaborate on the factors that contributed to the loss? How much has the institution invested in drug development, and will this loss cut into future investment, which, according to the institution's president Ronald DePinho, adds up to $800 million a year? And what, if anything, will it do to the "moonshots," DePinho's signature initiative?

"The overall long-term financial health of the University of Texas MD Anderson Cancer Center is strong," Dan Fontaine, executive vice president for administration, responded in an emailed statement to The Cancer Letter. "Like other major health care institutions locally and nationwide, MD Anderson faces significant financial challenges related to many different factors.

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Gross Patient Revenue
Clinical Margin and MDACC Margin

Dollars in Millions	Annual FY14	Annual FY15	Quarterly FY16 Q1	Quarterly FY16 Q2	Quarterly FY16 Q3	Quarterly FY16 Q4	Month Sept FY17
Average Gross Patient Revenue per Work Day	$28.0	$30.0	$31.5	$31.7	$27.0	$29.6	$30.0
Clinical Operating Margin Percent	40.1%	40.5%	40.1%	36.4%	31.1%	34.2%	29.7%
Total MDACC Operating Margin Dollars	$95.4	$144.9	$10.2	-$26.7	-$161.9	-$88.7	-$41.5

NOTES:

Average GPR per Work Day - recent	May, FY16	$29.2
	Jun, FY16	$28.8
	Jul, FY16	$30.2
	Aug, FY16	$30.0
	Sep, FY17	$30.0

Estimated FY17 MDACC Operating Margin if Average GPR remains $30.0 Million/day through fiscal year (all other factors at FY17 budgeted amounts):
$ 400.00 to $450.00 Million Operating Loss

Estimated equivalent expense reduction to mitigate $400.0 - $450.0 Million loss:
4,500 to 5,000 FTEs

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The Trends

- Gross Patient Revenue per work day has been flat for the past 5 months
- For many departments, productivity levels are not at FY 2015 levels
- Operating expense growth continues to exceed operating revenue growth
- Operating expenses are not slowing down due to lower volumes *(i.e., we are not staffing to the workload)*
- Some reasons why volumes are down ….
  - EPIC system (tools, reports, technology fixes)
  - Providers
  - Capacity (Mondays & Fridays; weekends for select services; services at right location)
  - Demand (wait times, rate of incoming calls/requests to set up appointments)
  - Insurance coverage

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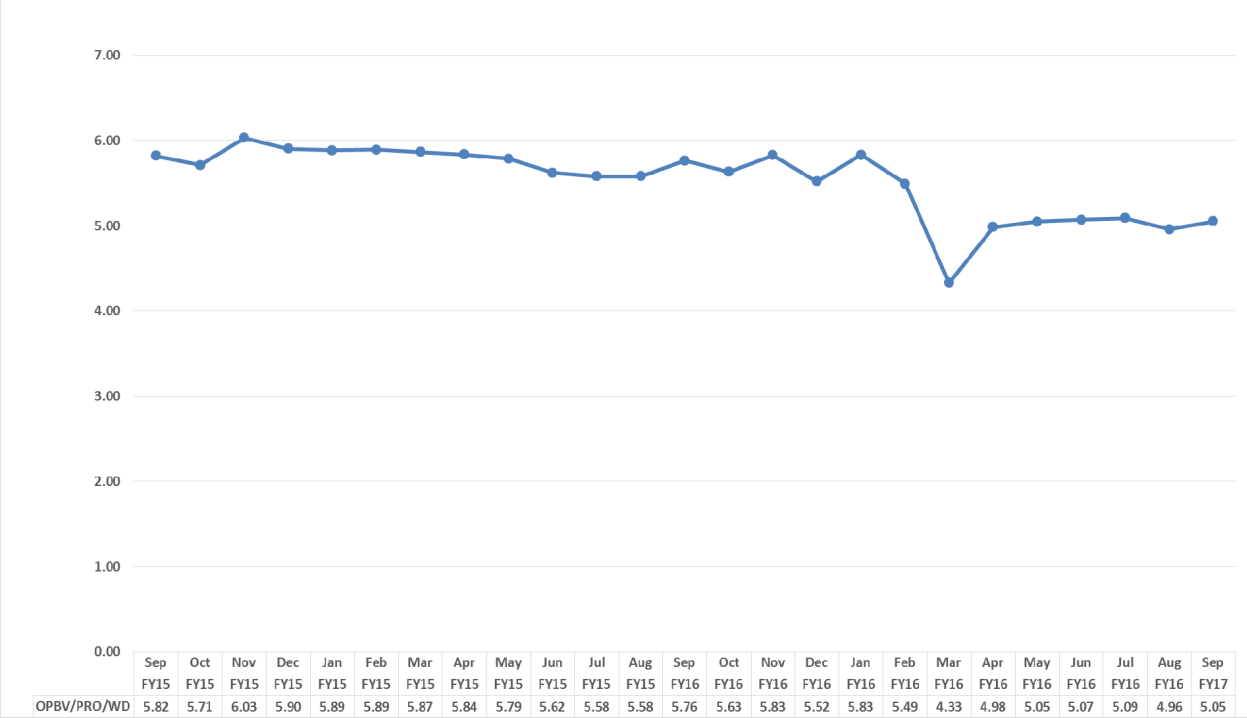
Outpatient Billable Visits per Upstream Provider per Work Day



	Sep FY15	Oct FY15	Nov FY15	Dec FY15	Jan FY15	Feb FY15	Mar FY15	Apr FY15	May FY15	Jun FY15	Jul FY15	Aug FY15	Sep FY16	Oct FY16	Nov FY16	Dec FY16	Jan FY16	Feb FY16	Mar FY16	Apr FY16	May FY16	Jun FY16	Jul FY16	Aug FY16	Sep FY17
OPBV/PRO/WD	5.82	5.71	6.03	5.90	5.89	5.89	5.87	5.84	5.79	5.62	5.58	5.58	5.76	5.63	5.83	5.52	5.83	5.49	4.33	4.98	5.05	5.07	5.09	4.96	5.05

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Ravi Salgia, M.D., Ph.D.


Steven T. Rosen, M.D.


Yuman Fong, M.D.

