

BIOCENTURY

REPRINT FROM FEBRUARY 22, 2021



BIOCENTURY & GETTY IMAGES

POLITICS, POLICY & LAW

Creating access to cancer drugs in Africa

BY STEVE USDIN, WASHINGTON EDITOR

At the beginning of the 21st century, governments, philanthropies and pharmaceutical companies came together to provide Africans access to HIV medications, saving millions of lives by reducing the disparities in access between wealthy and poor countries. Today, another massive access disparity — the lack of access to medicines and care for cancer — condemns hundreds of thousands of Africans every year to deaths that could be avoided.

Communicable diseases, not cancer, are the focus of most global health initiatives. While much more must be done to reduce the burden of infectious diseases in Africa, decades of investments by philanthropies, governments and biopharma companies in initiatives are paying off. Deaths from malaria have been halved over the last two decades.

The trajectory of cancer in Africa is more troubling. Incidence and mortality are on the upswing, cancers already kill more people on the continent than malaria, and the challenges of creating healthcare ecosystems that can effectively treat cancer are daunting.

At least one third of the projected 416,000 breast cancer deaths that will occur in sub-Saharan Africa in the coming decade could be prevented through achievable early detection and improvements in treatment, according to a study that assessed disparities in breast cancer outcomes on the continent. There are similar possibilities for improving outcomes in other cancers.

A handful of organizations, including some supported by biopharma companies, are working to improve cancer care in Africa. One is BIO Ventures for Global Health (BVGH), a non-profit that is applying the business acumen and scientific rigor biopharma executives employ in their companies to advancing cancer treatment in sub-Saharan Africa. It has established relationships with governments, mapped regulatory systems and supply chains, and systematically gathered information about the capabilities and needs of hospitals and health systems.

The data-driven approach gives a voice to the physicians who care for patients, ensuring that contributions are matched to needs and capabilities.

“WE ARE NOT FOCUSED ON DONATION OF DRUGS, WE ARE FOCUSED ON PROVIDING MORE AFFORDABLE, SUSTAINABLE AND SCALABLE ACCESS TO QUALITY DRUGS.”

JENNIFER DENT, BVGH

BVGH was founded in 2004 by BIO and the Bill & Melinda Gates and Rockefeller foundations. Today it is funded by two pharmas, Takeda Pharmaceutical Co. Ltd. (Tokyo:4502; NYSE:TAK) and Johnson & Johnson (NYSE:JNJ); the security company GardaWorld; and the law firm Faber Daeufer & Itrato. From 2017-2019 BVGH was funded by Pfizer Inc. (NYSE:PFE), and its projects rely on the collaboration of other biopharma companies that provide their medicines on a discounted basis.

BVGH's Africa initiatives grew out of a sense of urgency to make a tangible difference in the lives of people living in developing countries, Jim Greenwood, the organization's chairman and the former president and CEO of BIO, told BioCentury. As a board member, “I kept asking ‘where's the first person who is alive because BVGH exists.’”

The organization, which originally focused on infectious diseases, decided that it could answer that question and make the greatest impact by helping improve access to cancer medicines, Greenwood and board member James Geraghty told BioCentury.

“The world has changed as a result of the Gates Foundation's recognition of the need for R&D on infectious diseases,” said Geraghty, who chairs the boards of Idera Pharmaceuticals Inc. (NASDAQ:IDRA), Pieris Pharmaceuticals Inc. (NASDAQ:PIRS) and Orchard Therapeutics plc (NASDAQ:ORTX). In part because of the success of the Bill & Melinda Gates Foundation's initiatives, he predicted that in the next 25 years the global health focus will shift to non-infectious disease as a major area of philanthropic investment.

BVGH runs two programs in sub-Saharan Africa. The African Access Initiative provides heavily discounted drugs to hospitals that have had little or no access to therapies that are the backbone of cancer treatment in more affluent countries. The African Consortium for Cancer Clinical Trials is strengthening the clinical trial infrastructure across the continent. Both programs rest on a base of intense engagement with the individuals and institutions that provide care and are designed to create lasting improvements. They are not donation-based; countries, and in some

cases hospitals and individual patients, are required to make financial and other commitments.

BVGH's programs enable companies to contribute to reducing global inequities in care in ways that are more meaningful than simply cutting checks. Its diligence and work on the ground provide confidence that contributions will be targeted efficiently and will not be diluted through corruption. Beyond funding, biopharma companies are providing expertise and training to colleagues in institutions that are part of BVGH's initiatives.

