Expanded precision medicine capabilities for strengthening oncology drug development at Daiichi Sankyo

By **Masato Murakami,[1] Taro Tokui,[2] Kenji Nakamaru,[3] John Cogswell,[1] Shirin Khambata Ford,[1] and Gilles Gallant[1]**

Affiliation: 1. Daiichi Sankyo Inc., Basking Ridge, NJ, USA; 2. Daiichi Sankyo RD Novare, Tokyo, Japan; 3. Daiichi Sankyo, Tokyo, Japan.

Introduction to Daiichi Sankyo's next generation antibody drug conjugates (ADCs)

Daiichi Sankyo (DS) has significantly expanded its biomarker development and translational research capabilities and selectively invested to transform itself into a global pharma innovator with a competitive advantage in oncology. Over the past several decades, DS had focused on the development and commercialization of cardiovascular, metabolic, and infectious disease area therapeutics in the primary healthcare setting. In 2016, DS decided to make a major transformation in their focus to realize the full potential of their in-house pipeline and product portfolio and to continue to improve the lives of patients globally. Taking advantage of the strength of the company's pipeline, DS is now dedicated to developing current and next-generation antibody drug conjugates (ADCs), as well as other novel anticancer therapeutics, and therapeutics for non-oncology specialty medicines.

Each ADC is engineered using DS's proprietary and portable exatecan derivative (DXd) ADC technology which targets and then delivers a chemotherapeutic payload inside cancer cells that express a specific cell surface antigen (**Figure 1**). DXd ADCs consist of a monoclonal antibody attached by a stable tetrapeptide-based linker to a topoisomerase I inhibitor payload. The key characteristics of all DXd ADCs are: (1) a payload mechanism of action (topoisomerase I inhibitor); (2) a high potency of payload; (3) an optimized drug-to-antibody ratio; (4) a payload with short systemic half-life; (5) a stable linker-payload; (6) a tumor-selective cleavable linker; and (7) a bystander antitumor effect.

Current ADC Portfolio

The DXd ADC portfolio at DS has grown from a single ADC in 2016 to seven ADCs in 2021, six of which are currently in clinical development in multiple types of cancer (**Table 1**). This portfolio includes trastuzumab deruxtecan (T-DXd), a human epidermal growth factor receptor 2 (HER2) targeted ADC currently approved for patients with HER2 positive metastatic breast cancer who have two or more prior anti-HER2 regimens, or with HER2 positive unresectable advanced or recurrent gastric cancer who have progressed after chemotherapy. T-DXd is also in development for non-small cell lung cancer (NSCLC), colorectal cancer (CRC) and other cancer types. DS-1062,

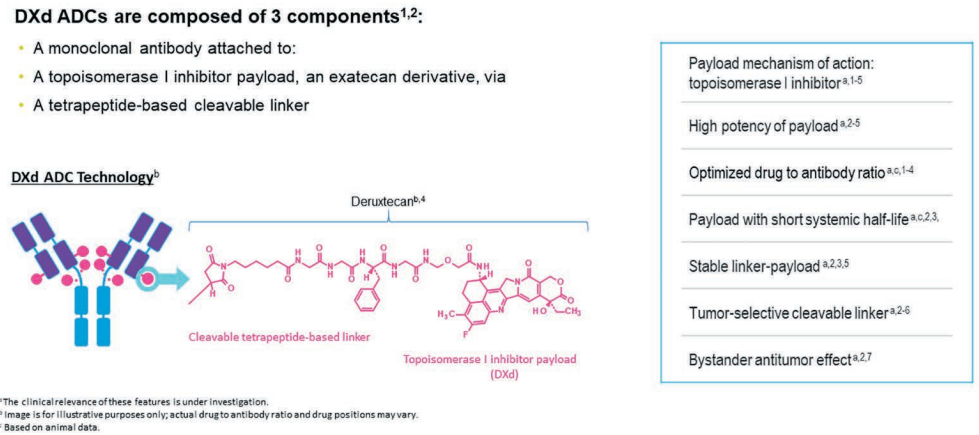


Figure 1: Key Attributes of DXd ADCs. Abbreviations: ADC, antibody-drug conjugate; DXd, exatecan derivative.

a trophoblast antigen 2 (TROP2) directed DXd ADC, is being evaluated in patients with advanced/unresectable or metastatic triple negative breast cancer following encouraging preliminary results for DS-1062 in patients with advanced NSCLC. Patritumab deruxtecan (U3-1402), a human epidermal growth factor receptor 3 (HER3) directed DXd ADC is being evaluated in patients with advanced breast cancer, epidermal growth factor receptor (EGFR) mutant NSCLC, and metastatic CRC.