Pictured above, clockwise from top left: Ravi Salgia, M.D., Ph.D., Chair and Professor, Department of Medical Oncology & Therapeutics Research; Steven T. Rosen, M.D., Provost, Director, Beckman Research Institute of City of Hope and Comprehensive Cancer Center; Yuman Fong, M.D., Chair and Professor, Department of Surgery, Professor, Department of Experimental Therapeutics.

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NCI Designated Comprehensive Cancer Center

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"To ensure our continued fiscal strength, we believe open and proactive communication among all institutional stakeholders is critically important. Faculty, administrators and staff are working collaboratively to reduce expenses and increase revenue. Through this early and swift action, our goal is to generate positive financial returns so we can continue to reinvest in our mission.

"We are committed to taking every reasonable action to avoid having to make serious decisions concerning our hard-working employees."

It remains unclear whether this downturn would affect the MD Anderson Institute for Applied Cancer Science.

In a recent editorial in ASCO Post, DePinho referred to the IACS cadre of "industry-seasoned professionals, numbering approximately 100… These professionals interact with MD Anderson's critical mass of 1,700 accomplished faculty, which is supported by an approximately $800 million annual research budget focused on cancer."

A recent memo from three members of the executive committee said that every part of MD Anderson is impacted by expense reduction actions. The memo, which appears on page 6 and 7, acknowledges that cost-cutting alone isn't going to solve the institution's money problems.

"Reducing our expenses is only part of the solution and won't address all of our financial challenges," the memo states. "Many additional clinical productivity and access measures are underway.

"Together, we can get our finances back on track and continues fulfilling our our shared mission to end cancer."

Meanwhile, all non-clinical staff positions and all positions that don't generate revenues have been put on hold. Staff requests that include increases in salary have been put on hold, and "the FY16 Incentive for Salary Awards that were scheduled for distribution in Dec. 2016, will be delayed and reassessed for possible allocations in Feb. 2017."

Overtime not tied to revenues is being eliminated, clinical overtime is being reduced by 15 percent, and restrictions are placed on business travel, both domestic and international.

"Effective immediately for new travel requests, institutional payment for upgrades to business class and first class airfare tickets is prohibited," the memo states.

Catering, too, is verboten. "Examples of exceptions include when an invited outside guest is involved, such as to deliver a lecture or a faculty recruitment," the memo states. "In these instances, reduce the expense (by limiting invitees to include just the guest and a few key people) and use MD Anderson catering rather than an external caterer."

Forget the booze, too: "There may be rare and unusual exceptions to the purchase of alcohol, and those will require executive vice president approval. Examples of exceptions include: small faculty recruitment dinners (no more than 5 people), hosted conferences with outside participants, and lecture series with outside speakers."

And no more funding for holiday parties:

"Encourage your teams to be creative or self-fund celebrations (e.g., pot luck)."

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MD Anderson Memo on Cost Containment

Dear Colleagues:

As you're aware, our spending has continued to outpace revenue and this trend is unsustainable. We all must take immediate corrective action. We need your help as every part of MD Anderson is impacted by these actions.

Groups across the institution, with broad representation, have been working together to determine ways to reduce expenses and increase revenue. **We want you to be aware of the actions to date.**

Hiring	With 21,000 employees, our personnel costs are our largest expense. **When employees voluntarily leave, make every effort to not backfill positions and, instead, find ways to cross-train and share the work.** **On hold:** · Non-clinical staff positions · Non-revenue generating staff positions · New requests for contingent workers through external staffing sources. Consider ending current engagements **However, there are some positions that can proceed:** · Each EVP area has position approval processes to consider exceptions ○ Physician-in-Chief and Administration areas continue with established review and approval processes ○ The Provost Office is creating guidelines for faculty and research-related positions. Decisions made to date are: § Term Tenure/Term Tenure Track faculty: – Those who are competitive for CPRIT and/or UT Stars § Positions that are contractually required, such as grant-funded roles § Research Faculty Appointment (RFA): – If offer letter has been extended – If budgeted in an awarded grant
Promotions and reclassifications	**On hold:** All pending staff requests that include increases in salary **Being considered:** If part of a total restructure plan **Will proceed:** · TT/TTT faculty scheduled for promotion review this year · CFA positions scheduled for promotion review this year, and others justified by clinical need · RFAs already submitted to AVA-Faculty
Faculty Incentive for Salary Award	The FY16 Incentive for Salary Awards that were scheduled for distribution in Dec. 2016, will be delayed and reassessed for possible allocations in Feb. 2017.
Time tracking/ approval	**Ensure all managers sign-off/approve employee time each week**, as required. **For non-exempt employees: Implement webstamping** in all areas where employees have access to computers.

Overtime	**Eliminate overtime for all non-clinical, non-revenue generating, non-grant/contract related positions**. **Reduce clinical overtime by 15%**; Exceptions to be approved by the executive director/vice president or above.
Travel	**Business travel (domestic and international) now is highly scrutinized**. Effective immediately for new travel requests, institutional payment for upgrades to business class and first class airfare tickets is prohibited. The travel policy committee, which is co-led by the Faculty Senate, will be meeting this week to provide guidelines and recommendations with regard to priority travel. This will help reduce travel costs while also facilitating clinical coverage. Details will be shared as decisions are made.
Catering	**Eliminate catering with few exceptions**. Examples of exceptions include when an invited outside guest is involved, such as to deliver a lecture or for a faculty recruitment. In these instances, reduce the expense (by limiting invitees to include just the guest and a few key people) and use MD Anderson catering rather than an external caterer.
Business Entertainment	**Eliminate alcohol in the vast majority of circumstances**. There may be rare and unusual exceptions to the purchase of alcohol, and those will require executive vice president approval. Examples of exceptions include: small faculty recruitment dinners (no more than 5 people), hosted conferences with outside participants, and lecture series with outside speakers.
Holiday parties	**No institutional funding for holiday parties**. Encourage your teams to be creative or self-fund celebrations (e.g., pot luck).

Reducing our expenses is only part of the solution and won't address all of our financial challenges. Many additional clinical productivity and access measures are underway.

