THE CANCER LETTER

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Conversation with The Cancer Letter

AstraZeneca Exec Discusses Iressa's Future in the U.S.

By Paul Goldberg

After a decade of near-absence from the US market, the AstraZeneca drug Iressa (gefitinib) is back.

The drug, which stayed on the market between 2003 and 2005, when it was pulled because clinical trials in a general population of patients failed to demonstrate a survival advantage, has returned. Now it is accompanied by a diagnostic tests that selects patients.

The Cancer Letter asked Andrew Coop, vice president, US medical affairs, oncology, at AstraZeneca to discuss the company's plans for the future of Iressa in the US, and lessons that have been learned.

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Report: Part D Drug Prices "Needlessly High"

By Matthew Bin Han Ong

Medicare's Part D program paid significantly higher prices for drugs than either Medicaid or the Veterans Health Administration, a study by Carleton University and Public Citizen found.

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In Brief

Lehigh Valley Joins MSK Cancer Alliance; Siteman Receives "Exceptional" NCI Score

LEHIGH VALLEY HEALTH NETWORK announced it will join the **Memorial Sloan Kettering Cancer Alliance**.

Established in 2013, the MSK Cancer Alliance is a partnership between MSK and community oncology providers.

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The Cancer Letter will be taking a short publication break, and will return Friday, Sept. 4.

AstraZeneca Exec Discusses Iressa's Future in the U.S.

(Continued from page 1)

Coop spoke with Paul Goldberg, editor and publisher of The Cancer Letter.

Iressa was approved for patients with metastatic non-small cell lung cancer whose tumors have epidermal growth factor receptor exon 19 deletions or exon 21 (L858R) substitution mutations as detected by an FDA-approved test.

The drug is approved concurrently with the therascreen EGFR RGQ PCR Kit as a companion diagnostic, which is sponsored by QIAGEN N.V.

Paul Goldberg: *First of all, congratulations on bringing back Iressa.*

Andrew Coop: Thank you. We're thrilled.

PG: *I was there, at the original ODAC, in 2002, when a large number of patients showed up to demand that the drug be approved. How has the state of oncology changed since that initial approval?*

AC: I think things have evolved, and have continued to evolve a lot in those last years.

Again, you know the history of Iressa—but within that time, as we think about the initial approval of Iressa, at that time it was in an unselected patient population. We've really spent a lot of time in the past years trying to understand the science, the molecular biology, the targets and the response.

And so that's something that AstraZeneca has certainly been very committed to—for over 20 years, for example, in this case. But broadly referring to your question as well as what's changed in oncology, is I think you'll see an absolute plethora; more and more of the desire to really understand the science of what's going on behind the tumors, which patients respond, and why. There have been more and more drugs—and you'll see this in AstraZeneca's portfolio—being developed with a diagnostic in mind.

So this idea of targeting the right drugs to the right patient and trying to understand what's going on in the tumor—and going back to what you said, there at the original ODAC—and where it's come from, I just think there's been a huge depth of understanding, certainly within AstraZeneca, but also in the work we do with the external research community.

Everyone is coming together to really understand these devastating diseases; these areas of high unmet medical need, and to have a thoughtful approach of how to target cancer. That, to me, is what I think has been my observation of the last few years.

PG: *Let me share an anecdote with you: an ODAC member at that time said to me, "first I was going to vote no, then I was going to vote yes; then no…" Ultimately he voted yes, but he said that had it gone on another 30 minutes, he would have voted no. It was a fascinating time—it feels like the Dark Ages in some ways.*

AC: I think what we're seeing is the acceleration of science.

What can science do for patients, how can we put our best minds forward, both inside and outside, with industry and academia, working with patients, with advocates. How do we work to understand the disease, and then finding out what are the smart solutions.

PG: *How has the science changed since the time when the drug was placed in restricted access?*

AC: When the drug first came out—again, at that time it was in an unselected patient population, before it was known that EGFR mutation was the target for Iressa, and where to actually find that benefit and which group of patients had the best response.

As it went through that time when we stopped commercializing—for those patients who were still benefiting, we provided access to those patients. In R&D, the research continued.

We continued to follow the science, see what we could further understand, and really, based on that, is where we've landed today.

What's happened in those last years is—obviously we had the IFUM study (http://www.astrazeneca.se/pressrum/pressmeddelanden-och-nyheter/Article/efficacy-of-iressa-confirmed-in-caucasians), which was the follow-up measure which was exploring the efficacy and safety in first-line, again in a specific population

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with patients with non-small cell with EGFR exon 19 deletions or the exon 21 substitutions, and that was a targeted trial as a follow-up measure.

We also did the exploratory analysis in the IPASS (http://jco.ascopubs.org/content/29/21/2866.full) pan-Asian study as well. Really furthering studies and working to confirm that benefit in those patients harboring the EGFR mutation and also exploring other data sets. There has been a real commitment to follow this science and understanding over the last years.