Translational research approaches

Within DS, translational research serves as the bridge between research and clinical development. DS has both the strategic vision and the required resources to translate basic scientific/medical research into assays, treatments, and practices that maximize therapeutic benefit for the patients.

Strategy components

The overarching goal of translational research at DS is to inform clinical development strategies that enable data-driven clinical decision-making for oncology drug development. DS executes its three-prong translational research *strategy* by 1) conducting data-driven, smart, and rational development, 2) identifying patients who are likely to derive optimal therapeutic benefit from the drug at the right doses, and 3) practicing open innovation to conduct translational research utilizing external collaborations.

Execution components

The four key components of the translational research *approach* at DS are: (1) a biomarker and translational research strategy that is created in alignment with research and clinical development; (2) biosample collection and management; (3) assay selection, validation, and data generation; and (4) data analyses

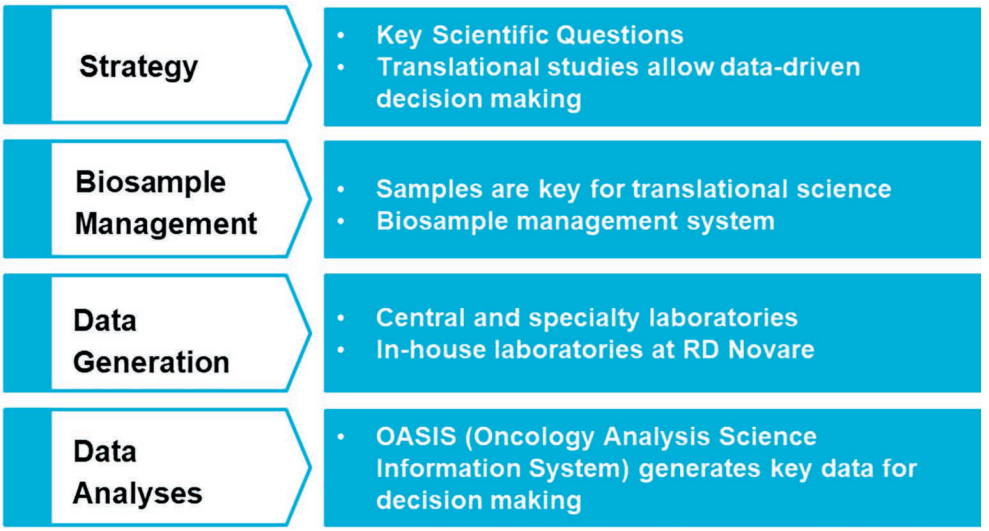


Figure 2: Overview of the translational research approach at Daiichi Sankyo.

(**Figure 2**). The following sections describe these components in more detail.

Biomarker and translational research strategy

Key scientific questions

Figure 3 provides an overview of the development of a translational research plan at DS. The plan starts with development of a deep understanding of the target molecular biology. A target product profile is then created that outlines the necessary characteristics required for drug development, and the potential diseases and indications that will be pursued.

Once the target product profile is in place, the key scientific questions are developed, and a translational research strategy is created. In the case of ADCs, key scientific questions could include: (1) What are the biomarkers that can select patients who derive therapeutic benefit? (2) What is the mechanism of action (MOA)? (3) What is the mechanism of resistance (MOR)? and (4) What are the rational drug combinations? Biomarker and translational research to address the above questions is conducted in a timely way such that the data can inform the therapeutic development strategy.

The translational research plans are monitored on an ongoing basis to determine how much value is added with each of the key activities and approaches, as well as budget and resources. As each ADC has the same therapeutic modality, it is also important to have a synergistic cross-ADC strategy and to consider how the work from one ADC program can inform and impact the development strategy for other ADC programs.

Translational expansion: forward and reverse translational research

In the conventional bench to bedside model of translational research, also known as forward translational research, the path starts with pre-clinical research and ends with clinical trials, while reverse translation moves in the opposite direction. For example, a drug may demonstrate greater antitumor activity in some patients than in others. By assessing the clinical and biomarker data from the clinical trials, hypotheses can be generated and taken to the bench for functional confirmation. The reverse translation approach can help to support the expansion to other indications and the possibility of new combinations of therapeutics, e.g., drug combinations with other MOAs to improve clinical efficacy. The biomarker-driven approach at DS drives the translational research cycle, which increases the probability of success and maximizes drug value. At DS, the clinical trial, forward and reverse translational research, and biomarker data are used to directly inform new discoveries.