Please note: this is a rapidly evolving situation. Decisions are continuing to be made and, therefore, communications will be ongoing to reflect the latest information. Please be vigilant in staying up to date and sharing appropriate information with those who report to you. A continuously updated list of questions and answers can be found, along with other communications, on the MD Anderson – Our Finances site.

We thank you for your response to these action plans. Together, we can get our finances back on track and continue fulfilling our shared mission to end cancer.

Sincerely,

Dan Fontaine, J.D., Executive Vice President for Administration
Tom Buchholz, M.D., Executive Vice President and Physician-in-Chief
Ethan Dmitrovsky, M.D., Provost and Executive Vice President

Sent to Executives, Division Heads, Department Chairs, Faculty, Administrators, Managers and Supervisors

San Antonio's CTRC Joins MD Anderson Network

By Paul Goldberg

The UT Health Science Center at San Antonio and MD Anderson Cancer Center announced an affiliation to create a cancer care program in San Antonio.

Under the agreement announced earlier this week, MD Anderson will join forces with the Cancer Therapy & Research Center of the UT Health Science Center.

The collaboration will be equivalent to MD Anderson's partnerships in Arizona (Banner), New Jersey (Cooper and Summit Medical Group), California (Scripps) and Florida (Baptist in Jacksonville), MD Anderson officials said.

MD Anderson offers multiple levels of affiliation, and at this highest level, the programs are co-branded and clinically integrated with MD Anderson. Though specifics of these affiliation agreements haven't been made public, it is known that money flows from the affiliate to the Houston-based cancer center.

The San Antonio partnership is expected to start functioning in mid-2017.

The deal includes upgrades to CTRC. "Funding will come will come from philanthropy, operating revenue and support from UT System using Permanent University Funds bonds," said Rosanne Fohn, a spokeswoman for the UT Health Science Center San Antonio. "The anticipated investment in the cancer center will be $60 million to $70 million through 2019."

According to the UT System officials, the partnership was envisioned by Chancellor Bill McRaven. "MD Anderson is the top-ranked cancer center in America, with unparalleled experience, resources and expertise," McRaven said in a statement. "This is a fine example of how we can leverage the expertise of our individual institutions with the size and excellence of the UT System to better serve people in our region, the state and beyond."

The agreement also will make it possible to renovate the patient and family welcome center, and an expanded and more efficient pharmacy, an infusion center, a diagnostic suite and a wayfinding system.

"These improvements will take time, which is why we will not offer the collaborative services until the middle of next year," UT Health Science Center President William Henrich, said in a statement.

The two organizations will jointly recruit cancer physicians and allied health staff members. A national search is underway to hire a medical director to lead the new program, officials said.

The CTRC website continues to identify Ian Thompson, a prostate cancer expert, as the center's director.

"The national search for a director has just been launched and is being managed by Meyer Consulting out of Scottsdale, AZ," Fohn said to The Cancer Letter. Asked whether Thompson is among candidates for this job, Fohn said, "As is common in senior leadership positions, the search is anticipated to take 3-6 months. Meyer Consulting does not publicly disclose applicants."

CTRC is one of four NCI-designated cancer centers in Texas. Fohn said that the center's current designation "will not be impacted and there are plans to advance it to comprehensive status."

CTRC is unusual—and especially challenged—because it has no inpatient beds. Though the center has a history of losing money, it has been breaking even over the past two years, Fohn said. "Services provided by the CTRC are outpatient only," she said. "It is not an inpatient facility, nor are there plans to provide inpatient beds."

Assets in this affiliation include the CTRC Institute for Drug Development operates a large early phase drug development program.

Another asset in the San Antonio Breast Cancer Symposium, which will be held Dec. 6-10. The meeting is co-sponsored by the CTRC, the American Association for Cancer Research and Baylor College of Medicine.

In 2015, the meeting drew 7,576 attendees, half of them from outside the U.S.

Moonshot Dollars Must Go to NCI—Not NIH—Groups Say

(Continued from page 1)

The letter, dated Nov. 3, was authored by One Voice Against Cancer, a broad coalition that convenes on national funding and policy issues in oncology.

"It is … imperative that funding provided for Cancer Moonshot research be specifically directed to NCI," the letter states.

The word "specifically" in this letter is rich in subtext.

The document responds to what insiders describe

as efforts by top NIH leadership to channel the moonshot research dollars away from NCI control. Capitol Hill sources say that in recent weeks, prominent cancer scientists and activists have been working to counter this offensive by NIH officials.

The Office of the Director of NIH controls several trans-NIH programs, including the Precision Medicine Initiative and the BRAIN Initiative. However, the moonshot, being specific to cancer, is different from these broad initiatives and should therefore be managed by NCI, several of the institute's supporters say.

NIH officials said they are not lobbying for the funding to go to NIH instead of NCI.

"The [OVAC] letter does not say, as suggested, that the funding is going anywhere but NCI," NIH officials said in a statement to The Cancer Letter. "NIH does not lobby Congress. The only proposal that has been put forward is in the president's FY2017 budget, which requests that Congress appropriate funds for Cancer Moonshot directly to the NCI."

The groups that signed the OVAC letter include the American Society of Clinical Oncology, the American Association for Cancer Research, the American Cancer Society Cancer Action Network, the Association of American Cancer Institutes, and Friends of Cancer Research.

The stakes are nontrivial—$680 million, which President Barack Obama's budget has designated for the cancer research portion of the moonshot. Congress did not provide funding for the moonshot in existing appropriations bills for fiscal 2017 (The Cancer Letter, Sept. 23).

It is unknown how much the moonshot will receive, but negotiators are optimistic that the initiative will be funded through the 21st Century Cures Act after the short-term continuing resolution expires in December.

The 21st Century Cures Act, which aims to expedite drug development and modernize clinical trials, calls for about $8.5 billion in additional funding for NIH over five years. Lobbyists say the final amount could likely be lower—about $6 billion—but an expected $1 billion to $2 billion increase in appropriations for NIH would make up the difference in fiscal 2017.

Ultimately, it will be up to appropriators to decide who should spend the moonshot research funds.

"The importance of Congress funding the Cancer Moonshot Initiative as soon as possible by enactment of the 21st Century Cures Act in 2016 is without question," the OVAC letter states. "Waiting until next year to act is not an option for cancer patients and their families."

