Cellworks Singula™ Accurately Predicts Clinical Outcome from Treatments in Patients with NSCLC

*Personalized Therapy Biosimulation Using Multi-Omic Data Predicts OS and PFS for NSCLC 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-022-05 prospectively designed study on a retrospective TCGA cohort, which demonstrate that the Cellworks Singula™ Therapy Response Index (TRI) is strongly predictive of Overall Survival (OS), Progression-Free Survival (PFS) and clinical benefit for non-small cell lung cancer (NSCLC) patients. In this study, Singula™ TRI provided predictive value to physicians beyond standard clinical factors, including patient age, patient gender and physician-prescribed treatment.

The results from the myCare-022-05 clinical study will be featured in a poster session with comments from Dr. Vamsidhar Velcheti, Associate Professor, Department of Medicine at NYU Grossman School of Medicine; Director, Thoracic Medical Oncology Program, as part of the 2021 ASCO Annual Meeting June 4-8th during the Lung Cancer – Non-Small Cell Metastatic Track and available online as abstract 9117.

The Cellworks Singula™ Therapy Response Index (TRI) has been developed to assist clinicians and NSCLC patients in choosing between competing therapeutic options. In contrast to approaches that consider a collection of single biomarkers, which often yield limited benefit, Cellworks utilizes an individual patient’s comprehensive next generation sequencing (NGS) results and the Cellworks Computational Omics Biology Model (CBM) to biosimulate downstream 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™ TRI Score.

The number of therapies available to treat NSCLC has increased significantly in recent years, but the multitude of drug choices also complicates therapeutic decision-making,” said Dr. Vamsidhar Velcheti, Associate Professor, Department of Medicine at NYU Grossman School of Medicine; Director, Thoracic Medical Oncology Program; and Co-Principal Investigator of the myCare-022-05 study. “Often single biomarker based approaches do not capture the true biological complexity of the patient’s cancer and have limitations in their ability to predict clinical benefit and duration of response with treatments. Knowing before treatment which therapy will be most efficacious for an individual NSCLC patient is a breakthrough for practicing Personalized Oncology. Cellworks Singula™ TRI can be a highly valuable decision-making tool for clinicians when discussing competing therapy options with patients.”

myCare-022-05 Clinical Study

In this prospectively designed study, the ability to predict patient response using Cellworks Singula™ was evaluated in a retrospective cohort of 446 NSCLC patients with OS, PFS and clinical outcome data from The
Cancer Genome Atlas (TCGA) Program and treated with physician-prescribed treatments. Cellworks Singula™ used Pubmed to generate protein interaction network-activated and inactivated disease pathways. Cellworks simulated physician prescribed therapies for each patient and calculated the quantitative drug effect on a composite NSCLC 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, PFS and CR above and beyond standard clinical factors. 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 above and beyond physician’s choice of treatment. The same Singula™ TRI algorithm and clinical cutoffs were used for all clinical outcome measures.

Multivariate Cox Proportional Hazards models revealed that Singula™ TRI was strongly predictive of OS, PFS and CR, while providing predictive value of OS beyond Physician Prescribed Therapies, patient age and patient gender. The resulting hazard ratio per 25 Singula™ units for OS was 0.5103 and the odds ratio for CR was 1.6161. 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 stratified by the Singula™ High and Low Benefit Groups resulted in a logrank p-value < 0.0001 and median survival times for OS of 60.16 and 28.57 months respectively. For each patient, a Singula TRI Score is generated for each alternative therapy. An example of the patient specific Singula™ TRI Score distribution of therapies is presented on the ASCO 2021 abstract 9117 poster, depicting the patient’s OS probability at 48 months relative to each potential treatment’s TRI score.

“Cancer therapy response levels for patients remain low - 30% on average across indications,” said Khush F. Mehta, CEO of Cellworks Group, Inc. “This reality demonstrates the critical need to improve upon the current treatment process by taking a personalized therapy approach - at the molecular level - to determine the most efficacious therapy for each patient prior to treatment.”

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.

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