Table 1: DXd-ADC Pipeline

ADC	Target Pathway	Tumor Type	Stage
DS-8201 (Trastuzumab Deruxtecan)	HER2	Breast, Gastric, NSCLC, CRC	Clinical
DS-1062	TROP2	NSCLC, Breast	
U3-1402	HER3	Breast, NSCLC, CRC	
DS-7300	B7-H3	Solid Tumor	
DS-6157	GPR20	GIST	
DS-6000	CDH6	Renal, Ovarian	
DS-3939	TA-MUC1	Solid Tumor	Pre-clinical

ADC, antibody drug conjugate; CDH6, cadherin-6; CRC, colorectal cancer; GIST, gastrointestinal stromal tumor; GPR20, G Protein-Coupled Receptor 20; HER2, human epidermal growth factor receptor 2; HER3, human epidermal growth factor receptor 3; NSCLC, non-small cell lung cancer; TA-MUC1, tumor-associated MUC1 epitope; TROP2, trophoblast antigen 2.

Biosample collection and management

Biosample collection begins with informed consent where trial participants are informed about the trial, including sample collection, data, and privacy protections. Important aspects to consider for the generation of high quality data are the sample custody chain, including the appropriate collection of the specimen, labelling of the sample, storage, shipping, and the tracking methods. The logistics of sample collection, custody tracking, and data management are complex and involve multiple, skilled stakeholders, including those at the clinical site, the person(s) collecting the tissue or blood sample, and shipping company personnel.

DS utilizes a validated cloud-based global biosample management system called GlobalCODE® (by Global Specimen Solutions, Covance) to appropriately track samples and their associated informed consent forms, and to comply with global laws and regulations. This management system feeds into the state-of-the-art internal downstream data analysis platform named the Oncology Analysis Scientific Information System (OASIS) (described in detail below and **Figure 6**) and allows the company to maximize translational research opportunities while maintaining regulatory compliance.

Figure 4 illustrates biosample workflow activities, starting with sample collection at the clinical site followed by shipping to a central laboratory. Samples may be shipped between the analytical laboratories and storage vendor, depending on the study involved, specific testing requirements and qualification of the sample. The analytical laboratories include both internal laboratories (e.g., Daiichi Sankyo RD Novare) and external laboratories (e.g., contract research organizations and specialty laboratories).

Assay development and selection

Biomarkers of interest initially identified as part of the translational research plan at DS consider both the target biology, disease context, and the stage of clinical development. Biomarkers are then classified by their value to clinical decision-making (MOA, pharmacodynamic, patient selection, or stratification) for efficacy and safety. Where decisional candidate biomarkers are unknown, biomarker discovery may be initiated through high-content discovery platforms.

Some biomarkers may consist of multiple analytes (DNA, RNA, protein, metabolite) or can be specific to a modification only occurring on a single analyte (e.g., mutation, post-translational protein modification). Early method development may involve testing multiple biomarkers, analytes, and detection methods to select the optimal biomarker(s) and analyte(s). The type of specimen (tissue, liquid biopsy) best suited for the reliable measurement of the analyte is further considered in context of the ease of collection and the least burden to patients. Where possible, existing biomarker tests are identified along with the laboratories that can perform them. Clinical biomarker scientists at DS review performance measures on the optimal analyte in diseases selected based on biomarker prevalence and clinical development interest. If the review identifies gaps in performance measures, further validation tests are designed and tested.