Some pharmas are working on their own or through other organizations to improve access to cancer care in Africa. The Bristol Myers Squibb Foundation's Global Cancer Disparities, for example, focuses on addressing lung cancer in Sub-Saharan Africa.

Access initiative

The access initiative is working in 40 hospitals in Cameroon, Cote d'Ivoire, Nigeria, Kenya, Rwanda and Senegal, countries with distinctly different cultures and levels of economic development that have in common a lack of widespread access to cancer care that is taken for granted in much of the world.

BVGH's prerequisites for working in a country include the ability to partner with government leaders and align with national objectives, Jennifer Dent, president and CEO of BVGH told BioCentury. It must be able to communicate directly with the minister of health, and the ministry must have and invest in a cancer control plan.

It has charted processes for importing drugs, a regulatory system for approving drugs, payer systems and supply chains.

“We are not focused on donation of drugs, we are focused on providing more affordable, sustainable and scalable access to quality drugs,” Dent said. Rather than attempt to create hospitals or cancer programs from scratch, “we are focused on building capacity where some capacity and infrastructure already exists.”

For each of the six countries, BVGH has created detailed maps of the cancer care ecosystem, collecting the kinds of market intelligence that pharmaceutical companies would assemble in countries where they expect to sell their products but is unavailable for countries where there is no commercial market.

It has gathered information on individual hospitals and hospital networks and conducted surveys to reveal the numbers of patients treated by cancer type, diagnostic capabilities, equipment on hand and needed, as well as the oncology drugs hospitals use and, most importantly, wish lists of drugs needed to treat their patients.

These surveys are the starting point for discussions with clinicians that in turn have led BVGH to contact manufacturers of branded and generic drugs to request proposals for providing medicines at discounts.

“OUR GOAL IS WITH MORE AWARENESS AND SUCCESS STORIES TO HAVE PATIENTS COMING IN WITH EARLIER STAGES.”

TOLULOPE ADEWOLE, LAGOS UNIVERSITY TEACHING HOSPITAL

BVGH ensures that hospitals have the necessary capabilities to support use of drugs, including pathology services that are necessary for the appropriate use of some targeted therapies.

The Africa Access Initiative’s virtual training sessions, funded by Merck & Co. Inc. (NYSE:MRK), reached 2,500 healthcare professionals in Africa in 2020.

BVGH ran a nine-week virtual pathology course in partnership with the American Society of Clinical Pathology. The course, which focused on topics prioritized by Nigerian pathologists and oncologists, taught 85 pathologists from 35 hospitals in Nigeria. Another BVGH training program on prostate cancer care reached over 600 participants in francophone Africa.

Access in Nigeria

The ubiquity of substandard and counterfeit drugs circulating in Africa underlines the importance of acquiring medicines that have been reviewed by regulators in the U.S. or Europe. More than one in 10 drugs sold in Nigeria is “substandard or falsified,” according to Faruk Mohammed, an oncologist and researcher at Ahmadu Bello University in Zaria, Nigeria.

Speaking at the Skoll World Forum on Social Entrepreneurship in April 2020, Mohammed described the work of BVGH’s access initiative in northern Nigeria, where the majority of the population lives on \$3 per

day and there is little access to cancer care. A network of eight hospitals in the region is receiving medicines through the Africa Access Initiative.

Pharma companies are providing the Nigerian hospitals 41 chemotherapy, hormonal and targeted therapies to treat breast, cervical, colorectal, head and neck, hematological, pediatric, and prostate cancers. The program is treating about 2,100 patients annually.

The companies are discounting prices 85-96%, Dent said.

The discounts are essential to change the paradigm of cancer care, Tolulope Adewole, CEO of the NSIA-LUTH Cancer Center at Lagos University Teaching Hospital, told BioCentury. “In Nigeria, healthcare is pretty much paid out of pocket,” with about 5% of the population having insurance coverage. One consequence is that even if patients receive a diagnosis when their cancer is at an early stage, the diagnosis often triggers a fundraising effort that delays treatment.

“Most of the patients we see are stage four,” Adewole said. “It is a cultural thing across Africa, a question of awareness and access,” and one of the major factors that leads to worse outcomes among Africans treated for many types of cancer compared with patients in countries with better access to medicines and care.