PG: *Are there still patients living who have been receiving Iressa since it went into restricted access?*

AC: There are patients that are continuing. We do have a program for those patients. That program is now closed for enrollment.

But there have been patients treated, as part of our commitment to make sure those patients that are still benefiting from treatment, to make sure that they have access.

PG: *Do we know whether Iressa responders are basically the same people as the Tarceva responders? Are these different cohorts, are these drugs interchangeable?*

AC: We don't have those head-to-head trials. Such a comparison isn't something that we speculate on. But we are continuing to understand this.

In answer to your first half of the question, they have slightly different labels; different populations. They are different drugs. We don't have the head-to-head data. But we are ready to explore that space.

PG: *Is anyone actually doing a clinical trial, or is this a basic science question at this point?*

AC: There are trials going on. If you go on clinicaltrials.gov, you'll see the research. But I think in general there's a lot of interest in these kind of questions around targeted treatments, per se, not just these agents, but also therapies in this space as well. I think it's fair to say that there is general interest in people really trying to understand the biology of this disease.

PG: *Who do you think should get Iressa now? I guess it's a label question now.*

AC: It is a label question, and I think it's an important one.

Again, we have a label that gives specific guidance on the population who would be eligible to receive Iressa. And we spent a lot of time on that evidence generation and with the agencies around the world to provide that information and to help inform healthcare providers. It is also important to give information about mutational status, but also using the FDA approved companion diagnostic, which is also very important when people are thinking about prescribing this drug.

PG: *Maybe I'm missing something hugely important, and I'm probably not alone, but I was actually fascinated to look at that page on the FDA website about approved companion diagnostics (http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/InVitroDiagnostics/ucm301431.htm). It was interesting, because the Tarceva companion diagnostic is different from yours. Is that significant? It's still EGFR.*

AC: I can't really talk to another drug or its companion diagnostic, but we've certainly worked with regulators and our companion diagnostic to make sure that people have a way of looking at this drug in combination with the diagnostic, so they can make informed treatment choices for their patients. Again, it goes back to what we said before about looking at the datasets, or where we're comparing one data set to another.

PG: *It's just a fascinating question, because there's EGFR testing going on that is called EGFR testing but each test is different.*

AC: That's why, within our label, we are talking about looking at positive testing on these deletions or substitute mutations as approved by an FDA-approved companion diagnostic test.

It speaks again to the robustness of the clinical data as we make these recommendations on our drugs. And it certainly is, as we look at our portfolio, something that we're spending time looking at, and trying to bring them into our portfolio as we develop drugs with an understanding of the molecular biology.

PG: *How much market exclusivity can you count on at this point?*

AC: What I can say is what our commitment to is, we see a big unmet need in lung cancer here.

We're happy to work with the FDA and bring it back, because we see an unmet medical need in this group of patients with lung cancer, and we're also continuing our programs and research in coordination with other agencies as well.

From a medical side, looking at the needs and research, this is something that began for AstraZeneca in lung cancer—and we see a high unmet medical need

and an opportunity to bring it forth, and in the future look at other combinations within our portfolio in that lung cancer space, where unfortunately the medical need remains very, very high.

PG: *It's likely that through combinations you could end up with more exclusivity?*

AC: I think that—not talking about exclusivity or that component—what I'm saying specifically is that we're committed to understanding the science. We have a responsibility to look at our portfolio with aims to improve patient outcomes.

PG: *The drug is on the market now. One can actually receive it, purchase it?*

AC: The drug is FDA-approved.

PG: *Can you tell me anything about pricing? How does that work?*

AC: What I can say is that we take that commitment very seriously and it's comparative to other TKIs.

PG: *So it's in that same range. Is there anything we've missed? Anything you'd like to add?*

AC: Yes, I think you touched on it, I think that this is a long heritage story for AstraZeneca. It started over 20 years ago, with this science with people looking at Iressa at that stage as a compound—and the consistent looking at the science, of working with regulators, of understanding the science, working externally to identify the groups of patients who can potentially benefit.

It speaks to what you mentioned earlier about looking at what's the best way to look at these agents; to bring them forward. We have a deep, deep understanding of the science and now can bring it back into the United States, having been there at the beginning. We're just very happy to be able to do this, given the high unmet medical need for these patients.

PG: *When I think about it, I think of humility as a lesson here, because here's this drug that was really the first EGFR drug, and it seemed that science understood what was going on, and yet it did not. It took so long for it catch up. Kind of an uplifting story, in some strange ways.*

AC: At that time we didn't know, but rather than shying away and not finding out—there had been signals of activity, it really was a case of going back and following that and understanding it more.

It's this pursuit of understanding the science, of what we've seen and why. And I think that, to us, is the story; our commitment to those patients who were still benefitting, to continue to provide access to those patients in the United States, while we continued to figure out the science and a regulatory path forward.