The letter can be downloaded here.

The letter is widely seen as the latest episode in NIH-NCI turf wars, which began in the run-up to enactment of the National Cancer Act of 1971. Three weeks ago, when the fiscal 2018 NCI Bypass Budget failed to appear on an originally scheduled date, Washington insiders immediately attributed NCI's failed effort to publish the document to an incursion by NIH leadership.

The document remains unpublished.

In his introduction to the stalled Bypass Budget, a summary of which was obtained by The Cancer Letter, NCI Acting Director Doug Lowy mentions NCI's scientific leadership of the moonshot and the institute's mandate to set the national agenda for cancer research (The Cancer Letter, Oct. 14).

"As coordinator of the National Cancer Program, NCI seeks and supports new ideas to understand and intervene in the cancer process, from the earliest stages to the most advanced," Lowy wrote. "The Cancer Moonshot aims to accelerate progress against cancer, accomplishing a decade's worth of advances in just 5 years.

"As part of this effort, a Blue Ribbon Panel of experts and cancer advocates from around the country identified specific opportunities poised to accelerate research progress and formalized a set of 10 bold, yet feasible, recommendations to the National Cancer Advisory Board."

NCI has the expertise and experience to carry out the panel's recommendations, the OVAC letter states.

"NCI is the scientific thought leader behind the Cancer Moonshot and the scientific recommendations in the Blue Ribbon Panel report," the letter states. "Directly funding the Cancer Moonshot at NCI will ensure that research recommended in the Blue Ribbon Panel report will proceed without delay."

Three major oncology organizations contacted by The Cancer Letter said they support funding NCI to carry out the moonshot's research goals:

American Society of Clinical Oncology:

"ASCO has been encouraged by the work of the Cancer Moonshot Initiative and is pleased with the recommendations of the Blue Ribbon Panel and the reports issued recently by the Cancer Moonshot Task Force and Vice President Joe Biden," said Richard Schilsky, ASCO's chief medical officer. "Robust and sustained federal funding is critical to advancing the

vision to accelerate progress against cancer expressed in each of these reports.

"Through letters, meetings, and congressional briefings, ASCO has advocated vigorously for increased funding for both the NCI and the U.S. biomedical research enterprise more broadly. NCI has played a pivotal role in virtually every major cancer prevention, detection, and treatment discovery. ASCO will continue to call on Congress to provide additional funding to the NCI to jumpstart and sustain the Cancer Moonshot Initiative."

American Association for Cancer Research:

"The AACR is deeply grateful to Vice President Biden for his passion and dedication to the success of the National Cancer Moonshot Initiative, for now is the time to support and build upon the spectacular discoveries in cancer science that will lead to further exciting breakthroughs against cancer," said AACR President Nancy Davidson, director of the University of Pittsburgh Cancer Institute. "We also congratulate the leadership of the NCI for spearheading many of these vitally important efforts, including the exceptional stewardship of the National Cancer Moonshot Blue Ribbon Panel, which in record speed resulted in the development of ten innovative recommendations for transforming the future of cancer research, treatment, and prevention in all populations.

"These remarkable efforts, which underscore the extraordinary opportunities that exist today in cancer research, more than justify the President's budget request for significant resources to fund the Moonshot Initiative, especially if we are to meet Vice President Biden's inspiring goal of achieving a decade's worth of advances in five years.

"Clearly, if we are to make significant inroads against cancer and respond without delay to the recommendations in the Blue Ribbon Panel Report, the Moonshot Initiative will require robust, sustained, and predictable funding increases for the NCI. The 21st Century Cures Bill offers a novel model for providing supplemental research dollars to the NCI. It will allow the Institute to support and oversee the Panel's recommendations for projects that are poised to speed the conquest of cancer. Failure to seize upon this momentum for accelerating progress and for making a positive difference for cancer patients and their loved ones is simply not an option."

American Cancer Society Cancer Action Network:

"The Moonshot offers an historic opportunity to accelerate the pace and progress of cancer research in this country," said Chris Hansen, president of ACS CAN. "The NCI—as it has for more than 40 years—is best poised to maximize that potential and achieve the Moonshot's goals of improved prevention, detection and treatment for years to come. We hope that Congress acts swiftly to provide NCI with the necessary resources to fully implement the Blue Ribbon Panel report recommendations."

Association of American Cancer Institutes:

"AACI and its 96 cancer centers firmly believe in the goal of the Cancer Moonshot—to make a decades worth of progress in 5 years," Barbara Duffy Stewart executive director. "We joined nearly 50 other cancer organizations in asking Congressional leaders to not delay and enact the 21st Century Cures Act in the 114th Congress."

A Countdown: Top 10 Problems With NCI-Designated Cancer Centers

(Continued from page 1)

All the big names are there: UCLA, Stanford, Memorial Sloan Kettering, Dana-Farber, MD Anderson, etc. The NCI "designates" centers for containing organizational structures that create synergies among cancer researchers. Designated centers promote multi-disciplinary collaborations, provide scientific tools too expensive for individual laboratories (core resources), incentivize translation of scientific ideas into therapies, etc.

The goal is to create an interactive cancer research organization among otherwise disparate researchers.

Such synergies are essential, but more than forty years of evolution have left the NCI's Cancer Centers program mired in counterproductive ritual, bureaucratic bean counting, and doctrinal rigidity.

"Designation" is a high political priority for virtually all centers, implying that the NCI designation process (also known as the competitive application for the Cancer Center Support Grant (CCSG)) dominates institute-wide decisions related to research strategy, allocation of discretionary resources, recruitment, etc.

This is unfortunate, because the process does not encourage the creativity needed to conquer a truly vexing disease. The centers, and the designation process, need a bureaucratic angioplasty.

The top ten problems with NCI-designated cancer research centers are:

10. *Designation creates a race to the middle against a disease requiring the exceptional*: Some centers excel at basic laboratory science, some at bioengineering, others at innovative clinical programs, etc. However, designation incentivizes a relatively uniform model. The emphasis is on shoring up weaknesses, not building strengths.