Poor outcomes and fear of bankrupting families drive a pessimism that further deters patients from seeking care, he said. “Our goal is with more awareness and success stories to have patients coming in with earlier stages.”

BVGH has reached an agreement with Pfizer to supply drugs in Nigeria and has “engaged with AstraZeneca on forecasting and pricing for their cancer drugs” in the country, Dent said.

In addition to “helping us to negotiate deals with pharmaceutical companies to get good quality oncology drugs at cheaper prices,” Adewole said BVGH has increased his center’s ability to help patients by providing training. His hospital is equipped with advanced technologies including linear accelerators.

AAI in Cameroon

When the Mbingo Baptist Hospital received the first shipment of drugs from BVGH in 2020, it was the “first time we had a good quantity of FDA approved drugs for use in Cameroon,” Dennis Palmer, an internist and missionary who has been working in the country for 40 years, told BioCentury. Mbingo is the main referral hospital for a network of six hospitals run by Cameroon Baptist Convention Health Services.

When BioCentury videoconferenced with Palmer in his office in Mbingo, he was juggling work that would be familiar to hospital administrators in the U.S. with tasks that are unique to rural Africa, including completing a hydroelectric dam that will provide reliable, low-cost power. The hospital is in a conflict zone and has been the scene of violent confrontations between francophone government forces and anglophone residents who are seeking independence. Mbingo runs one of two pediatric oncology units in Cameroon and serves patients from throughout the country, as well as Central African Republic and Chad.

“Before we were affected by the conflict, this was a very poor region of Cameroon,” Francine Kouya, a pediatric oncologist who treats patients at Mbingo, told BioCentury. “Most of our patients are farmers. Before the conflict it was challenging for them to care for themselves. Now with the crisis, it is even more challenging.” The hospital has continued to function and patients travel there despite the conflict, Kouya and Palmer said.

The higher quality and lower cost drugs received through BVGH will make it possible for patients to be treated who otherwise would get no effective care and will allow patients to who previously would have been unable to afford multiple courses of chemotherapy to complete treatment, Kouya said. “If the cost of the drugs is reduced it will increase compliance and patients will have a chance to survive.” Inability to pay for a full course of therapy often causes patients who could have survived to progress to advanced, untreatable disease, she said.

“IF THE COST OF THE DRUGS IS REDUCED IT WILL INCREASE COMPLIANCE AND PATIENTS WILL HAVE A CHANCE TO SURVIVE.”

FRANCINE KOUYA, MBINGO BAPTIST HOSPITAL

The anticoagulant Xarelto rivaroxaban, which Bayer AG (Xetra: BAYN) is providing through BVGH, is having a big impact, Kouya said. Many cancer patients are transferred to Mbingo from other hospitals with venous thromboembolisms (VTEs). “We used to give those patients Lovonox [low molecular weight heparin] and the cost was enormous. Now the cost has been greatly reduced.”

BVGH worked with a team at Mbingo to develop a poverty index that Bayer uses as the basis for tiered pricing.

Cancer drugs provided by Novartis AG (NYSE: NVS; SIX: NOVN) and its Sandoz generic unit through BVGH in 2020 will treat 1,400 breast, cervical, hematological, and pediatric cancer patients in Cameroon and the Democratic Republic of the Congo. DRC is not a member of the Africa Access Initiative, but BVGH has agreed to negotiate supplies of drugs for one hospital in Kinshasa. The nine drugs supplied by Novartis include methotrexate, rituximab, filgrastim and doxorubicin.

BVGH is finalizing arrangements for Pfizer to supply drugs to Cameroon, including cytarabine and cisplatin.

The non-profit is also trying to secure access to discounted tenofovir from Gilead Sciences Inc. (NASDAQ: GILD) to treat hepatitis B.

Mbingo’s patients have in the past relied on drugs from sources that provided little assurance of quality, Palmer said. “Being able to use FDA-approved drugs is a major advance for our patients.”

BVGH is seeking to expand industry participation in its Africa initiatives. “At a time when equity, science, diversity, and access to quality healthcare are converging, BVGH’s African Access Initiative presents a unique model that is delivering life-saving cancer medicines to patients in Africa,” Greenwood said. He called on “international companies with oncology portfolios to join AAI and support BVGH in this critical initiative and journey that is changing cancer paradigm in Africa.”