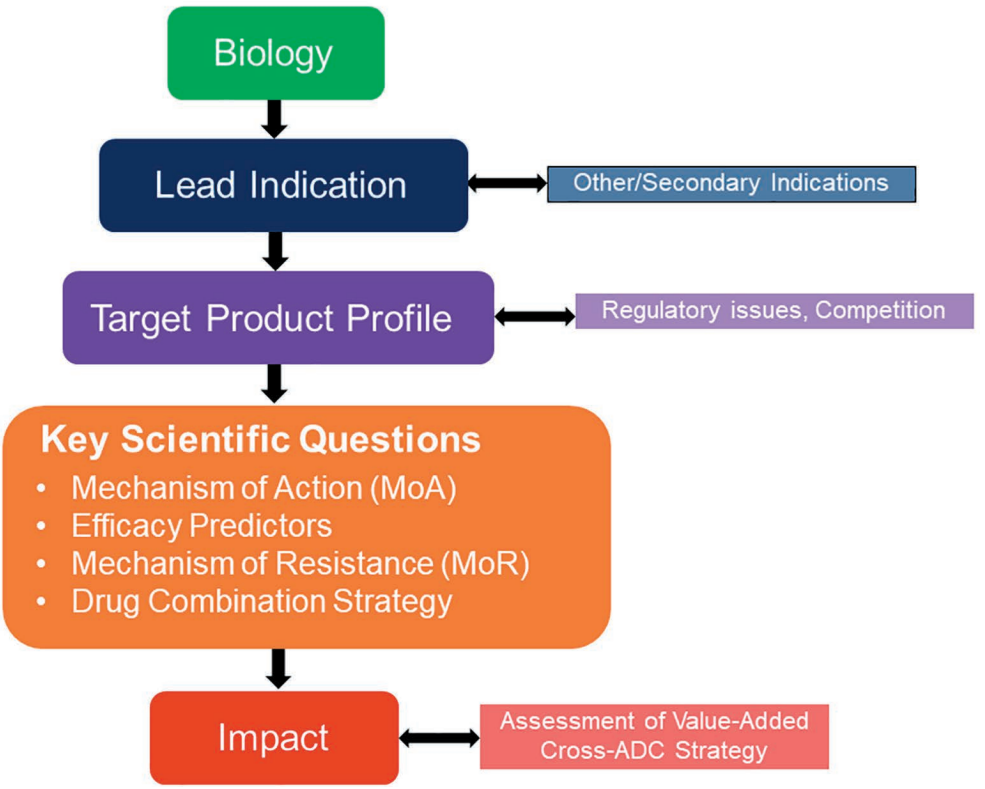


Figure 3: Development of a translational research plan at Daiichi Sankyo.
Abbreviation: ADC, antibody-drug conjugate.

Where biomarker tests do not exist, prototypes are often developed within DS internal laboratories before transfer to clinical trial sample analysis locations such as external partner laboratories chosen based on their operational capability and their experience with the technology and test method. If the biomarker has potential as a patient selection biomarker, development of the assay at DS and the selection of an external partner is aligned to the downstream diagnostic development path where possible. The biomarker test fitness for clinical sample analysis may be verified during assay development through assessments of specificity, sensitivity, accuracy, and precision with the level of the biomarker test fitness depending on type of biomarkers, assay platforms, and context of use.

Critical performance measures may be repeated after transfer of the assay to ensure the analysis laboratory can match expected measures on chosen method using method-specific intrinsic controls or extrinsic controls developed during test method development. Finally, assays validated initially at one partner location may need to be transferred into other geographical hubs through qualification tests if the analyte has a short stability, or where distributing those tests brings the time from sample collection to biomarker results within optimal timelines for patient enrollment.

An analytically validated test is necessary to establish clinical validity to determine whether the test's performance predicts a clinical outcome of interest. If the test is already an approved diagnostic test it may be used to enrich patients such that only biomarker positive patients above a pre-specified cutoff are enrolled. A stratified design, where all patients independent of their biomarker results are enrolled and randomized to treatment and control groups, can be used to ensure balance between biomarker positive and negative groups especially if the biomarker has low prevalence or its value needs to be evaluated independent of the clinical efficacy.

Data generation platforms

As discussed in the previous section, DS uses external partner laboratories for biomarker analyses in clinical samples. Recently DS has also upgraded their internal capabilities and can additionally use their in-house laboratories at RD Novare for biomarker analyses in clinical samples. The mission of the RD Novare clinical research laboratory is to implement cutting-edge technologies in molecular pathology, genomics, proteomics, and cell biology in their clinical trials and collaborations. Having internal laboratory capabilities increases flexibility and can accelerate study timelines and decision-making. **Figure 5** provides an overview of analytical capabilities of the DS RD Novare research laboratory.

High quality data can be generated from miniscule amounts of specimen using high content analysis methods. This can be critical when dealing with precious samples. For example, multiplex immunohistochemistry technology allows efficient use of precious samples by co-localization of up to six markers. Next-generation sequencing optimized for small sample inputs has enabled a revolution in the scale of results for reverse translation.

The DS RD Novare laboratory has a high capacity, fast, and secure data storage infrastructure, leading-edge computational capabilities, and has implemented a laboratory information management system for sample and process tracking. Further expansion of the laboratory is ongoing with more automation and higher throughput because of the greater analyses needs.

