Cellworks Singula™ Delivers Superior OS and DFS Predictions for Brain Cancer Patients in myCare-022-03 Clinical Trial

*Personalized Therapy Biosimulation Using Multi-Omic Data Accurately Predicts Clinical Outcomes for GBM Patients*

SOUTH SAN FRANCISCO, Calif., June 4, 2021 – Cellworks Group, Inc., a world leader in Personalized Medicine in the key therapeutic areas of Oncology and Immunology, today announced results from the myCare-022-03 clinical trial, which demonstrate that the Cellworks Singula™ Therapy Response Index (TRI) is strongly predictive of Overall Survival (OS) and Disease-Free Survival (DFS) for Glioblastoma (GBM) patients. The study also validates that Singula™ TRI provides predictive value to physicians beyond standard clinical factors, such as patient age, patient gender and physician-prescribed treatment.

The results from the myCare-022-03 clinical study will be featured in a poster discussion session with comments from Dr. Manmeet Ahluwalia, M.D., M.B.A., Chief of Medical Oncology, Chief Scientific Officer and Deputy Director at Miami Cancer Institute, as part of the 2021 ASCO Annual Meeting June 4-8th during the Central Nervous System Tumors Track and available as online as Abstract 2017.

In contrast to approaches that consider a collection of single biomarkers, which often yield limited benefit, Cellworks utilizes an individual patient’s next generation sequencing (NGS) results and the Cellworks Computational Omics Biology Model (CBM) to biosimulate molecular effects of cell signaling, drugs, and radiation on patient-specific in silico diseased cells. For an individual patient and alternative therapy, Cellworks integrates this biologically modeled multi-omics information into a continuous Singula™ Therapy Response Index (TRI) Score, scaled from 0 (low therapeutic benefit) to 100 (high therapeutic benefit).

“Knowing the precise level of therapeutic benefit a GBM patient will receive from a specific drug prior to treatment is extremely useful, particularly when choosing between competing therapy options,” said Patrick Wen, MD, Director, Center for Neuro-oncology, Dana-Farber Cancer Institute; Professor, Neurology, Harvard Medical School; and Co-Principal Investigator for the myCare-022-03 clinical study. “This study demonstrates how using multi-omics data algorithms to biosimulate therapy responses for individual patients can positively effect clinical outcomes for brain cancer patients.”

“In order to address the inconsistency in therapy response rates and empower physicians to know before they treat, we need to move beyond the prevalent one-mutation, one-drug approach,” said Dr. Manmeet Ahluwalia, M.D., M.B.A., Chief of Medical Oncology, Chief Scientific Officer and Deputy Director at Miami Cancer Institute; and Co-Principal Investigator for the myCare-022-03 clinical study. “Cellworks therapy biosimulation provides key insights into patients’ mutanome, drug resistance pathways and novel biomarkers for drug response. This approach can improve patient outcomes, reduce healthcare costs and advance Personalized Oncology.”
myCare-022-03 Clinical Study

In this prospectively defined study, the ability to predict patient response using Cellworks Singula™ was evaluated in a retrospective cohort of 100 GMS patients treated with physician-prescribed treatments and with OS and DFS data from the Cancer Atlas (TCGA) project. Cellworks Singula™ used Pubmed to generate protein interaction network-activated and inactivated disease pathways. Cellworks simulated physician-prescribed treatments for each patient and calculated the quantitative drug effect on a composite GBM disease inhibition score based on biosimulated changes in phenotypes while blinded to clinical response.

As a primary analysis of the Cellworks CBM and TRI Score, Cox Proportional Hazards (PH) regression and likelihood ratio (LR) tests were used to assess whether Singula™ is predictive of OS and DFS above and beyond patient age, patient gender and Physician Prescribed Therapies. A p-value < 0.05 for the corresponding likelihood ratio statistic was required to be considered significant. Multivariate analyses were performed to assess the performance of the predefined CBM biosimulations and associated Singula™ TRI after adjusting for the contribution of standard clinical factors. The same Singula™ TRI algorithm and clinical cutoffs were used for all clinical outcome measures.

