By Taren Grom

Collaborations Across the Ecosystem

Over the past couple of years, there has been an increase in the number of collaborations designed to accelerate progress to solve R&D and patient challenges.

Daiichi Sankyo and AstraZeneca Tackle Cancer

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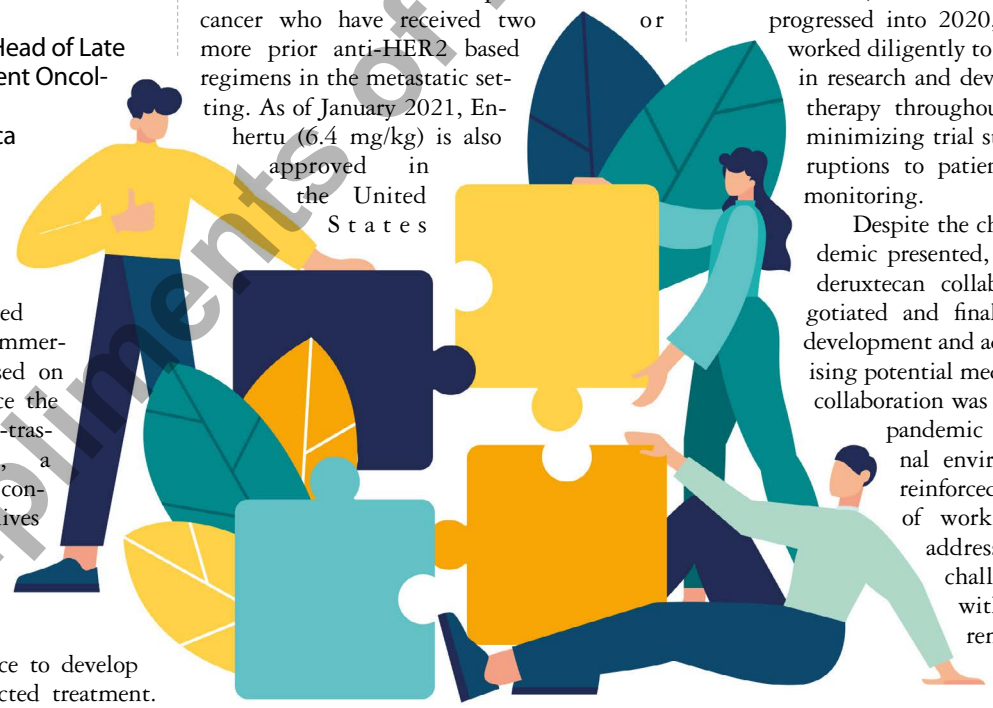
In March 2019, Daiichi Sankyo and AstraZeneca first entered a global development and commercialization collaboration focused on accelerating science to advance the development of Enhertu (fam-trastuzumab deruxtecan-nxki), a HER2-directed antibody drug conjugate (ADC), to improve the lives of patients with cancer.

The primary goal was to apply key learnings from the development of earlier ADCs and leverage the science to develop a next-generation HER2-directed treatment. The companies are putting intense effort and focus into developing a robust clinical development program that explores the potential of this next-generation ADC in patients with HER2-positive tumors that are known to benefit from anti-HER2 therapies, and also in patients where the presence of HER2 is known but there are currently no approved HER2-directed medicines. Enhertu has shown transformational potential across multiple HER2-targetable tumors, including breast and gastric cancer, demonstrating impressive and durable efficacy not previously seen in patients in these settings, and has been approved in several markets:

Enhertu (5.4 mg/kg), approved under accelerated approval in the United States in December 2019, is under conditional marketing authorization in the EU and the UK and under the conditional early approval system in Japan for treating adult patients with unresectable or metastatic HER2-positive breast cancer who have received two or more prior anti-HER2 based regimens in the metastatic setting. As of January 2021, Enhertu (6.4 mg/kg) is also approved in the United States and in Japan for the treatment of adult patients with locally advanced or metastatic HER2-positive gastric or gastroesophageal junction adenocarcinoma who have received a prior trastuzumab-based regimen.



Building on the success of the initial collaboration, in July 2020, the two companies entered into another global development and commercialization collaboration for datopotamab deruxtecan (Dato-DXd), a TROP2-directed ADC that is being evaluated across multiple solid tumors, including non-small cell lung cancer (NSCLC), triple negative breast cancer, and HR-positive breast cancer.

Daiichi Sankyo and AstraZeneca continue to drive toward the goal of improving the lives of those living with cancer by pushing the limits of innovation to advance these next-generation ADCs.

The Enhertu collaboration came to fruition in March 2019, and as clinical development progressed into 2020, both companies worked diligently to ensure continuity in research and development for this therapy throughout the pandemic, minimizing trial stoppages or interruptions to patient treatment and monitoring.