PG: *Congratulations again.*

Report: Medicare Part D Prices "Needlessly High"

(Continued from page 1)

Prices paid by Medicare Part D were also above those in 30 other countries.

The price is caused by congressional restrictions on the federal government's ability to negotiate with the pharmaceutical industry, the study said.

As a result, government agencies of 27 other countries that are part of the Organization for Economic Co-operation and Development were able to purchase the medications studied from manufacturers at less than 50 percent of the U.S. purchase price.

The study compared prices paid to manufacturers for a standardized group of brand-name medications in the 31 OECD countries, including the U.S.

The study was conducted by Marc-Andre Gagnon, an associate professor at the School of Public Policy and Administration at Carleton University in Ottawa, and Sidney Wolfe, co-founder and senior adviser of Public Citizen's Health Research Group.

Medicare Part D was implemented in 2006 to broaden pharmaceutical coverage for seniors 65 and older and for people with disabilities. It is the largest federal drug program, covering 39.1 million people and spending $69.3 billion on prescription medications in fiscal year 2013. Approximately 58 percent of Medicare Part D spending is paid to brand-name manufacturers, according to the study.

"Medicare Part D was designed less as a system for social protection for the sick and more as a system of corporate welfare for brand-name pharmaceutical companies," Wolfe said in a statement. "Lower prices would alleviate the current de facto rationing that occurs because so many Medicare recipients cannot afford these inordinately high prices and suffer the health consequences of cost-related non-adherence to drugs prescribed for them. That's just wrong."

Medicare Part D is not allowed to "interfere with the negotiations between drug manufacturers and pharmacies and [Part D plan] sponsors," according to the law that created it.

"We thought that brand-name medicines were a little bit more expensive for Part D, but we never thought that it would be twice as much as in other developed countries," Gagnon said. "It is like pouring money down the drain."

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Lowering Medicare Part D prices to Medicaid or VHA levels could save Medicare between $15.2 billion and $16 billion a year and reduce the number of people who don't fill their prescriptions for financial reasons, the authors say.

"Based on this information, we urge that a joint House-Senate Committee be formed to draft legislation that would lower Medicare Part D prices," Gagnon and Wolfe wrote in a letter to Sen. Bernie Sanders (I-Vt.) and Rep. Rosa DeLauro (D-Conn.) July 23.

Proposals to fundamentally alter the structure of the "successful" Medicare Part D program would hurt both taxpayers and beneficiaries, PhRMA, the industry lobby group, said in a statement to The Cancer Letter.

"Part D program has been widely successful, keeping total costs low—$349 billion lower than initial CBO 10-year projections—through plan competition and negotiation," PhRMA said. "Robust negotiation occurs in Medicare Part D between plans and biopharmaceutical companies, resulting in substantial rebates, often as much as 20 to 30 percent, with average rebate levels increasing each year of the program.

"Further, spending on retail prescription medicines has consistently accounted for just 10 percent of U.S. health care spending and is expected to remain stable through the next decade, compared with other OECD countries that spend a higher percentage of their health care dollars on prescription medicines.

Proposals that could jeopardize beneficiaries' access to medicines by driving up premiums, reducing choice and restricting coverage are misguided and misplaced."

Comparing Prices

Overall, U.S. costs per capita for pharmaceuticals ($1,010) are more than twice as high as the OECD average ($498) and more than threefold those of New Zealand, Denmark and Israel.

According to the study, Medicare Part D spends 198 percent, almost twice the median, of the amount paid for brand-name medications in the 31 OECD countries. Medicare Part D pays on average 73 percent more than Medicaid and 80 percent more than the VHA for brand-name drugs.

Under current Part D pricing, new "me-too" drugs similar to older drugs are priced just as high or higher.

"The rationale for higher prices is supposedly to help pay research costs for innovative products," Gagnon said. "By paying for 'me-too' drugs at such high prices, not only do Part D beneficiaries not get value for their money, they end up providing incentives to develop me-too products to the detriment of innovative medicines for unmet needs."

According to the study, proponents of the status quo argue that pharmaceutical R&D investment will "flee abroad" if any country enacts regulations to reduce prices.

"For many years, higher price levels often were cited as an important policy lever for attracting R&D investment," the authors wrote. "Drug companies argued that if they could not obtain high prices in a country, they would move their R&D out of the country."

Domestic and international data have not supported this link, the study's authors said.

"Several countries that have patented drug prices which are, on average, substantially lower than in the U.S., have achieved domestic R&D-to-sales ratios (a standard index to measure R&D intensity) well above those in the U.S.," Gagnon and Wolfe wrote. "Increasingly, analyses show that the impact of drug prices on companies' decision on where to invest and conduct research are, at best, of marginal importance.