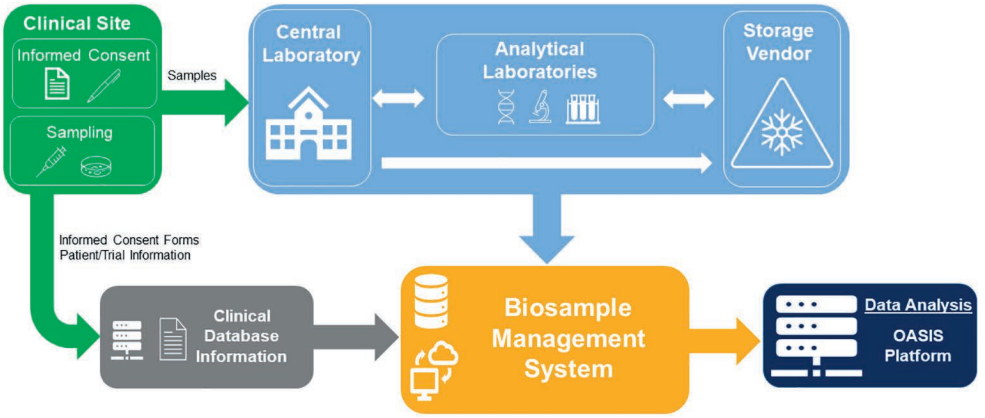


Figure 4: Biosample workflow and management system.
Abbreviation: OASIS, Oncology Analysis Scientific Information System.

Data analytical platforms

For success in oncology drug development, DS focuses on combining biological findings, genomics, proteomics, metabolomics, biomarker imaging, and publicly available or proprietary real-world data from databases. To that end, DS has instituted a broad program to leverage its research and clinical data to gain insights into disease targets, drug candidates, and biomarker candidates. To support this new approach, the company is leveraging OASIS; **Figure 6** provides a high-level overview of the OASIS platform.

OASIS is a global, extendable, clinical/multi-omics/real-world data platform that supports the deep analytics needed to develop oncology precision medicine at DS. We configured the OASIS to integrate and analyze structurally diverse types of internal and external data. Internal data include trial data from clinical trial databases, laboratory data from DS RD Novare and specialty laboratories, gene alteration and expression data, cytogenetics data, and epigenomics data. External data or real-world data includes family history, response to therapy, treatment details, publicly available data, and data from collaborations. A key objective for analyzing these multiple data types is to facilitate analyses that may span trials and indications to generate insights into mechanisms of disease, drug action, and drug resistance.

A primary objective of the OASIS program is to rapidly integrate a large number of high-volume, independent datasets in accordance with established standard operating procedures and data governance oversight. To accomplish this efficiently, DS has developed an orchestration process to coordinate the activities of data managers and bioinformaticians as datasets are processed through the analytic pipeline. This process allows for editing/cleaning, integrating, and standardizing analytics-grade clinical and omics data from diverse sources; supports compliance with data governance decisions; and enables managers to address issues and delays in real-time.

To maintain the OASIS platform, new and existing capabilities have been deployed and updated globally, including: (1) security and compliance (e.g., enforcing authorized user access to data, data classification and protection, immutable audit trails to monitor appropriate use, security hardened systems, and cloud services to mitigate internal and external cyber threats); (2) cloud infrastructure; (3) data governance (to control who obtains access to what data, and for what purpose); (4) service management (e.g., user access management, issue or incident resolution, change management); and (5) quality management (e.g., quality policy enforcement, training effectiveness, root cause analysis, corrective and preventive action plans).

A recent example of valuable data generated by OASIS is a subgroup analysis of the DESTINY-Breast01 trial, a phase 2 trial of T-DXd in metastatic breast cancer. In this subgroup analysis, data were examined for clinical and molecular variables predictive of patient outcomes.[8] T-DXd treatment was associated with clinically significant objective response rate (ORR) and durable responses across pre-specified patient

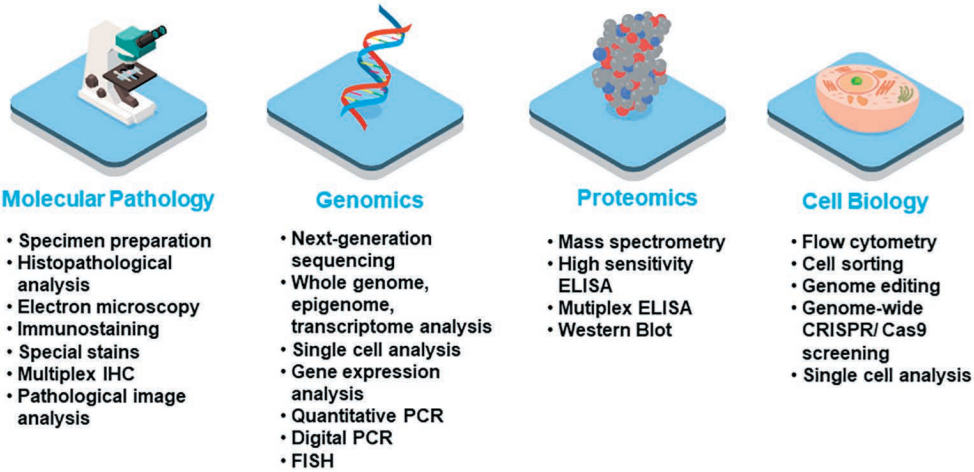


Figure 5: Analytical capabilities at Daiichi Sankyo RD Novare. Abbreviations: Cas9, CRISPR associated protein 9: CRISPR, clusters of regularly interspaced short palindromic repeats; ELISA, enzyme-linked immunosorbent assay; FISH, fluorescent *in situ* hybridization; IHC, immunohistochemistry; PCR, polymerase chain reaction.