Expanding access through trials

In affluent parts of the world, the best cancer care is often provided in clinical trials and at centers that participate in clinical research, and a lack of access to trials contributes to health disparities. The clinical trial gap widens to a chasm when access in countries like the U.S. is compared to access in sub-Saharan Africa.

BVGH’s African Consortium for Cancer Clinical Trials (AC³T), established in 2017, is intended to reduce that gap by providing training and other resources to bolster the cancer clinical trial capabilities.

In addition to enhancing clinical trial capacity, BVGH has created an online platform that provides detailed data on the capabilities of specific clinical centers to make it easier for academic and commercial researchers to identify potential partners in sub-Saharan Africa.

“We have profiled over 40 sites across sub-Saharan Africa to understand their readiness,” Dent said. “We are working with sites now on having their clinical trial proposals reviewed by fellows from Takeda who are working on this program, and have mapped out virtual fellowships with industry and academic PIs” to set up cancer trials.

“The urban legend is that you can’t run a complex cancer clinical trial in Africa, certainly not in sub-Saharan Africa,” Chris Reddick, VP and head of R&D health Equity at Takeda, told BioCentury. “When we did assessments for gaps, we actually found out that there were a number of centers that were ready, or they have one or two missing pieces that could be filled in relatively quickly. We then pivoted to create two arms of this initiative. One is highlighting the centers that are ready now, and BVGH has created an open source website that tells you here they are,” and the second is filling in the gaps.

BIOCENTURY

Enhancing clinical trial capacity directly helps patients who participate in trials, builds infrastructure that helps future patients, and can create knowledge that benefits patients across the African continent, Reddick told BioCentury. “Clinical trials are the largest patient interface that a pharmaceutical company has, so if you can address inequities in the clinical trial space and create access to new medicines, you can really make an impact for patients.”

The benefits to patients who participate in cancer trials are clear.

“There are very few placebo-controlled trials in cancer, so even in the control arm and cancer, you are getting the best care and the best medicine possible for your type of cancer,” Reddick said. “If you are in the investigational arm, you are getting the latest thinking.”

Reddick noted another important patient benefit. “If you participate in a trial, whether you are in the control arm or the active treatment arm, medicines are provided for free. It is a major work-around for the cost of those medicines.”

He stressed the importance of strengthening institutions that participate in clinical research. “Any initiative that focuses on clinical trials has to build the capacity of the community to be stronger after the trials are done. It’s no good if we just enroll the patients, say thank you for helping us, and complete the trial.”

Preparing hospitals to conduct clinical research can require helping them acquire equipment and expertise, for example pathology labs and trained staff capable of making appropriate diagnoses.

Clinical trials can become a revenue source for hospitals and a tool for retaining talented physicians.

“It really is about leaving the community stronger, building the community’s capacity, which they can use to do the trial, and making sure they’re left with something that they can use to take care of their patients,” Reddick said.

EDITORIAL & RESEARCH

NEWSROOM:

news@biocentury.com

SAN CARLOS, CA:

+1 650-595-5333

CHICAGO:

+1 312-755-0798

WASHINGTON, DC:

+1 202-462-9582

UNITED KINGDOM:

+44 (0)1865-512184

C. Simone Fishburn, Ph.D., Editor in Chief

Editors Emeritus: Susan Schaeffer (2012-2018);
Karen Bernstein, Ph.D. (1992-2012)

Jeff Cranmer, Selina Koch, Ph.D., Executive Editors

Steve Usdin, Senior Editor/Washington & Head:
Policy & Regulation

Lauren Martz, Senior Editor & Head: Translation &
Clinical Development

Karen Tkach Tuzman, Ph.D., Senior Editor & Head:
Discovery and Preclinical Development

Paul Bonanos, Stephen Hansen, Virginia Li, Associate
Editors

Meredith Durkin Wolfe, Winnie Pong, Ph.D., Associate
Editors, Data & Analytics

Sandi Wong, Ph.D., Assistant Editor

Danielle Kopke, Ph.D., Gunjan Ohri, Claire Quang, Analysts
& Staff Writers

Alanna Farro, Valerie Rodriguez, Cole Travis, Graphics,
Podcasts & Publishing

USE OF IMAGES: Certain Images used in BioCentury Inc.'s Publications, Video Content, Websites, Services, Notices and/or Marketing Materials are licensed from Getty Images (US), Inc. Any such image of a person or object so displayed is being used for illustrative purposes only and any such person or object depicted, if any, is merely a model. For more information see "Use of Images" found under the "Legal" section on the footer of the homepage at www.biocentury.com.