"Other factors—such as where companies can find the best science base at reasonable cost, taxation incentives, flexible labor markets and economic stability—are seen as having greater importance in companies' decisions than drug prices.

"There is no reason to believe that Medicare Part D price reductions would cause a flight of pharmaceutical R&D investment outside the country."

Besides lowering Part D prices, Gagnon and Wolfe recommend introduction of mandatory generic substitution for all plans under Part D, and that price reductions be used to reduce co-payments and deductibles.

"To preserve freedom of choice, patients wanting access to treatments that are more expensive than equivalent, equally safe and effective treatments covered under Medicare Part D should have the opportunity to access these treatments, but they should have to pay the price difference out-of-pocket," Gagnon and Wolfe wrote.

"Given the complex nature of this issue, it is recommended that members of Congress create a joint working group to investigate the ways and means of implementing the recommended reforms.

"The mandate of this working group should not be *if* the structure and pricing for Medicare Part D drugs should be reformed, but *how* they should be reformed to ensure the greatest benefit to the American people."

FDA News

FDA Publishes Draft Guidance For Facility Quality Assessment; Teva Parenteral Recalls Adrucil

The FDA published a draft guidance for the pharmaceutical industry to ensure that FDA-regulated medications are continually manufactured under strict quality standards.

The draft guidance, published July 27 and titled "Request for Quality Metrics," describes a set of measurements that the agency would use to evaluate the quality of the facilities and the processes that manufacturers use to make FDA-regulated drugs and biologics.

These include prescription drugs and certain biological products. The guidance also encourages these manufacturers to conduct robust quality measurements on their own products.

"We believe a careful analysis of quality metrics can help FDA better identify which facilities are at the highest risk for quality problems," FDA officials Ashley Boam and Mary Malarkey wrote on FDA Voice. "This will help us use our inspection resources most efficiently and effectively.

Boam is FDA acting director of the Office of Policy for Pharmaceutical Quality, Center for Drug Evaluation and Research, and Malarkey is FDA Director of the Office of Compliance and Biologics Quality, Center for Biologics Evaluation and Research.

"FDA has been working for many years on solutions to encourage an support the modernization of pharmaceutical manufacturing, such as the use of risk-based regulatory strategies for oversight," Boam and Malarkey wrote. "Our quality metrics initiative is one of several approaches we believe will further support this effort."

FDA is receiving comments on the draft for 60 days from the publication of the guidance.

The agency will host a public meeting Aug. 24.

Teva Parenteral Medicines has recalled six lots of Adrucil due to the potential presence of particulate matter identified as aggregate of silicone rubber pieces from a filler diaphragm and fluorouracil crystals.

Adrucil Injection (fluororacil injection, USP) 5g/100 mL (50 mg/mL) is used in the palliative management of carcinoma of the colon, rectum, breast, stomach and pancreas and is packaged in pharmacy bulk packages.

Administration of an intravenous product with particulate matter has the potential to result in inflammation, allergic reactions, or blockage of blood vessels—leading to tissue death, which may be life-threatening if vital organs are affected.

According to FDA, Teva has not received any reports of adverse events related to this recall. The product lot numbers affected by this recall can be found here.

Anyone with an existing inventory of the recalled lots should stop use and distribution, and quarantine the product immediately, according to FDA.

Customers should notify all users in their facility. Customers who have further distributed the recalled product should notify any accounts or additional locations which may have received the recalled product and instruct them if they have redistributed the product to notify their accounts, locations or facilities to the user level.

Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to FDA's MedWatch Safety Information and Adverse Event Reporting Program.

Obituary

Carolyn Kaelin, 54, Surgical Oncologist and Researcher

Carolyn Mary Kaelin, a surgical oncologist in the Women's Cancers Program at Dana-Farber and director of the Breast Clinic at Brigham and Women's Hospital, died July 28, surrounded by loved ones. Kaelin was 54.

Kaelin graduated from Smith College and Johns Hopkins School of Medicine. She earned her master's degree from the Harvard School of Public Health. At 34, she became the founding director of the Comprehensive Breast Health Center at BWH, at that time the youngest woman singled out for a job of this caliber at a major Harvard teaching hospital.

Also active in research, she focused on how doctors and patients make medical decisions and on quality-of-life issues for breast cancer survivors, particularly the role of exercise. In 2001, Newsweek featured her as one of "15 Women of the New Century."

Kaelin received numerous honors, including an Exceptional Woman Award from Candy O'Terry and WMJX, as well as the Mary Horrigan Connors Award

at BWH, recognizing her outstanding commitment to women's health.

An avid athlete, Kaelin participated several times in the Pan-Mass Challenge, a 192-mile bicycle ride fundraiser for Dana-Farber. Shortly after a training ride in 2003, she noticed early signs of her own breast cancer. After several attempts at breast conservation surgery failed, she had a mastectomy. Nonetheless, while still recovering from surgery, she rode the challenge with Team WOW, Women Oncologists on Wheels.