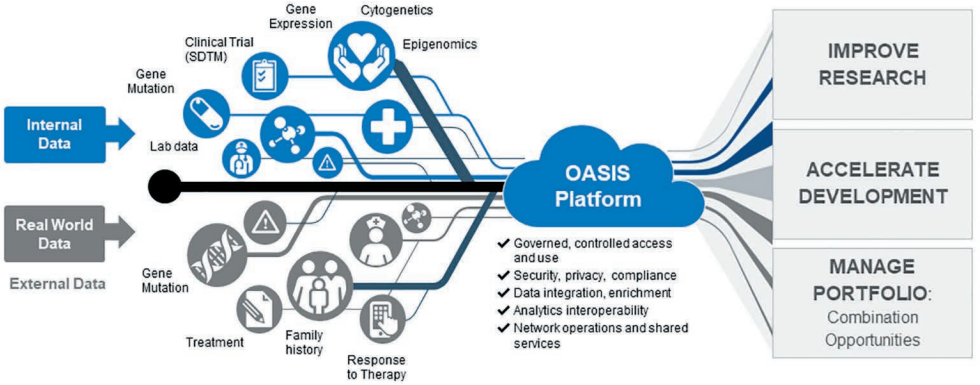


Figure 6: Overview of the Oncology Analysis Scientific Information System (OASIS). Abbreviations: SDTM, study data tabulation model.

subgroups. Variables associated with improved ORR, duration of response, or median progression-free survival included hormone receptor positive status, pertuzumab given in the first- or second-line, fewer prior treatment regimens, and normal renal and hepatic function. A decrease of ERBB2 copy number in circulating tumor DNA (ctDNA) was seen with treatment and correlated with clinical response. These data provide important insights into the factors associated with improved clinical benefit, and identification potential biomarkers of response to treatment in these patients.

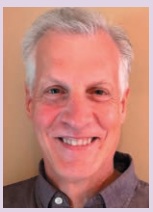
Companion diagnostics

Companion diagnostics (CDx) play a critical role in identifying patients who are either likely to benefit, or not benefit, from a treatment. CDx may also be used to monitor response to a treatment and are a requirement for some therapeutic products to meet their labeled safety and effectiveness claims. CDx and other biomarkers may also be used to exclude patients or clinical trial subjects who may not benefit from the therapy or may suffer an adverse event. At DS, CDx are used extensively to identify patients with the best chance of deriving benefit from treatments. For ADCs, patient selection assays that are based on tumor expression of targets have been found to have the greatest potential value in early clinical trials.

The decision to develop CDx that can select patients for treatment typically occurs during, or at the end of, the phase 1 study. Development of further CDx for patient selection that use markers other than tumor expression of targets or known genomic alterations typically occurs as the translational data emerges from late-stage clinical trials. The design of CDx strategies for assays used in early-stage clinical trials is influenced by several factors, such as the prevalence of the potential patient selection biomarker, the dynamic range of target expression in a particular tumor type, and the heterogeneity and other characteristics of the biomarker. At these early stages, the goal is to generate data for assay assessment; hence, the company does not invest in full development of CDx assays (selected biomarkers plus protocol) but uses prototype assays instead. In the selection of the diagnostic partner company and relevant platform and assay, multiple factors are carefully evaluated including the ability for the test to be approved as a CDx by different health authorities globally. Also of importance is to select an assay that can be deployed globally and that is affordable and can get adequate reimbursement from payer bodies.

Once a decision has been made to use CDx to identify patients suitable for a given treatment, DS oversees the development of an "investigational use only" assay in collaboration with a diagnostic partner company. In order to validate the clinical utility of the assay, large clinical trials are used to confirm that the assay is correctly implemented and can accurately identify patients who will benefit, or should be excluded, from treatment.