Despite the challenges the pandemic presented, the datopotamab deruxtecan collaboration was negotiated and finalized to expedite development and advance this promising potential medicine. While this collaboration was not driven by the pandemic itself, the external environment certainly reinforced the importance of working together to address global health challenges, including within oncology. It remains imperative that companies unite to help minimize the impact the pandemic has on access to patient care and the development of new therapies.

Now more than ever, the oncology community must find new and innovative ways to collaborate on science's biggest challenges. As researchers, it is our responsibility to push the boundaries of science to deliver improved, targeted medicines for patients with cancer.

Collaboration allows diverse opinions to be shared more readily, allowing companies to test hypotheses more quickly and more accurately, ultimately accelerating a high-quality drug development process. By pooling resources, the two companies have been able to get more done, in a more efficient manner than they would have ever been able to do as two separate organizations. Ultimately, this means they will be able to bring our innovative medicines to more patients as quickly as possible.

Genmab and AbbVie Team Up for Antibody Therapeutics

JAN VAN DE WINKEL
CEO
Genmab

At Genmab, we believe partnerships and collaborations are foundational to accelerate innovation and bring medicines to people with cancer as quickly as possible, which is why in June 2020, we entered a broad oncology collaboration with AbbVie to jointly develop and commercialize three of Genmab's next-generation bispecific antibody products and enter into a discovery research collaboration for future differentiated antibody therapeutics for cancer. The collaboration allows us to accelerate as well as broaden and maximize the development of some of our promising early-stage bispecific antibodies.

At the time it was announced, this deal was one of the largest oncology partnerships on record. The partnership combines the strengths of Genmab's world-class knowledge in antibody biology and deep expertise in innovative next-generation antibody technology platforms, with AbbVie's R&D prowess and leadership position in hematological cancers.

In November 2020, we were proud to announce the initiation of a Phase III study of epcoritamab, an investigational bispecific antibody created using Genmab's proprietary technology in patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL), which is aggressive and the most common form of non-Hodgkin's lymphoma worldwide. In collaboration with AbbVie, we have planned a broad, expansive, accelerated epcoritamab clinical development plan to maximize the potential of this promising bispecific antibody, with the ultimate goal of bringing new differentiated treatment options as soon as possible to patients.

The COVID-19 pandemic certainly highlighted the importance of science-driven innovation and collaboration to help solve the world's most pressing health issues. However, collaborating with companies to advance treatments for patients was not new for Genmab. In our 22-year history, we've had more than 20 key partnerships to create next-generation therapies. We currently have eight clinical-stage investigational therapies and the majority of these are being co-developed with partner companies, including BioNTech and Seagen. Our partnerships expand beyond clinical development as well. For example, we have a strategic collaboration with Tempus, a company advancing precision medicine through the practical application of AI in healthcare to advance new disease targets and biomarkers that may have the potential to generate new treatments in oncology.

At Genmab, collaboration has always been a part of our DNA. We understand that it takes an innovation ecosystem with partnerships between biotech and big pharma, academia, research institutes, data sciences companies, and medical device companies to nurture innovation.

Horizon and HemoShear Address Gout

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The goal of the collaboration between Horizon Therapeutics and HemoShear Therapeutics is to identify and validate novel therapeutic targets followed by drug discovery that will lead to new treatments to address the underlying cause of gout, or elevated uric acid. Gout is a chronic, progressive inflammatory form of arthritis that is a common, yet largely undertreated condition with many comorbidities.

Our collaboration is working toward identifying therapies with novel mechanisms of action to help address the unmet medical needs of patients with gout — especially for those who live with the most severe forms of the condition. We are achieving this by combining Horizon's expertise in gout with HemoShear's proprietary discovery platform, Reveal-Tx. In just two years, this collaboration has yielded two highly attractive, novel therapeutic targets by leveraging sophisticated human tissue culture approaches and computer-aided modeling of signaling pathways and protein interactions. Drug discovery is currently underway to identify inhibitors of these targets.

The Horizon and HemoShear collaboration began in January 2019 and was well-established before the pandemic. Although the pandemic has curtailed travel and face-to-face meetings, the team's overall efforts have not been disrupted. In fact, it's quite the opposite — lab and analytical operations increased at many locations throughout the world, and two drug discovery programs were initiated during the pandemic.

We firmly believe that R&D collaborations will continue to be part of the lifeblood of success within the biotechnology industry. We know innovation cannot just come from within our walls. Biotech companies and academic labs bring pioneering technologies, creative platforms, and discovery efforts to the table while industry brings drug development experience, clinical expertise, and execution proficiency. Together, they are a winning combination. Partnerships like Horizon and HemoShear are mutually beneficial and ultimately bring better therapies to patients with unmet medical needs. Cross-disciplinary collaboration helps to expand the technical prowess that's needed to bring about successful innovation.