A rare complication of breast cancer therapy prevented Kaelin from returning to clinical practice. Instead, she focused on her patient education and survivorship efforts, with an emphasis on the underserved.

She initiated research on the value of rowing for patients with postoperative lymphedema, with an assist from Olympian Holly Metcalf, the founder of We Can Row. She co-authored two award-winning books, Living through Breast Cancer and The Breast Cancer Survivor's Fitness Plan, and helped create an innovative, exercise-centered breast cancer recovery program for the YMCA.

Kaelin also established the Quality of Life Fund at BWH to support breast cancer survivorship projects and launched the successful Knowledge, Strength, and Grace conference series for breast cancer patients and their families.

In Aspen, Colo., Carolyn's adopted second home where she loved to bicycle and hike, she cofounded the Quality of Life Cancer Fund with her friend Barbara Berger. Under the stewardship of the Berger family, this fund raises more than $100,000 each year to support indigent cancer patients living in Colorado's Roaring Fork Valley.

In 2010, Kaelin was diagnosed with brain cancer unrelated to her previous breast cancer. She had two brain surgeries, each requiring extensive rehabilitation so that she could relearn to walk.

"We will miss her warmth, energy, intelligence, compassion, and humor," said Eric Winer, director of the Breast Oncology Center in the Susan F. Smith Center, and Kaelin's oncologist following her breast cancer diagnosis. "She was uncompromising in her pursuit of truly outstanding care for each and every patient. I learned more from guiding her through the breast cancer experience than one could imagine."

Kaelin is survived by her husband William Kaelin, Jr., a Howard Hughes Medical Institute investigator at Dana-Farber and a professor at Harvard Medical School, and her children, Kathryn Grace and William (Tripp).

Kaelin's obituary published in the Boston Globe is available here.

In Brief

Lehigh Valley Health Network Joins MSK Cancer Alliance

(Continued from page 1)

The Lehigh Valley Health Network includes five hospital campuses—three in Allentown, one in Bethlehem and one in Hazleton, Pa., as well as 13 health centers in five counties, and numerous primary and specialty care physician practices throughout the region.

Lehigh Valley's cancer program has been selected a National Cancer Center Community Cancer Centers Program, and was responsible for the care of 3,200 newly diagnosed cancer patients in 2014. Children's Hospital at Lehigh Valley Hospital, the only children's hospital in the region, provides care in 28 specialties and general pediatrics.

Lehigh Valley Health Network has been recognized by US News & World Report for 20 consecutive years as one of America's Best Hospitals and is a national Magnet hospital for excellence in nursing.

"Our collaboration with MSK will save lives by bringing evidence-based, world-class standards to our entire health network," said Brian Nester, president and CEO of Lehigh Valley.

Over the next several months, healthcare providers from both institutions will work to ensure that resources, capabilities, and standards of care are in line the MSK Cancer Alliance.

Additionally, Lehigh Valley physicians will have opportunities to visit MSK's New York City facilities to observe techniques, and both institutions will share educational resources and begin the process of putting into place the infrastructure necessary to measure outcomes data.

Educational programs and opportunities for the general public and professional audiences will be made available on-site at Lehigh Valley campuses.

"Central to our mission is eradicating cancer, and through the MSK Cancer Alliance—and in collaboration with Lehigh Valley Health Network—we have a unique opportunity to share our knowledge and best practices with a wider patient population," said Craig Thompson, president and CEO of MSK.

With more than 800 clinical trials currently available at its facilities, MSK will be able to provide Lehigh Valley patients the opportunity to participate in clinical trials not previously open to them.

"We look forward to learning firsthand how advances can be more easily applied in a community

setting through the MSK Cancer Alliance, while doing so in the most cost-effective way, since our Alliance does not require major structural changes such as the development of new facilities," said José Baselga, MSK physician-in-chief.

SITEMAN CANCER CENTER at Barnes-Jewish Hospital and Washington University School of Medicine in St. Louis **was awarded an "exceptional" rating**, the highest possible, by the NCI, based on a rigorous peer review of Siteman's research programs. Siteman is an NCI-designated Comprehensive Cancer Center.

Siteman earned its rating based on a January site visit by 26 researchers and administrators from academic cancer centers across the U.S.

"While this rating speaks to the extraordinary quality of our research, many of our researchers also are physicians who treat patients," said Timothy Eberlein, director of Siteman Cancer Center and head of the School of Medicine's Department of Surgery. "Being recognized as exceptional by one's peers makes our work on behalf of our patients even more meaningful."

During the visit, Washington University researchers and physicians presented their research programs in genomics, cancer imaging, cancer prevention and disparities, immunology and immunotherapy, and early-phase clinical trials.

including: vaccines against breast cancer and melanoma; goggles that help surgeons visualize cancer cells in the operating room; community-based research to understand cancer disparities; and promoting patient participation in innovative clinical studies.

