Cellworks Singula™ Predicts Personalized Therapy Responses for Pancreatic Cancer Patients with 94% Accuracy

myCare Study Shows Cellworks Multi-omics Biosimulation is a Superior Predictor of Therapy Response in PDAC Patients Compared to Physician Prescribed Treatment

SOUTH SAN FRANCISCO, Calif., May 14, 2020 – Cellworks Group, Inc., a world leader in Personalized Medicine in the key therapeutic areas of Oncology and Immunology, today announced results from the myCare-009-05 clinical study in which Cellworks Singula™ correctly predicted 94.2% of Pancreatic Cancer (PDAC) responders and non-responders with 100% sensitivity and 90.3% specificity, compared to a 40.4% physician prescribed treatment response rate. The strong study results indicate that Cellworks Singula™ has the potential to improve the median progression-free survival (PFS) and overall survival (OS) for PDAC patients by validating treatment selection decisions prior to treatment.

The complete results from the myCare-009-05 clinical study are now available in the ASCO Meeting Library as abstract e16766.

“Current therapies for pancreatic cancer have modest impact and new ways of treatment selection are urgently needed,” said Dr. Eileen O’Reilly, MD, Medical Oncologist, Memorial Sloan Kettering Cancer and Primary Investigator for the myCare-009-05 study. “This study demonstrates that Cellworks Singula™ can predict, with very high accuracy, whether an individual pancreatic cancer patient will respond to a treatment. By providing oncologists with accurate predictions of therapy responses for individual patients prior to treatment, this tool has the potential to improve the median survival rates for pancreatic cancer patients.”

PDAC treatment selection guidelines are typically limited to single aberrations and ignore most molecular pathways, downstream effects and relevant patient-specific ‘omics. However, the majority of pancreatic cancer patients have multiple aberrations which create patient-specific resistance pathways that cancer cells use to resist ‘one-mutation one-drug’ physician prescribed treatments, contributing to low treatment response rates.

“Pancreatic cancer patients are faced with very low survival rates,” said Yatin Mundkur, CEO of Cellworks. “In order to move the needle toward improved outcomes for these patients, oncologists seek a highly personalized therapy that doesn’t waste precious time with ineffective treatments. Cellworks Singula™ utilizes multi-omics data to biosimulate the patient-specific biomarker and phenotype responses of a personalized disease cell to drug agents, radiation and cell signaling. This personalized approach delivers highly accurate therapy response predictions, which enable physicians
to prescribe the most efficacious treatment the first time. The next step will be to prospectively validate the findings from this study.”

Cellworks Singula™ therapy response predictions are generated through extensive biosimulation of a personalized patient disease model based on the patient’s multi-omics data. Utilizing an in-silico model of thousands of genes, Cellworks Singula™ analyzes the downstream pathway impact of genomic, proteomic, transcriptomic and epigenomic aberration information on a patient’s disease. These downstream effects generate phenotypic impact, which are calculated against specific drugs or drug combinations to determine treatment efficacy. The Cellworks biosimulation platform can predict an individual patient’s therapy response prior to receiving the treatment, thereby reducing the patient risks and payer costs of unsuccessful treatments and ultimately saving lives.

myCare-009-05 Clinical Study Methods and Results

An independent cohort of 52 Stage I-IV PDAC patients aged 35-85, whose ‘omics data was available in The Cancer Genome Atlas (TCGA) and the International Cancer Genome Consortium (ICGC), were included in this retrospective study. The accuracy of Cellworks Singula™ therapy response predictions was compared to the accuracy of prescribed therapies and clinical outcomes. Comparisons in the accuracy were enabled using McNemar’s test to account for the correlation between Cellworks Singula™ and physician recommendations. Logistic regression was used to model complete response (CR) as a function of age, prescribed therapies and Cellworks Singula™ against non-response (NR). Similar analyses were performed for progression-free survival (PFS) and overall survival (OS) using proportional hazards regression.

Study results indicate that Cellworks Singula™ is a superior predictor of complete response (CR) compared to physician choice (McNemar’s $\chi^2 = 26.0$, p-value < 0.0001), with an overall accuracy of 94.2% (Exact 95% CI: 84.1%, 98.8%) compared to a 40.4% (95% CI: 27.0%, 54.9%) physician prescribed treatment response rate. Cellworks Singula™ exhibited 100% sensitivity (95% CI: 83.9%, 100%) and 90.3% specificity (95% CI: 74.2%, 98.0%). Cellworks Singula™ was the only significant predictor of PFS ($p = 0.0002$) and OS ($p = 0.0096$) after adjustment for physician prescribed treatment and patient age, suggesting that Cellworks Singula™ is a superior predictor of both OS and PFS. In addition, for all 28 true negatives, Cellworks Singula™ generated alternative therapy selections with predicted responses.

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 Sequoia Capital and Artiman Ventures, 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.

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