9. *The review process has become ritualized*: Total research volume, number of patients accrued to clinical trials, peer-reviewed article counts, frequency of research program meetings, and other parameters dominate the designation review process. Centers have been known to hold meetings simply to have minutes available at site visits.

8. *There is a Potemkin Village Effect*: Knowing the metrics, the experienced cancer center director can "goose the numbers." "Grantsmanship" (the art of good grant writing to compensate for less good science) is excessive in the NCI designation and review process. Centers knowingly fund unproductive research projects to improve metrics.

7. *Centers are reviewed for organizational effectiveness by scientists and physicians*: Designation concerns both organizational effectiveness and science. Researchers comprising the review teams have little training in organizational behavior, hence reliance on ritualized metrics.

6. *The centers overemphasize translational research*: Progress in cancer is limited by our understanding of basic biology. Designation involves showing the "translational" potential of virtually every research project. It favors a false sense of near-term relevance over generating essential knowledge.

5. *The process is too political*: Why would a governor or senator appear at a grant review when only a small amount of research funds are at stake? Center designation involves political symbolism with little connection to science. Some university officials see designation as a critical advertising device for their hospitals and clinics.

4. *There has been inflation*: Political significance means every state wants a designated center. Eight centers in the 1960s have grown to 69, while funding for the overall program lags. Funding should be increased or the program should be downsized. Meaningful research funding, not politics, should motivate the desire for designation.

3. *The application process has become silly*: Centers may begin preparing their five-year grant renewal application a year or more in advance. Scientific leaders are diverted from the laboratory while graphic artists, proofreaders, formatters, and IT specialists are hired. Application preparation costs can exceed the resulting research funding.

2. *It is a closed society*: There are few fresh faces and ideas. Newcomers feel naïve for their unfamiliarity with the rituals. A small circle of interlocking reviewers and advisory boards insure that ritual maintains dominance over creativity.

And the #1 problem with NCI-designated cancer centers is:

1. *The system cannot reform itself*: With ritual so important, centers constantly ratchet up the absurdities with more elaborate preparations for site visits and core grant applications. NCI attempts at streamlining somehow morph into new complexities as they move through an endless governmental approval process. Centers continue to fulfill abandoned requirements in fear that a site visitor remains loyal to ancient ways.

The intended goals of cancer centers, collaborations, appropriate translation and core resources, are critical scientific needs, but politics and ritual don't make for good science.

A review by an independent body of scientists, physicians, and experts in organizational behavior is badly needed. Experts not directly involved with NCI cancer centers should dominate this review. The NIH director and the Secretary of Health and Human Services must personally drive such a process to insure that recommended reforms are implemented.

David Rubenson is director of the scientific communications firm nobadslides.com. He has had 16 years of experience in senior administrative positions at NCI-designated cancer centers.

In Brief

Inova and UVA to Develop a Comprehensive Cancer Center

INOVA HEALTH SYSTEM and **the University of Virginia** agreed to form a research and education partnership to collaborate on research, medical education, and the recruitment of researchers, scientists and investigators.

The planned affiliation includes:

- A cancer research partnership between the Inova Schar Cancer Institute and UVA Cancer Center, including efforts to achieve NCI designation as a comprehensive cancer center.
- A research partnership to develop the Global Genomics and Bioinformatics Research Institute located at the Inova Center for Personalized Health. The institute will recruit researchers, scientists and investigators who will engage in collaborative research focused on genomics, functional biology, bioinformatics, biologically driven engineering, precision medicine, translational research, developmen of targeted therapeutics, and commercialization of new discoveries.
- A regional campus of the UVA School of Medicine at Inova, which would enable UVA medical students to complete their clerkship and post-clerkship education in Northern Virginia at Inova facilities, with an opportunity for a differentiated medical education experience during the post-clerkship phase.
- UVA and Inova will explore the creation of a biomedical investment vehicle to advance discovery through to commercialization.

The two institutions said they expect to finalize a definitive agreement later this year.

The Virginia General Assembly contributed $28 million in funding for the partnership in its fiscal 2017-2018 budget. Inova committed another $56 million, and UVA $28 million, which adds up to $112 million.

"As you know, a consortium Cancer Center Support Grant is a big deal, requiring lots of common infrastructure/joint programs," said Donald "Skip" Trump, CEO and executive director of Inova Schar Cancer Institute. "We are committed to working hard to explore possibilities."

S. GAIL ECKHARDT was named the inaugural director of the **LIVESTRONG Cancer Institutes** of the Dell Medical School at the University of Texas at Austin.

She was also appointed **associate dean of the medical school**.

The appointment was made possible by a $6 million recruitment grant from the Cancer Prevention and Research Institute of Texas.

In her new post, Eckhardt will oversee the design of new care models in cancer diagnosis and treatment, using a multidisciplinary team-based approach. She will build disease-focused research teams and an innovative developmental therapeutics program, leveraging the assets of The University of Texas at Austin and collaborations with CPRIT, the LIVESTRONG Foundation and cancer institutes within the state.

Eckhardt will come to the Dell Medical School from the University of Colorado Denver Anshutz Medical Campus, where she has led the Division of Medical Oncology for eight years. She holds the Stapp/Harlow Endowed Chair for Cancer Research, is associate director of translational research, and directs the Phase I Program at the NCI-designated University of Colorado Cancer Center.

Before moving to Colorado, served as associate director of clinical research at the Cancer Therapy and Research Center, Institute for Drug Development, in San Antonio.

The LIVESTRONG Cancer Institutes were created through a $50 million donation by the LIVESTRONG Foundation to the medical school in 2014. The institutes seek to reinvent the way cancer patients and survivors are cared for and supported – rethinking the range of cancer care from prevention to diagnosis, treatment and survivorship while focusing on patients' lives within a framework of patient-centered research.

LISA KACHNIC, chair of the Department of Radiation Ocology at Vanderbilt University Medical Center, was elected **president of the American Board of Radiology**, succeeding Milton Guiberteau.