IQVIA Collaborating Across the R&D Journey

SARAH LYONS
General Manager
Privacy Analytics, an IQVIA company

Rapid healthcare digitization and COVID-19 learnings suggest organizations known for collaborative data sharing have an edge in today's data-rich healthcare ecosystem.

Networked providers increasingly collaborate using shared data and evidence to deliver high-quality, standardized care. Data is facilitating and accelerating evidence-based standardization of diagnosis and treatment. Physicians have become digitally enabled team members operating in a health system, multi-specialty practice, or informal network. And as healthcare organizations have become both research sites and suppliers of real-world information, drug manufacturers are seeing the need to build trust, deepen relationships, and collaborate to achieve aligned healthcare objectives.

For clinical trial sponsors, the pandemic also underscored the importance of clinical

data access to support research, decision-making, and public confidence in vaccines and therapeutics. The importance of data access was recently emphasized by the International Coalition of Medicines Regulatory Authorities (ICMRA) and the World Health Organization (WHO). They called on the pharmaceutical industry to provide voluntary unrestricted access to trial results data within short timelines for the benefit of public health. The emergence of clinical trial data sharing consortiums and platforms reflect this shift. TransCelerate BioPharma is an example of a nonprofit that fosters collaboration across the global biopharma research and development community.

Organizations must earn trust to collaborate in emerging data-sharing networks. Those that are not perceived to contribute to collaborative advancements in patient health will find themselves losing ground. Sharing data safely and responsibly can help life-sciences organizations earn trust.

This trust translates to patient recruitment outcomes and access to collaboration opportunities, which enhances data access. Data can subsequently fuel innovation for faster drug discovery, better trial design, and, ultimately, better R&D results. These results enhance trust to continue the cycle.

As an example of data sharing for pandemic response collaboration, Novartis proactively planned to share COVID-19 trial data with unprecedented speed.

Novartis concluded a Phase III trial (known as the CAN-COVID trial) in 2020 to test the efficacy of Novartis Ilaris (canakinumab) for treating cytokine release syndrome. This syndrome occurs during the hyper-inflammatory stage of COVID-19 if the condition of the patient worsens without successful treatment.

With time of the essence, Novartis wanted to share its insight-rich trial data safely and quickly. Novartis partnered with Privacy Analytics to anonymize the data so that it could be made immediately accessible via TransCelerate's DataCelerate platform. As described by Peter Mesenbrink, executive director of biostatistics at Novartis, "We are hopeful that what will come out of the pandemic response — in addition to new treatments and vaccines — is a set of best practices for greater efficiency and transparency for sharing data in the future."

This example and others illuminate the rapid shift from competitive data-sheltering to collaborative data sharing in the life-sciences industry. Biopharmaceutical leaders are embracing the notion and benefits of transparency and data sharing to earn stakeholder trust. And given the broader digitization shifts in healthcare, R&D collaborations will continue as a necessary evolution for drug development sustainability and business resiliency in a digital world.

NeoGenomics and Elevation Oncology Focus on Patient Matching

MARK MALLON
CEO
NeoGenomics Inc.

NeoGenomics has been keenly focused on partnering with biopharma companies to help speed the development of promising medicines. A key area of ours has been in patient selection in support of clinical trials and, in particular, using our expertise in genetic testing services and ability to identify hard-to-find patients with low-prevalence biomarkers.

Our recent collaboration with Elevation Oncology is based on a shared goal of matching cancer patients to clinical trials and therapies that are precisely targeted to the unique tumor types and genomic biomarkers of patients. Specifically, we are partnering with Elevation Oncology to expand genomic testing for NRG1 fusions across solid tumors in support of the company's Crestone study, a Phase II tumor-agnostic trial of anti-HER3 mAb seribantumab in this targeted patient population. Though rare, gene fusions are a proven target for precision oncology therapeutics, with over a dozen FDA-approved therapies now available for hematologic and solid tumors driven by gene fusions.

RNA-based sequencing is the most sensitive detection method for structural variants that span large intronic regions, such as those leading to NRG1 fusions, and which may not be detectable by most DNA-based sequencing techniques. Accurate and widespread identification of gene fusions is critical to ensure patients can be matched to the growing number of approved and investigational precision therapies for these key oncogenic drivers.

