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Daiichi-Sankyo

Press Release

Daiichi Sankyo and DarwinHealth Announce Strategic Partnership to Deploy a Quantitative Systems Biology Discovery Platform to Prioritize Daiichi Sankyo Cancer Enterprise Compounds for Development

Tokyo, Japan, Parsippany, NJ, and New York, NY – (December 12, 2016) – Daiichi Sankyo Company, Limited (hereafter, Daiichi Sankyo) and DarwinHealth today announced a strategic partnership to use quantitative systems biology-based algorithms and novel, validated approaches focused on tumor checkpoints -- a new class of cancer targets -- to help prioritize investigational compounds in the Daiichi Sankyo Cancer Enterprise pipeline for clinical development.

Utilizing DarwinHealth's proprietary, oncotecture-based technology, the vast majority of investigational compounds in the Daiichi Sankyo Cancer Enterprise portfolio will be evaluated and compared against an extensive repository of patient-derived tumor samples to measure their efficacy in disrupting the master regulator proteins that represent the most critical vulnerabilities of each specific tumor. These studies will provide a comprehensive readout of each compound's potential clinical value, including its genome-wide mechanism of action, its tumor-specific biomarkers of sensitivity and resistance, and its ability to synergize with other drugs for combination therapy applications. Through quantitative modeling, the developmental trajectory of each potential treatment will be predicted to help Daiichi Sankyo design more effective, successful and focused clinical studies to leverage key opportunities that are currently being missed or may not be identified using traditional methodologies.

"As we begin to see quantitative science revolutionize the approach to clinical development, we are very excited about entering into this partnership with DarwinHealth," said Igor Matushansky, MD, PhD, Global Head Oncology Translational Development, Daiichi Sankyo. "These insights will help us to focus on compounds with a higher likelihood of success to ultimately ensure the best treatment options are reaching patients with cancer sooner."

"Genetics has been the basis of the development of precision medicine, but even more targeted and integrative approaches are now needed to deal with the complexity of cancer," explained Dr. Andrea Califano, Clyde and Helen Wu Professor and Chair of Systems Biology at Columbia University and co-founder of DarwinHealth. "The evolution of cancer research has expanded our universe from gene mutations to the ultimate effects these genomic alterations have on protein activity. Virtual, computation-based methods have finally achieved the accuracy necessary to systematically detect aberrantly activated proteins representing the master regulators of a cancer cell. We have created sophisticated tools, such as

the VIPER algorithm, to identify tightly-knit modules of master regulator proteins – which we call tumor checkpoints – that represent a new class of actionable therapeutic targets in cancer."

About DarwinHealth

DarwinHealth: Precision Therapeutics for Cancer Medicine is a "frontiers of cancer," technology-focused company, co-founded by CEO Gideon Bosker, MD, and Professor Andrea Califano, PhD. The company's technology was developed by the Califano lab over the last 13 years and is exclusively licensed from Columbia University.

DarwinHealth utilizes proprietary, systems biology algorithms to match virtually every cancer patient with the drugs and drug combinations that are most likely to produce a successful treatment outcome. "Conversely, these same algorithms also can prioritize investigational drugs and compound combinations of unknown potential against a full spectrum of human malignancies," explained Dr. Bosker, "which make them invaluable for pharmaceutical companies seeking to optimize and repurpose their compound pipelines."

DarwinHealth's mission statement is to deploy novel technologies rooted in systems biology to improve clinical outcomes of cancer treatment. This is articulated along two complementary axes. First, DarwinHealth's technologies support the systematic identification and validation of drugable targets at a more foundational, deep state of the cancer cell's regulatory logic so we and our scientific partners can move to and exploit next generation actionability based on fundamental and more universal tumor dependencies and mechanisms. Second, from a therapeutic perspective, the same technologies capable of identifying such nodal points of attack also can accurately prioritize compounds and compound combinations capable of targeting them at the molecular level. This is where the oncotectural approach, with its emphasis on elucidating and targeting tumor checkpoints, provides its most important solutions and repositioning roadmaps for advancing precision-focused cancer drug discovery and therapeutics.

The unique, precision medicine-based methods employed by DarwinHealth are supported by hundreds of publications and are summarized in a *Nature Reviews Cancer* perspective that will be published in mid-December. These proprietary strategies leverage the ability to reverse-engineer and analyze the genome-wide regulatory and signaling logic of the cancer cell, by integrating data from *in silico*, *in vitro*, and *in vivo* assays. This provides a fully integrated drug characterization and discovery platform designed to elucidate, accelerate, and validate precise developmental trajectories for pharmaceutical assets, so their full clinical and commercial potential can be realized.

About Daiichi Sankyo Cancer Enterprise

The vision of Daiichi Sankyo Cancer Enterprise is to push beyond traditional thinking to align world-class science to create innovative treatments for patients with cancer. The oncology pipeline of Daiichi

Sankyo continues to grow and currently includes more than 20 small molecules, monoclonal antibodies and antibody drug conjugates with novel targets in both solid and hematological cancers. Compounds in development include: quizartinib, an oral FLT3 inhibitor, for newly-diagnosed and relapsed/refractory FLT3-ITD+ acute myeloid leukemia (AML); pexidartinib, an oral CSF-1R inhibitor, for tenosynovial giant cell tumor (TGCT), also known as pigmented villonodular synovitis (PVNS) and giant cell tumor of the tendon sheath (GCT-TS), which also is being investigated in combination with anti-PD1 immunotherapy, pembrolizumab, in a range of solid tumors; tivantinib, an oral MET inhibitor, for second-line treatment of patients with MET-high hepatocellular carcinoma in partnership with ArQule, Inc.; and DS-8201, a HER2 targeting antibody drug conjugate, for HER2-expressing breast or gastric cancer or other HER2-expressing solid tumors.

About Daiichi Sankyo

Daiichi Sankyo Group is dedicated to the creation and supply of innovative pharmaceutical products to address diversified, unmet medical needs of patients in both mature and emerging markets. With over 100 years of scientific expertise and a presence in more than 20 countries, Daiichi Sankyo and its 16,000 employees around the world draw upon a rich legacy of innovation and a robust pipeline of promising new medicines to help people. In addition to a strong portfolio of medicines for hypertension and thrombotic disorders, under the Group's 2025 Vision to become a "Global Pharma Innovator with a Competitive Advantage in Oncology," Daiichi Sankyo research and development is primarily focused on bringing forth novel therapies in oncology, including immuno-oncology, with additional focus on new horizon areas, such as pain management, neurodegenerative diseases, heart and kidney diseases, and other rare diseases. For more information, please visit: www.daiichisankyo.com. Daiichi Sankyo, Inc., headquartered in Parsippany, New Jersey, is a member of the Daiichi Sankyo Group. For more information on Daiichi Sankyo, Inc., please visit: www.dsi.com.

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