Kachnic heads the Radiation Oncology service at Vanderbilt-Ingram Cancer Center with a personal research focus on optimizing sphincter-preserving chemoradiation therapy for locally advanced anal cancer. In a national trial Kachnic demonstrated that intensity-modulated radiation therapy, which focuses the radiation dose on the tumor and not the surrounding

normal structures in the body, was effective in reducing the high rate of normal tissue toxicities associated with chemoradiation. Following that study, IMRT has become standard practice for anal cancer.

Kachnic serves in several leadership positions among the National Cancer Institute's adult research bases. She is involved in NRG Oncology's gastrointestinal and outcome strategic committees, and is co-chair of their cancer prevention and control program. She is also an executive officer, GI Radiation Oncology chair, anal rectal cancer chair and discipline vice-chair of the Radiation Oncology committee for the Southwest Oncology Group.

She has also served as chair of the Department of Radiation Oncology at Boston Medical Center and professor of Radiation Oncology at Boston University School of Medicine. She also served on the Radiation Oncology faculty at Massachusetts General Hospital.

MICHAEL O'CONNELL received the 2016 Clinical Research Award at the **Association of Community Cancer Centers** 33rd National Oncology Conference in St. Louis. The award recognizes O'Connell's research on the oncology patient, family and the community.

O'Connell has helped direct numerous studies that have resulted in better treatment protocols for cancer of the colon and rectum, and is currently a leader of a national study on the efficacy of a new anti-angiogenesis therapy combined with standard chemotherapy in patients who have had surgery for stage II or stage III colon cancer.

O'Connell serves as an associate chairman of the National Surgical Adjuvant Breast and Bowel Project and on the Board of Directors for the Coalition of National Cancer Cooperative Groups. He is also a member of the NCI steering committee for gastrointestinal cancer cooperative group clinical trials.

In other awards:

Cary Presant received the **David King Community Clinical Scientist Award** for his work in the development, participation, and evaluation of clinical studies for cancer patients.

Presant is assistant clinical professor at City of Hope Medical Center, professor of Clinical Medicine at the University of Southern California Keck School of Medicine, and currently serves on the board of the Medical Oncology Association of Southern California. He is a past president of the California Division of the American Cancer Society, and past president and chairman of the Board of the Medical Oncology Association of Southern California. He is a past director of the American Society of Clinical Oncology, having served a five-year term as ASCO's representative to the House of Delegates of the American Medical Association, where he was also secretary of the Cancer Caucus and an expert advisor to the Diagnosis and Therapy Technology Assessment Program.

The ACCC Innovator Awards were given to eight cancer programs that have demonstrated forward-thinking strategies and creative solutions.

Innovations pioneered by the award winners include training programs designed to improve provider communication and care coordination, access to free mobile clinics to reach underserved populations, community outreach campaigns emphasizing the importance cancer prevention and HPV vaccinations, and initiatives to improve the patient understanding of opioid use and decrease out-of-pocket costs.

This year's recipients are:

- **Baton Rouge General Medical Center,** Pennington Cancer Center, Baton Rouge, LA,
- **Cone Health System,** Cone Health Cancer Center, Greensboro, NC,
- **Fox Chase Cancer Center,** Philadelphia, PA,
- **Mary Bird Perkins Cancer Center,** Baton Rouge, LA,
- **Park Nicollet HealthPartners**, Frauenshuh Cancer Center, St. Louis Park, MN,
- **Sanford USD Medical Center**, Sanford Cancer Center, Sioux Falls, SD,
- **The Outer Banks Hospital**, The Outer Banks Hospital Cancer Services, Nags Head, NC,
- **University of Maryland Upper Chesapeake Health**, Kaufman Cancer Center, Bel Air, MD.

The ACCC Innovator Awards have honored exceptional cancer programs that advance the goal of improving cancer care access, quality, and cost-effectiveness.

THE AMERICAN SOCIETY OF CLINICAL ONCOLOGY and **Innovative Oncology Business Solutions Inc**. announced a collaboration, ASCO COME HOME, an oncology medical home program designed to transition community oncology practices from volume-based to value-based care by structuring reimbursement around the full range of services needed by patients with cancer.

ASCO COME HOME will also prepare oncology practices for full implementation of the Quality Payment Program, authorized by the Medicare Access

and CHIP Reauthorization Act and will be available across the country starting Jan. 1, 2017.

The joint effort is an expansion of IOBS's COME HOME program, an oncology-specific patient-centered medical home that integrates oncology care with symptom management processes to provide patients with enhanced access to evidence-based care, while offering practices a clear path for transitioning to an advanced alternative payment model under MACRA.

Under the collaboration, ASCO has licensed the COME HOME name from IOBS, as well as the program's readiness assessment and implementation tools. One set of tools helps practices assess whether or not they are ready to transition to an APM. Other tools help practices actually make the change. ASCO plans to replicate and expand the successful COME HOME program across the U.S.

Initial COME HOME practices have demonstrated the model's effectiveness at improving health outcomes, enhancing patient care experiences, and positioning practices for success in an evolving healthcare delivery environment. Early results from the first seven COME HOME practices show a reduction in 30-day hospital readmission rates (down 11.7 percent), emergency department visits (down 6.6 percent), inpatient hospital admissions (down 12.5 percent), and the overall cost of care (down 7.2 percent). The COME HOME practices, combined, also maintained a high patient satisfaction rate, averaging from 91.3 to 98.1 percent, throughout the COME HOME Program grant period.

This program builds on years-long efforts by ASCO to develop and implement alternative payment systems that support high-quality, patient-centered, value-based cancer care. In 2015, ASCO released its Patient-Centered Oncology Payment model which, similar to the COME HOME approach, bundles payments for oncology and better aligns practice reimbursement with the current realities of today's cancer care.

COME HOME began in 2012, when the Center for Medicare and Medicaid Innovation awarded IOBS a grant to implement and test an oncology medical home model for newly diagnosed or relapsed Medicare beneficiaries, as well as commercially insured patients, with one of seven common cancer types.

UPMC and **Bon Secours Health Systems Ltd**. announced they will own and operate an advanced radiation therapy center for the treatment of cancer patients in Cork, Ireland.

This joint venture will combine the expertise of Ireland's largest independent health care provider with UPMC's model of cancer care that brings personalized treatments close to where patients live.