DS has established strategic collaborations with numerous diagnostic partner companies, including



John Cogswell, PhD

John joined Daiichi Sankyo Inc. in 2018 and became the U.S. Head of Clinical Biomarkers responsible for the development, transfer, and validation of biomarker assays for clinical sample analysis for oncology clinical development. Dr. Cogswell oversees a group of technology experts who select biomarker assays and vendors and create sample and lab workflows closely coordinated with global development functions to deliver decisional biomarker results from exploratory and companion diagnostic assays. Prior to Daiichi Sankyo Inc, he directed biomarker assay assay development teams at Bristol Myers Squibb and GlaxoSmithKline. At Bristol-Meyers Squibb, Dr. Cogswell led development and validation of their PD-L1 antibody from discovery through approval of the PD-L1 IHC 28-8 PharmDx as a complementary diagnostic. His career spans drug and biomarker discovery through cutting-edge technology applications in genetics, genomics, functional genomics, immunohistochemistry, and digital pathology. He received his Ph.D. in immunology from Duke University (USA).

Kenji Nakamaru, PhD

Kenji is Vice President and Head of the Translational Science Department at Daiichi Sankyo Co., Ltd. in Tokyo, Japan. Dr. Nakamaru started his career in genetic research in 2000, working to identify new drug targets in legacy Sankyo, and experienced the early days of translational research by combining patient genetics, disease, and laboratory biology. He later joined the Translational Medicine and Clinical Pharmacology function at Daiichi Sankyo. There, he established biomarker research and development activities in the company which led to the current Translational Science and Precision Medicine functions at Daiichi Sankyo. Together with Dr. Murakami, he built the Biomarker and Translational Research department and took responsibility for overseeing translational research, molecular pathology, clinical biomarker analysis, and bioinformatics in Japan. He succeeded Dr. Murakami as head of the Biomarker and Translational Research department after Dr. Murakami's transition to the chair of the Precision Medicine Committee. Prior to joining Sankyo he worked to develop a virus vector based on simian immunodeficiency virus, and received a PhD in medicine from the University of Tsukuba, Japan.

Taro Tokui, PhD

Taro is President and Chief Executive Officer at Daiichi Sankyo RD Novare Co., Ltd. (Japan), which serves as an advanced drug discovery platform consisting of cutting-edge drug discovery technology and high-quality clinical development. He joined Sankyo Co. Ltd. (Japan) in 1986 after receiving a master's degree in pharmacy from Kyoto University (Japan). He received a PhD in pharmacy from Kyoto University in 1995. He was then sent by Sankyo to the Renal Division of the Brigham Women's Hospital, Harvard University (USA) as a visiting scientist from 1995 to 1997. At Sankyo, he was responsible for pharmacokinetics research for the development of compounds including Pravastatin, Troglitazone, and Olmesartan. When Daiichi Pharmaceutical Co., Ltd. (Japan) and Sankyo Co., Ltd. merged in 2007, he was assigned to oversee the clinical pharmacology group at Daiichi Sankyo Pharma Development (USA). In 2012, he was appointed Vice President of Translational Medicine and Clinical Pharmacology at Daiichi Sankyo and, as a member of the global strategy team, he was involved in development of the drugs Lixiana and Enhertu. In 2017, he joined Daiichi Sankyo RD Novare as Board Member in charge of Translational Research and has served in his current position since 2019.

those with capabilities in immunohistochemistry and *in situ* hybridization (e.g., Roche Tissue Diagnostics), and next-generation sequencing (e.g., Thermo Fisher Scientific). The Company's first approval of CDx in Japan was Invivoscribe's LeukoStrat FLT3 mutation assay for DS's quirzartinib (Vanflyta) for the treatment of relapsed/refractory FLT3-ITD acute myeloid leukemia.

At DS, consideration is routinely given to the CDx and diagnostic partnerships that are needed to achieve approval of new treatments, and plans are implemented at early stages to ensure that CDx development strategies and timelines align with drug development strategies and timelines.

New directions

A major initiative at DS is to expand the translational medicine platform (including for ADCs) using cutting-edge science and technologies. Expansion of the translational medicine platform, along with systematic and integrated approaches, are keys to accelerating research and development, and to increasing the probability of success. The multiplex data assessment platform OASIS is being expanded to facilitate multifaceted and deeper profiling of drug and disease in humans, and to validate and create new targets. Emerging technologies will be implemented, and disease models will be expanded to enhance research capability and tackle new modalities.