In the areas of therapy adoption and precision medicine, we have been pleased to work with pharma companies on sponsored testing programs. Just recently, we announced the launch of such a program with Amgen. As part of Amgen's Biomarker Assist KRAS Gene Testing Program, Amgen will sponsor testing for the KRAS G12C biomarker for patients suffering from advanced or metastatic (stage IV) non-small cell lung cancer (NSCLC) through NeoGenomics. Biomarkers such as KRAS G12C increasingly serve as a critical tool to identify the personalized treatment strategy for cancer patients. This program leverages our experience and expertise in biomarker testing, with Amgen funding the total costs of the tests, regardless of the patient's insurance coverage.

Cross-industry collaborations can help unlock significant efficiencies in the development and delivery of both diagnostics and targeted therapeutics. More importantly, they can pave the way for more patients living with cancer to have the access and opportunity to be treated with cutting-edge approaches to precision medicine. I expect the pace and scope of these collaborations to grow as companies continue to find novel ways to leverage the strengths of industry members in their R&D efforts.

The COVID-19 pandemic has negatively impacted diagnostic workups across hospitals and health centers and slowed the pace of clinical trial enrollment, to the point where some trial recruitment stopped completely. If there is a silver lining to the myriad challenges brought on by the pandemic, it is that companies across the life-sciences ecosystem have found new ways to collaborate and leverage the strengths of their partners in ways that can improve the treatment of cancer patients in the future.

Ogilvy Health, the Mayor's Office of Community Mental Health, the NYC Department of Education, the NYC Health Department, and The Jed Foundation Center on Mental Health

KATE CRONIN
Global CEO
Ogilvy Health

In May, Ogilvy Health, in partnership with the Mayor's Office of Community Mental Health, the NYC Department of Education, the NYC Health Department, and The Jed Foundation, launched the Let's Talk NYC campaign to support the mental health of high school students citywide.

Ogilvy Health became involved with this initiative through its long-standing relationship with The Jed Foundation, an organization that protects emotional health and prevents suicide for our nation's teens and young adults. For years, Ogilvy Health employees have volunteered their time and services with the nonprofit through the agency's Annual Community Outreach Day, while others have continued working with the group independently.

Long before COVID-19 hit the United States, The Jed Foundation, along with the NYC Health Department, approached Ogilvy Health asking for help to address a concern

they were hearing from NYC youth. They shared that their peers didn't know what to expect when they were urged to talk openly about their mental health with school staff and, therefore, often didn't take advantage of the resources available. The result: a student awareness campaign to encourage high school students citywide to reach out to trained, trusted adults in their school communities to talk about mental health and get support when needed. In preparation for the 2021-2022 school year, the city will offer widespread training to teachers and school staff to help equip them for mental health conversations with students. The training will provide tips for understanding student needs, connecting students to appropriate services and resources, navigating the referral process, and remind teachers of the importance of taking care of their own mental health, as well.

The Ogilvy Health team spearheaded the development of many of the campaign components from inception to the May launch, which coincided with Mental Health Awareness Month. The agency held insightful focus groups with a cohort of passionate students to ensure that the proposed concepts and school staff trainings would address their concerns and resonate well with other teens. Originally the campaign was focused primarily on reaching the students and teacher populations within the school building environment. However, due to the pandemic, the team had to swiftly pivot the execution to comprise a more hybrid and digital approach.

Ogilvy Health helped drive awareness by creating posters, one-pagers, social media graphics, flyers, teacher lanyards, and electronic badges to help both remote and in-person students identify trained staff members, while helping foster an atmosphere to empower students to take charge of their own mental health and seek help when needed. The agency also created a student-facing guide that addresses potential uncertainties students may have about confiding in trained school staff. This is available on the Let's Talk NYC website.

"With all the added pressures on our students during this last year or so, there has never been a more important time to find ways to help normalize the idea that reaching out for help is okay," says Kate Cronin, global CEO, Ogilvy Health. "This initiative offers important resources to students who might not otherwise have access to them. We're so pleased we could play a part in such a meaningful, and potentially life-changing, effort."

Jacqueline Vidal, an account executive at Ogilvy Health who was deeply immersed in the campaign development, shared "Every young person deserves to have the security of knowing that they don't need to deal with their mental health struggles alone. This relatable campaign hopes to remind students of the positive solutions to all of the 'What-ifs' in their minds that might be stopping them from getting the help they need and pursuing the dreams and potential they're made for."

As students return to school in the fall, whether in the school building full-time, virtually, or via a hybrid model, staff will be ready to help students navigate the "new normal" of the school year and provide them with access to the mental health support they need, in a safe and trusted environment. Mental health awareness has arguably never been more important, and the team at Ogilvy Health is honored to have worked on this timely campaign to prioritize the importance of high school students' mental health needs. The group eagerly looks forward to participating in the broad rollout of this important initiative in Fall 2021. PV