The radiotherapy center will be built on the Bon Secours campus in Cork as part of a new, six-story expansion currently under construction. It will be managed by UPMC and owned equally by both partners. Beginning 2019, it expects to treat patients with two advanced Varian True Beam Radiotherapy System linear accelerators, providing image-guided radiation therapy and intensity-modulated radiation therapy. Used for a variety of cancers, these approaches are designed to improve patient outcomes while minimizing side effects.

The center in Cork will also benefit from access to the entire UPMC Cancer Center network, comprising more than 40 sites in the U.S. and around the world. As part of that network, patients have access to treatments, protocols and technologies guided by the latest scientific evidence. UPMC Cancer Center partners with the University of Pittsburgh Cancer Institute, western Pennsylvania's only NCI-designated Comprehensive Cancer Center.

In 2006, UPMC CancerCenter opened its first international cancer center, UPMC Whitfield, which was accredited by the Joint Commission International two years later. UPMC also operates a radiation center in Rome and works with partners in Kazakhstan, Lithuania, Colombia, Russia, Myanmar and other nations to improve cancer care worldwide.

SCHULMAN IRB will launch its new **Central Oncology Review** division at PRIM&R's 2016 Advancing Ethical Research Conference. The launch of COR represents Schulman's response to requests from institutional research centers looking for a more advanced level of partnership and service integration.

COR will be led by Michele Russell-Einhorn, vice president of oncology services, and Judith Carrithers, director of oncology services. Russell-Einhorn is the former senior director of Dana-Farber Cancer Institute Office for Human Research Studies and also currently serves as co-chair of the Subpart A Subcommittee of the HHS Secretary's Advisory Committee on Human Research Protections. She is a founding member and leader of the IRB Directors group for the National Comprehensive Cancer Network.

Carrithers previously served as the assistant dean for human research protection and director of the Human Research Protection Program at Johns Hopkins University School of Medicine.

COR will feature an IRB roster of oncology industry leaders, academics and scientists, each with a background in managing specialized oncology research. It will provide collaborative, flexible IRB review services for organizations conducting oncology research, the launch of COR represents Schulman's response to requests from institutional research centers looking for a more advanced level of partnership and service integration.

COR's staff and IRB members include research professionals and clinicians with significant firsthand experience in contemporary oncology research and the associated unique human subject protection requirements.

Schulman offers IRB review services--including dedicated review capabilities for all phases of research across all therapeutic areas--to clinical trial sponsors, CROs, investigators and institutions. Schulman also provides global consulting services through its Provision Research Compliance Services division.

HENRY ENGLEKA joined the communications and public relations firm **Burson-Marsteller**, as chair, U.S Healthcare Practice. His expertise includes positioning, corporate image, rankings, physician and patient self-referral, reputation management, cause-related marketing, crisis communications, internal communications and media relations.

Prior to his work in communications, Engleka served as chief operating officer for the Mount Carmel Guild Behavioral Health System managing day-to-day operations and focusing on revenue cycle management. Engleka also served as Assistant Executive Director and Staff Director for the American Psychological Association.

Engleka has also served as senior consultant and Marketing Steering Committee member at the John Theurer Cancer Center at Hackensack University Medical Center.

ONCOLOGY HEMATOLOGY CARE, a provider of treatments for cancer and blood disorders in the Cincinnati area, joined **The US Oncology Network**.

The network is supported McKesson Specialty Health.

OHC is one of more than 30 practices and over 1,000 physicians supported by McKesson Specialty Health nationally who have been selected to participate in the CMS Innovation Oncology Care Model, representing roughly 32 percent of all physicians selected to participate in the program.

MERCK KGaA of Germany and **the American Cancer Society** published a report indicating that all four of the top causes of cancer deaths in women worldwide are mostly preventable or can be detected early.

Titled "The Global Burden of Cancer in Women," the report, which was released at the World Cancer Congress, examines the increasing impact of cancer among women in low- and middle-income countries - and outlines potential solutions to minimize the economic and societal impact of the disease for women, their families and healthcare systems.

Cancer is the second leading cause of death in women, with breast, colorectal, lung and cervical cancers claiming the most lives each year. With cancer rates on the rise as the global population grows and ages, the number of women who will lose their lives to cancer is expected to increase, particularly in low- and middle-income countries. In 2012, there were 3.5 million deaths among women due to cancer and that number is expected to increase by 57% to 5.5 million deaths by 2030.

The study found that in 2009, the global economic burden of cancer was estimated at about $286 billion, and much of that cost was due to premature death of members of the workforce. In the United States alone in 2008, years of productive life lost due to cancer in women corresponded to $82 billion, not to mention the many professional achievements that might have been realized.

The partnership between Merck and the society will also help promote the All of Me Young Scholars program, which aims to educate and cultivate health and civil society professionals in Brazil, Mexico, Colombia and India to affect meaningful change in prevention and early detection of cancers among women in low- and middle-income countries.

The full report is available here.

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Drugs And Targets

Roche Receives FDA Approval for Tecentriq Complementary Diagnostic in NSCLC

VENTANA PD-L1 assay received **FDA approval** as a complementary diagnostic to identify PD-L1 expression levels in patients considering treatment with the FDA-approved Roche cancer immunotherapy **Tecentriq (atezolizumab)** for previously treated metastatic non-small cell lung cancer.

The PD-L1 (SP142) assay is also indicated to identify patients with urothelial cancer who may benefit from treatment with Tecentriq. The assay is sponsored by Roche.

The biomarker assay is the first to evaluate patient PD-L1 expression using both tumor cell and immune cell staining, the company said. Determining a patient's PD-L1 expression level can provide insight into the survival benefit that may be achieved from treatment with Tecentriq.

The company said it will continue to seek additional indications for this drug and diagnostic.

Ventana PD-L1 (SP142) assay is a qualitative immunohistochemical assay using rabbit monoclonal anti-PD-L1 clone SP142 intended for use in the assessment of the PD-L1 protein in formalin-fixed, paraffin-embedded urothelial carcinoma and non-small cell lung cancer tissue stained with OptiView DAB IHC Detection Kit and OptiView Amplification Kit on a Ventana BenchMark ULTRA instrument. Determination of PD-L1 status is indication-specific, and evaluation is based on either the proportion of tumor area occupied by PD-L1 expressing tumor-infiltrating immune cells (% IC) of any intensity or the percentage of PD-L1 expressing tumor cells (% TC) of any intensity.