Digital transformation in informatics is a key driver in translational research and development and has evolved significantly in recent years. "Big data" and artificial intelligence will be used to generate hypotheses and gain novel insights into causal relationships and underlying mechanisms. Together, these advances and expansions will help to facilitate world-class precision medicine and maximize and differentiate DS medicines for patients. JoPM

Masato Murakami, MD PhD MBA

Masato is Vice President and Global Precision Medicine Committee Chair of Daiichi Sankyo, Inc. in Basking Ridge, NJ, USA. Dr. Murakami's professional experience spans basic research to translational clinical research and drug development, specializing in clinical pathology, molecular biology, translational medicine, and drug discovery and development. At Daiichi Sankyo Co. Ltd. Oncology R&D function in Tokyo, Japan, he built the Daiichi Sankyo Biomarker and Translational Research department to strengthen translational capabilities in support of the Daiichi Sankyo Oncology transformation. This department plays a central role in science-driven decision-making in drug development and the Global Precision Medicine Committee. Prior to joining Daiichi Sankyo Co. Ltd. in 2016, Dr. Murakami was Head of the Molecular Pathology Department, Oncology Disease area, Novartis Institutes for Biomedical Research, Basel, Switzerland. Dr. Murakami received an MD from Tokai University School of Medicine (Japan), a PhD in molecular biology from the University of Tokyo, and an MBA from La Salle University (USA). He completed post-doctoral fellowships in vascular biology at IFOM, Milan, Italy, and the University of Tokyo. He received several company awards and scientific society awards including the Werner Risau Award in Arteriosclerosis, Thrombosis, and Vascular Biology from the American Heart Association.

Shirin Khambata Ford, PhD

Shirin has been Head of Clinical Biomarkers and Companion Diagnostics at Daiichi Sankyo since 2019, leading two groups responsible for the implementation of clinical biomarkers and the end-to-end strategic oversight for companion diagnostics development and regulatory approvals. Prior to this she was the Global Head of Biomarkers and Diagnostics in Oncology Global Medical Affairs at Merck and led a team that was responsible for leading activities to support biomarker testing for Keytruda and all oncology assets pre-, during, and post-launch in 80 countries globally. Dr. Khambata Ford also previously served as Global Head of Correlative Sciences, Oncology Global Development, Novartis. She led a group focused on clinical biomarker development and translational research for twenty full development programs. Prior to this she was a Senior Biomarker Experimental Medicine Leader at Roche where she led biomarker work for early development oncology programs. She was previously Director of Oncology Biomarkers at Bristol Myers Squibb where she led a group responsible for the discovery, validation, and implementation of clinical biomarkers for the late stage portfolio. Her key accomplishments include being the lead researcher on the team that discovered that EGFR ligand expression and KRas mutation status are predictive of benefit from cetuximab in metastatic colorectal cancer. This resulted in a seminal publication in the Journal of Clinical Oncology. Her research has led to numerous publications in journals such as the New England Journal of Medicine, Journal of Clinical Oncology, and the British Journal of Cancer, over 50 presentations at oncology conferences (American Society of Clinical Oncology, American Association for Cancer Research, European Society for Medical Oncology), and three patents. Dr. Khambata Ford obtained a PhD in genetics from Rutgers University, NJ, USA and completed her post-doctoral training at Stanford University School of Medicine, CA, USA.

Gilles J. A. Gallant, BPharm PhD FOPQ

Gilles is an oncology expert with broad biotechnology and pharmaceutical experience in strategic cancer drug development, evaluation, and innovations. He joined Daiichi Sankyo, Inc. (Basking Ridge, New Jersey) in 2017 as Vice President, Global Team Leader, Oncology R&D. Daiichi Sankyo Cancer Enterprise's mission is to leverage world-class, innovative science and push beyond traditional thinking to create meaningful treatments for patients with cancer. He is now leading the global development of all Daiichi Sankyo oncology assets. Prior to joining Daiichi Sankyo, he designed and directed global registrational and non-registrational clinical trials of Bristol-Myers Squibb oncology pipeline resulting in the worldwide approval of three indications (lung cancer [NSCLC], breast cancer, and ovarian cancer) for the blockbuster Taxol. As Vice President of Clinical Oncology, he has led the development strategy and clinical implementation for all oncology and hematology assets at Human Genome Sciences (HGSI) and later at BioMarin Pharmaceutical (BMRN) leading to the approval of Talzenna. At Daiichi Sankyo, he has led the development and global approval of Enhertu for patients with advanced breast and gastric cancer. Gilles has guided oncology, hematology, and immunology in- and out-licensing activities leading the in-licensing of two oncology drug candidates, the GlaxoSmithKline acquisition of HGS and the acquisition of talazoparib by Medivation. Dr. Gallant received his doctorate in medicinal chemistry and bachelor's degree in pharmacy from the Université de Montréal in Montréal (Québec) Canada. He is an emeritus graduate of Collège André-Grasset, Montréal (Québec) Canada. He has been named Fellow of the Ordre des Pharmaciens du Québec (FOPQ) for his impressive international career in oncology research and for the impact he has had on the life of thousands of patients by developing new oncology drugs. He has co-authored numerous scientific abstracts and peer-reviewed publications in the oncology research field.

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