BioCentury®; Because Real Intelligence is Hard to Find™; BCIQ™; The BioCentury 100™; and The Clear Route to ROI™ are trademarks of BIOCENTURY INC. All contents Copyright © 2021, BIOCENTURY INC. ALL RIGHTS RESERVED. No part of BioCentury's Publications or Website may be copied, reproduced, retransmitted, disseminated, sold, distributed, published, broadcast, circulated, commercially exploited in any form or used to create derivative works without the written consent of BioCentury. Information provided by BioCentury's Publications and Website is gathered from sources that BioCentury believes are reliable; however, BioCentury does not guarantee the accuracy, completeness, or timeliness of the information, nor does BioCentury make any warranties of any kind regarding the information. The contents of BioCentury's Publications and Website are not intended as investment, business, tax or legal advice, and BioCentury is not responsible for any investment, business, tax or legal opinions cited therein or for any decision made or action taken in reliance upon such information.

All use of BioCentury and its contents by current subscribers is governed by the BioCentury User Agreement and by all others is governed by the BioCentury Terms of Use, unless a written agreement to the contrary has been executed by BioCentury Inc.

CORPORATE, SUBSCRIPTIONS & PRIVACY

BioCentury's mission is to provide value-added business intelligence & analysis for life science companies, investors, academia and government on the strategic issues essential to the formation, development and sustainability of life science ventures.

BioCentury Inc.
BioCentury International Inc.

MAIN OFFICES

1235 Radio Road, Ste. 100
Redwood City, CA 94065-1217
+1 650-595-5333; Fax: +1 650-595-5589

CORPORATE

Karen Bernstein, Ph.D., Co-Founder & Chairman

David Flores, Co-Founder, President & CEO

C. Simone Fishburn, Ph.D., Vice President/Editor in Chief

Adam Gordon: Vice President/
Product Management & Marketing

David Smiling: Chief Technology Officer

Bennet Weintraub: Vice President/
Administration & CFO

Eric Pierce: Publisher

Susan Morgan: Senior Director/
Administration & Human Resources

BUSINESS DEVELOPMENT

Joshua Berlin, Executive Director

Juli Balestrieri, Hongjiang Li, Ph.D., Business Development
Managers

PRODUCT MANAGEMENT & MARKETING

Aaron Gadowski, Director, Product Management

Kim Gordon, Senior Marketing Manager

Lam Lu, Business Systems Manager

Josephine Ascitutto-Bunn, Marketing Automation Manager

Marilyn Smith, Customer Data Manager

SUBSCRIBER SERVICES

Tim Tulloch, Senior Director

**Orlando Abello, Alan John, Matt Krebs, Michelle Ortega,
Frank Perry, Ron Rabinowitz**, Account Managers

Robin Leathers, Customer Success Director

Hannibal Adofo, Larry Campbell, Kevin Lehnbeuter,
Customer Success Managers

TECHNOLOGY

Jenny Nichols, Director, Publishing

Victoria Chou, Business Intelligence Group Manager

Alicia Parker, Business Intelligence Analyst

Akemi Mori, Senior Quality Assurance Engineer

David Ghio, Senior IT Systems Engineer

Deepa Srigiri, Senior Software Engineer

Doreen Arthur, BioPharma Informatics Analyst

Kelly Burriss, Senior Network Engineer

Michael Ilyin, Senior Data and Infrastructure Architect

Tejpal Virk, Data Scientist

BUSINESS SERVICES

Accounting & Billing: finance@biocentury.com

Conferences: conferences@biocentury.com

Data Solutions Support: support@biocentury.com

Privacy Policy: privacy@biocentury.com

Reprints/Permissions:
businessservices@biocentury.com

PRIVACY & ADVERTISING

In accordance with its Privacy Policy, BioCentury does NOT sell its customer information or usage data to third parties. BioCentury sells advertising in its BioCentury product emails and on its website. BioCentury is pleased to acknowledge its conference and events partners and sponsors through promotional announcements, on our web site, at our events and in our product emails. BioCentury also provides advertising opportunities to partners, sponsors, and advertisers through stand-alone emails to our community.

This edition and the information contained in BioCentury's publications and services are solely for your own personal, non-transferable licensed use and cannot be shared with any other individuals. For information about adding subscribers to your account or obtaining article reprints, please contact support@biocentury.com.