Siteman was named Missouri's only NCI-designated Cancer Center in 2001 and the state's only Comprehensive Cancer Center in 2005.

JOHN CUNNINGHAM was appointed chairman of the Department of Pediatrics at the **University of Chicago.**

In December 2006, Cunningham joined the University of Chicago to become professor of pediatrics and section chief of hematology/oncology and stem-cell transplantation. He was named vice chairman for research in pediatrics in 2008. He also serves as the Donald N. Pritzker Professor, and has served as interim chair of the pediatrics department since 2014.

Previously, he was part of the Divisions of Experimental Hematology and Bone Marrow Transplantation at St. Jude Children's Research Hospital, and was appointed director of the cell and gene therapy laboratories, as well as chair of the institutional review board.

A native of Ireland, Cunningham came to the U.S. in 1991 as a visiting associate in clinical hematology at the National Heart, Lung, and Blood Institute.

Cunningham research focuses on childhood leukemia as well as hemoglobinopathies. He is known for his work on understanding the molecular mechanism underpinning red blood cell production, and has developed stem cell transplant techniques for the 70 percent of children who do not have a sibling match.

Cunningham earned his medical degree from University College Dublin, followed by a master of science degree in biochemistry from King's College London. He completed his residency at St. Laurence's Hospital and a hematology fellowship at the Mater Misericordiae University Hospital, both in Dublin.

In addition, he was a Wellcome research fellow in clinical science at the Royal Free Hospital School of Medicine in London, where he also completed his clinical training in bone marrow transplantation.

He served on the editorial board of the Journal of Biological Chemistry, and is a reviewer for Blood; Molecular and Cellular Biology; Cancer Research; and Genomics. He is a member of the American Cancer Society's Council for Extramural Grants, and pediatric series editor for The Oncologist.

JINGHUI ZHANG was named as the first chair of the Department of Computational Biology at **St. Jude Children's Research Hospital**. She will hold the St. Jude Endowed Chair in Bioinformatics.

The department will occupy an entire floor in the Kay Research and Care Center, the newest building on the St. Jude campus. The 28,700-square-foot space will be named the Brooks Brothers Computational Biology Center and hold both laboratories and offices. It will also house a genome sequencing laboratory. The department plans to grow to include nine faculty members during the next several years.

"Dr. Zhang has created new computational methods for analyzing genomic data, leading to new directions in research involving high-risk leukemia, brain and solid tumors," said James Downing, St. Jude president and CEO.

Five years ago, the hospital launched the St. Jude-Washington University Pediatric Cancer Genome Project to map the genomes of childhood cancers. Data generated from the project, 100 trillion-plus pieces,

encompass the complete normal and cancer genomes of 700 children and adolescents with 23 different childhood cancers.

Zhang joined St. Jude in 2010, leading the effort to analyze PCGP data and the creation of several new computational tools that have been adopted by biologists worldwide.

Her work has helped define the landscape of mutations that underlie pediatric cancers, resulting in the identification of new pediatric cancer genetic subtypes, insights into cancer-drug resistance and metastatic behavior, and new therapeutic targets against which drugs can be developed.

Prior to St. Jude, Zhang led genetic variation analysis of the first assembled human genome. She also contributed to key discoveries in the pilot phases of the NCI's Cancer Genome Atlas Project and the Therapeutically Applicable Research to Generate Effective Treatment initiative.

STEPHEN LESSNICK was named director of the Center for Childhood Cancer and Blood Disorders at the **Research Institute at Nationwide Children's Hospital**.

Lessnick plans to foster collaborations with the clinical team within the Division of Hematology/ Oncology/Blood and Marrow Transplantation at Nationwide Children's.

The research team's areas of focus include biology and therapy of a broad array of diseases that affect young children, adolescents, and young adults, including neuroblastoma, brain tumors, leukemia, and sarcomas. Lessnick's personal research interest is in the area of Ewing sarcoma.

Lessnick is also a professor of pediatrics in the Division of Pediatric Hematology and Oncology at The Ohio State University College of Medicine.

He attended Brandeis University for his undergraduate education and earned his MD and PhD degrees from the University of California in Los Angeles.

After completing his internship and residency at Children's Hospital in Boston, Lessnick finished his pediatric hematology and oncology fellowship at Children's Hospital and the Dana-Farber Cancer Institute.

He completed his postdoctoral research in their Pediatric Oncology Department, where he studied the transcriptional consequences of the Ewing sarcoma fusion gene. He joined the University of Utah faculty in January 2004 and served as the director of the Center for Children's Cancer Research at Huntsman Cancer Institute.

LOPA MISHRA has decided to leave **MD Anderson Cancer Center**, effective Aug. 31.