Multivariate Cox Proportional hazards models found Singula™ TRI was strongly predictive of OS and DFS, while providing predictive value beyond patient age, patient gender and Physician Prescribed Therapies. The resulting hazard ratio per 25 Singula™ units for OS was 0.7146 and for DFS was 0.7741. Additionally, Singula™ Low and High Benefit Groups were defined a-priori based on the median Singula™ TRI Score. The resulting Kaplan-Meier plots for OS and DFS stratified by the Singula™ High and Low Benefit Groups resulted in a logrank p-value < 0.0001 and presents a sizeable difference if predicted median overall and disease-free survival times.

The incorrect assumption that similarly diagnosed patients are basically the same has resulted in low therapy response rates for patients,” said Khush F. Mehta, CEO of Cellworks. “In reality, every cancer patient’s tumor has a unique set of molecular abnormalities and therefore we need to approach all cancer treatments from a personalized perspective. At Cellworks, we embrace the uniqueness of each cancer patient’s disease in order to identify the most efficacious therapy using a personalized oncology technology approach.”

About Cellworks Group

Cellworks Group, Inc. is a world leader in Personalized Medicine in the key therapeutic areas of Oncology and Immunology. Using innovative multi-omics modeling, computational biosimulation and Artificial Intelligence heuristics, Cellworks predicts the most efficacious therapies for patients. The Cellworks unique biosimulation platform is a unified representation of biological knowledge curated from heterogeneous datasets and applied to finding cures. Backed by UnitedHealth Group, Sequoia Capital, Agilent and Artiman, Cellworks has the world’s strongest trans-disciplinary team of molecular biologists, cellular pathway modelers and software technologists working toward a common goal – attacking serious diseases to improve the lives of patients. The company is based in South San Francisco, California and has a research and development facility in Bangalore, India. For more information, visit www.cellworks.life and follow us on Twitter @cellworkslife.

About Miami Cancer Institute

Miami Cancer Institute brings to South Florida access to personalized clinical treatments and comprehensive support services delivered with unparalleled compassion. No other cancer program in the region has the
combination of cancer-fighting expertise and advanced technology—including the first proton therapy center in South Florida, Latin America and the Caribbean, and one of the only radiation oncology program in the world with each of the newest radiation therapies in one place—to diagnose and deliver precise cancer treatments that achieve the best outcomes and improve the lives of cancer patients. The Institute offers an impressive roster of established community oncologists and renowned experts, clinical researchers and genomic scientists recruited from the nation’s top cancer centers. Selected as Florida’s only member of the Memorial Sloan Kettering Cancer (MSK) Alliance, Miami Cancer Institute is part of a meaningful clinical collaboration that affords patients in South Florida access to innovative treatments and ensures that the standards of care developed by their multidisciplinary disease management teams match those at MSK.

Miami Cancer Institute is part of Baptist Health South Florida, the largest healthcare organization in the region, with 11 hospitals, more than 23,000 employees, 4,000 physicians and 100 outpatient centers, urgent care facilities and physician practices spanning across Miami-Dade, Monroe, Broward and Palm Beach counties. Baptist Health has internationally renowned centers of excellence in cancer, cardiovascular care, orthopedics and sports medicine, and neurosciences. In addition, it includes Baptist Health Medical Group; Baptist Health Quality Network; and Baptist Health Care On Demand, a virtual health platform. A not-for-profit organization supported by philanthropy and committed to its faith-based charitable mission of medical excellence, Baptist Health has been recognized by Fortune as one of the 100 Best Companies to Work For in America and by Ethisphere as one of the World’s Most Ethical Companies. For more information, visit BaptistHealth.net/Newsroom and connect with us on Facebook, Instagram, Twitter and LinkedIn.

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**Media Contacts:**
Barbara Reichert
Reichert Communications, LLC
Barbara@reichertcom.com
415-225-2991

Michele Macpherson, Chief Business Officer
Cellworks Group, Inc.
michele.macpherson@cellworksgroup.com
650-346-9980