FDA has accepted for review the Abbreviated New Drug Application for generic **doxorubicin hydrochloride liposome injection**, submitted by Merrimack Pharmaceuticals Inc. partner--Actavis LLC (an indirect, wholly owned subsidiary of Teva Pharmaceuticals USA, Inc.).

This is the first product developed by Merrimack under a partnership agreement with Actavis LLC pursuant to which Merrimack is responsible for the development and commercial supply of bulk drug product and Actavis LLC is responsible for fill/finish activities, regulatory approvals and commercialization in the United States.

Doxorubicin HCl liposome injection is marketed as Doxil in the U.S. by Janssen Products LP, a Johnson & Johnson company. The approved indications for the product are ovarian cancer, AIDS-related Kaposi's sarcoma and multiple myeloma.

Doxil generated approximately $600 million annually in global revenue prior to Johnson & Johnson's 2011 manufacturing disruption, which resulted in the placement of Doxil on the FDA's drug shortage list. While Doxil was on the drug shortage list, the FDA approved a generic version of doxorubicin HCl liposome injection marketed by Sun Pharma Global FZE, and both products now share the U.S. market.

If approved, Merrimack is eligible to receive a royalty rate in the mid-twenties of net profits on sales of doxorubicin HCl liposome injection under the agreement with Actavis.

BRISTOL-MYERS SQUIBB was granted conditional approval by **Health Canada** for the treatment of previously untreated adults with unresectable or metastatic melanoma using Opdivo and Yervoy.

The first-ever combination of two immuno-oncology agents has the potential to increase progression-free survival in certain patients. Health Canada also issued a Notice of Compliance with conditions for the OPDIVO monotherapy for the treatment of unresectable or metastatic BRAF V600 mutation-positive melanoma in previously untreated adults. An improvement in survival has not yet been established in either indication.

This approval is based on data from the pivotal study, CheckMate -067, which compared progression-free survival and overall survival of Opdivo combined with Yervoy to Yervoy monotherapy and of Opdivo monotherapy to Yervoy monotherapy in subjects with previously untreated, unresectable or metastatic melanoma.

More than 6,800 Canadians are estimated to be diagnosed with melanoma in 2016 and 1,200 Canadians will die from melanoma. Of the new cancer cases found in young adults aged 15-29, melanoma, is one of the most common types of cancers found. It is one of the most serious forms of skin cancer because it has the potential to metastasize and spread to the lymph nodes as well as distant organs.

ALECENSARO (alectinib) received approval from **Health Canada** as a monotherapy for the

treatment of patients with anaplastic lymphoma kinase-positive, locally advanced (not amenable to curative therapy) or metastatic non-small cell lung cancer who have progressed on or are intolerant to crizotinib.

The drug is marketed under the name Alecensa in the US.

The drug, which is sponsored by Hoffmann-La Roche Ltd. (Roche Canada), received the approval under provisions made in its Notice of Compliance with Conditions policy, which facilitates earlier access to promising new medicines that treat, prevent or diagnose serious, life-threatening and/or severely debilitating diseases for which there is no alternative medicine available in Canada, or where the new medicine offers a significant improvement through its risk/benefit profile over existing medicines.

Patients with ALK-positive, NSCLC are typically younger in age and either have no history of smoking or are former light smokers. A common place for this type of cancer to spread during initial targeted treatment is the central nervous system, including the brain.

Approximately 26 per cent of ALK-positive NSCLC patients have brain metastases at the time of their initial diagnosis, and up to 60 per cent of patients have brain metastases when their disease worsens or spreads. The majority of individuals with lung cancer do not survive longer than three months after the diagnosis of brain metastasis.

NOVOGEN Ltd. and **Genentech** entered an agreement to develop and commercialize GDC-0084, a small molecule inhibitor of the phosphoinositide-3-kinase pathway.

Genentech is a member of the Roche Group. Novogen is an Australian-based company.

The lead indication for GDC-0084 is glioblastoma multiforme.

GDC-0084 is distinguished from most molecules in the class by its ability to cross the blood-brain barrier, potentially making it suitable for cancers of the central nervous system, the company said.

Genentech has completed a phase I study of GDC-0084 in patients with recurrent GBM, recruiting 47 patients at five centres in the United States and Spain, including UCLA, Dana-Farber Cancer Institute, and Massachusetts General Hospital. In addition, GDC-0084 has an open Investigational New Drug application with FDA, and the transaction includes a quantity of pre-manufactured drug substance that is expected to be sufficient to support a proposed phase II clinical trial.

Under the agreement, Novogen will pay Genentech an upfront payment of US$ 5 million and performance-related consideration linked to regulatory and commercial outcomes. In addition, Genentech will receive royalty payments in-line with industry benchmarks.

Genentech said it will immediately initiate transfer of the IND for GDC-0084 to Novogen, as well as key manufacturing and analytical processes. Novogen anticipates being able to provide an update to the market in the design, project cost, and timelines of the proposed phase II study early in 2017.

THE NATIONAL INSTITUTE OF HEALTH AND CARE, England, recommended **Eribulin** for the treatment of adults with locally advanced or metastatic breast cancer who have progressed after at least two chemotherapeutic regimen for advanced disease.

In the European Union, The DRUG is indicated as at least one chemotherapeutic regimen and marketing authorization was granted in 2014. Prior therapy may have included an anthracycline or a taxane, and capecitabine.

Developed by Eisai EMEA, eribulin is the first breast cancer treatment to be recommended by NICE in over a decade.

Approximately 44,500 women are diagnosed with breast cancer in England annually, of whom one third subsequently develop metastatic disease. Only 15% of women with metastatic breast cancer will survive beyond five years. Eribulin is one of the most prescribed treatments within the CDF and to date approximately 4,000 patients have been able to access eribulin in the UK since 2011.

Eribulin is approved in more than 60 countries around the world including all of the European Union, Canada, United States, Russia, Switzerland, South Korea, Japan and Singapore.