Mishra joined MD Anderson in December 2009 as professor and chair of Gastroenterology, Hepatology and Nutrition. In 2010, she was named holder of the Del & Dennis McCarthy Distinguished Professorship. Mishra also serves as associate director of the Texas Digestive Diseases Center.

During Mishra's tenure, the department grew from one clinical program to eight programs in GI cancers.

In 2013, Gastrointestinal Cancer Program was awarded an "exceptional-outstanding" score by NCI as part of MD Anderson's cancer center support grant. Mishra also initiated the first MD Anderson Global Academic Program with sub-Saharan Africa, including Ethiopia, Kenya and South Africa.

Mishra's research has focused on targeting liver and GI cancers using the TGF-beta signaling pathway and stem-like tumor initiating cells. Using mouse and human genetic studies, her team identified a group of liver and GI stem cell proteins crucial for TGF-beta signaling and modulation of human GI cancers and Beckwith-Wiedemann Syndrome. Studies have yielded insights into the origins of hepatocellular carcinoma, 40 percent of which are clonal and could arise from STICs. Her research has led to more than 80 original articles in peer-reviewed journals.

Mishra has received many honors including: American Gastroenterological Association Award for Top Women in Gastroenterology (2008), Funderburg Scholar in Gastric Cancer (2003-05), Betty and Harry Myerberg Award for Excellence in Research in Liver Development (1998), Elisabeth and John Cox Award for Innovative Clinical Therapy of Esophageal Cancer (1996), USV Industry New Investigator Award (1995) and the Stuart Mill Prize in Tropical Medicine (1981).

Marta Davila will serve as chair ad interim.

Davila earned her medical degree from Harvard and completed her residency in Internal Medicine and Fellowship in Gastroenterology at the University of California, San Francisco. Her first faculty appointment was as assistant professor at Stanford Medical School.

She joined MD Anderson in 2004 as associate professor, and was promoted to professor in 2010. In 2014 Davila was named medical director of endoscopy. From 2007 to 2009, she served as interim deputy chair.

THE LEUKEMIA & LYMPHOMA SOCIETY received a charitable donation from **Bristol-Myers Squibb Company** for chronic myeloid leukemia patients who need help paying for PCR testing.

The donation will also support awareness activities focused on educating patients, caregivers and healthcare providers about the importance of continued monitoring with PCR testing.

"Routine PCR testing is critical because oncologists rely on the results to determine their patients' clinical status of early and ongoing response to CML treatment and to help detect when patients are potentially becoming resistant to treatment, which may allow for earlier intervention," said Louis DeGennaro, LLS president and CEO. "Research indicates that early response to treatment and careful monitoring correlate with better overall survival rates."

Recommendations suggest that a CML patient should receive a PCR test every three months for the first three years after diagnosis, and every three to six months thereafter based on how well their treatment is working. The average cost of a PCR test is $345 and can be as high as $500 per test.

The program will assist insured and uninsured patients with out-of-pocket costs for PCR testing.

LLS will also partner with The Max Foundation, Cancer Support Community and the National CML Society to facilitate ongoing promotion and awareness about the PCR Financial Assistance and Awareness Program.

THE COMMISSION ON CANCER of the American College of Surgeons granted its bi-annual Outstanding Achievement Award to 20 accredited cancer programs throughout the U.S. The awards were based on surveys conducted during the first half of the year.

The full list of award-winning cancer programs is available here.

The 20 award-winning programs represent approximately 9 percent of programs surveyed.

THE CALIFORNIA DEPARTMENT OF PUBLIC HEALTH announced a big data partnership with **St. Joseph Health**, in which the health system would collect and send structured pathology cancer data directly to the California Cancer Registry.

The pilot project—which began in January 2014—is the result of a collaboration between CDPH, St. Joseph Health, mTuitive and the College of American Pathologists.

Ten hospitals within the St. Joseph Health system are now sending data to the registry, and more health care facilities are expected to participate.

The partnership is the first of its kind in the U.S., said CDPH Director and State Health Officer Karen Smith.

"Every second we save in sharing data gives researchers more time to spend on curing cancer," Smith said in a statement.

According to CDPH, the project enables the cancer registry to perform real-time surveillance on data reported via project partners—providing new research opportunities focused on patient outcomes.

Prior to the project, cancer pathology data was stored within a facility's electronic records system as "narrative text data", which limits its uses.

Members of the partnership use a system called the CAP electronic Forms and Reporting Module. With CAP eFRM, pathologists are able to securely share cancer data with CCR.

"This partnership is another way in which the California Department of Public Health works with the private sector and health care systems to optimize the health and well-being of the people in California," Smith said.

A total of 6,000 cyclists participated in **THE PAN-MASS CHALLENGE**, a two-day bike fundraiser involving 12 routes and 46 Massachusetts towns, raising over $33.5 million.

Joined by Governor Charlie Baker and Boston Mayor Marty Walsh, cyclists from 40 states and five countries rode to raise money for adult and pediatric cancer research at Dana-Farber Cancer Institute through the Jimmy Fund. The goal was to bring the PMC's 35-year fundraising total to a half billion dollars raised since the organization's inception in 1980.

"Each year, we are astonished by the unparalleled support that Dana-Farber receives from the PMC, and this year is no different," said Edward Benz Jr., president and CEO of Dana-Farber. "We are deeply grateful for the PMC's partnership and unwavering commitment."

One-day routes include riding from Wellesley or Sturbridge to Bourne, Wellesley to Patriot Place and Bourne to Provincetown. Two-day routes include Wellesley or Sturbridge to Provincetown, and Wellesley or Sturbridge to Bourne and back. The average cyclist trains for three months, solicits 40 sponsors, and raises more than $6,500, according to PMC.

The PMC is presented by the Red Sox Foundation and the New Balance Foundation. Another 200 companies support the event by providing more than $4 million in goods and services each year. During PMC weekend and throughout the year, more than 4,000 volunteers donate their time to support the organization.

Drugs and Targets

Canada Approves Imbruvica In Mantle Cell Lymphoma

Health Canada issued a Notice of Compliance with Conditions for Imbruvica (ibrutinib) an oral, once-daily single-agent therapy for the treatment of patients with relapsed or refractory mantle cell lymphoma.

The approval with conditions is based on phase II clinical trial data that were published in the New England Journal of Medicine, showing an overall response rate of nearly 68 percent based on investigator assessment.

Imbruvica is co-developed by Cilag GmbH International, a member of the Janssen Pharmaceutical Companies, and Pharmacyclics LLC, an AbbVie company. Janssen Inc. markets Imbruvica in Canada.

Imbruvica was first approved in Canada in November 2014 for the treatment of patients with the blood cancer chronic lymphocytic leukemia, including those with 17p deletion, who have received at least one prior therapy, or for the frontline treatment of patients with CLL with 17p deletion. For this clinical use, Imbruvica was issued marketing authorization without conditions.

The European Commission, acting on the positive recommendation from the European Medicines Agency Committee for Orphan Medicinal Products, **granted orphan drug designation to synthetic hypericin**, the active pharmaceutical ingredient in SGX301, for the treatment of cutaneous T-cell lymphoma, a rare disease and a class of non-Hodgkin's lymphoma.

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

Soligenix Inc., the drug's sponsor, is currently working with leading CTCL centers, as well as with the National Organization for Rare Disorders and the Cutaneous Lymphoma Foundation to begin a 120 subject pivotal phase III clinical trial with SGX301 in the second half of 2015.

SGX301 is a novel, first-in-class, photodynamic therapy utilizing visible light for activation. Synthetic hypericin is a potent photosensitizer which is topically applied to skin lesions and activated by visible fluorescent light.

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

AstraZeneca and Heptares Therapeutics entered into a licensing agreement under which AstraZeneca will acquire exclusive global rights to develop, manufacture and commercialize the adenosine A2A receptor antagonist HTL-1071, a small molecule immuno-oncology candidate.

AstraZeneca will focus on exploring HTL-1071 and any additional compounds across a range of cancers, including in combination with its existing portfolio of immunotherapies.

The companies will also collaborate to discover further A2A receptor-blocking compounds for development in cancer immunotherapy.

Heptares will receive an upfront payment of $10 million and is eligible to receive additional milestone payments based on agreed pre-clinical and clinical events. Subject to successful completion of development and commercialization milestones, Heptares is also eligible to receive more than $500 million as well as royalty payments.

Mirati Therapeutics Inc. and MedImmune, the global biologics research and development arm of AstraZeneca, announced they **have entered into an exclusive clinical trial collaboration.**

The phase I/II study will evaluate the safety and efficacy of Mirati's investigational spectrum-selective histone deacetylase inhibitor, mocetinostat, in combination with MedImmune's investigational anti-PD-L1 immune checkpoint inhibitor, durvalumab (MEDI4736).

This novel combination will initially be evaluated in patients with non-small cell lung cancer with the potential to explore additional indications in the future.

Mocetinostat selectively inhibits class I HDAC enzymes, which has the potential to enhance the positive effect of checkpoint inhibitors, such as durvalumab, on tumor immunity, while durvalumab is designed to counter the tumor's immune-evading tactics by blocking a signal that helps tumors avoid detection.

Under the terms of the agreement, Mirati will conduct and fund the initial phase I/II clinical trial, which is expected to start in 2016, and MedImmune will supply durvalumab for the trial.

In the event that the initial clinical trial demonstrates positive results, MedImmune will have an exclusive period of time in which to negotiate a commercial license for the combination in this indication.