Cellworks Singula™ Predicts Personalized Therapy Responses for AML and MDS Patients with Higher Accuracy than Physician Prescribed Treatments

myCare Studies Show Cellworks Multi-omics Biosimulation is a Superior Predictor of Complete Response to Therapies for AML and MDS Patients

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-009-01 and myCare-009-02 clinical studies in which Cellworks Singula™ performed as a superior predictor of complete response (CR) to therapies for Acute Myeloid Leukemia (AML) and Myelodysplastic Syndrome (MDS) cancer patients compared to physician prescribed treatments (McNemar’s p < 0.00001).

Cellworks Singula™ correctly predicted 88.5% of AML responders and non-responders with 97.0% sensitivity and 68.0% specificity, compared to a 70.2% physician prescribed treatment response rate in the myCare-009-01 study. Cellworks Singula™ also correctly predicted 73.3% of MDS responders and non-responders with 97.0% sensitivity and 68.0% specificity, compared to a 37.7% physician prescribed treatment response rate in the myCare-009-02 study. Cellworks Singula™ was a significant predictor of overall survival (p-value < 0.0001) and provided predictive information above and beyond physician prescribed treatments in both studies.

The complete results from the myCare-009-01 and myCare-009-02 clinical studies are now available in the ASCO Meeting Library as abstracts e19502 and e19528, respectively.

“These studies validate that Cellworks Singula™ is a leap forward for Personalized Medicine,” said Dr. Guido Marcucci, MD, Chair and Professor, Department of Hematologic Malignancies Translational Science, Director, Gehr; Family Center for Leukemia Research, Professor, Department of Hematology & Hematopoietic Cell Transplantation, City of Hope; and Primary Investigator for the myCare-009-01 and myCare-009-02 clinical studies. “Most AML and MDS patients have not just one, but multiple molecular aberrations, each of which impacts how individual patients respond to treatments. Cellworks Singula™ is a breakthrough technology that biosimulates how individual AML and MDS patients with multiple aberrations respond to specific therapies and then produces personalized therapy response predictions with very high accuracy. This novel capability has the potential to increase AML and MDS therapy response rates and improve patient outcomes.”
The current overall outcomes for AML and MDS patients remain relatively poor. Physicians select therapies for patients based on information that only considers cytogenetics and single molecular aberrations and ignores other potentially impactful molecular pathways, downstream effects and patient-specific ‘omics data that have the potential to inform more effective treatments.

“Cellworks biosimulation is an exciting technology that delivers Personalized Medicine to AML and MDS patients,” said Dr. Anthony Stein, MD, Hematologist/Oncologist, Director of the Leukemia Program; Co-Director of the Gehr Family Center for Leukemia Research; Clinical Professor of Hematology & Hematopoietic Transplantation at City of Hope; and Primary Investigator for the myCare-009-01 and myCare-009-02 clinical studies. “These studies show that Cellworks Singula™ can accurately predict how an individual AML or MDS patient will respond to specific therapies. These precise, data-driven predictions can enable physicians to avoid prescribing inefficacious treatments and can empower physicians to make more efficacious therapy decisions based on their patient’s unique molecular biology.”

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 saving lives.

myCare-009-01 Clinical Study

An independent cohort of 494 AML patients, 2 to 85 years in age (median age 54) and treated with physician prescribed therapy, were randomly selected for this prospective retrospective study. Patient ‘omics data from PubMed was used for the study. The accuracy of Cellworks Singula™ therapy response predictions was compared to the accuracy of prescribed therapies and clinical outcomes. Accuracy comparisons 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 overall survival (OS) using proportional hazards regression.

Study results show that Cellworks Singula™ is a superior predictor for complete response (CR) in AML patients (McNemar’s χ² = 72.0, p < 0.0001) with an overall predictive accuracy of 88.5% (Exact 95% CI: 85.3%, 91.1%) relative to physician prescribed treatments, compared to a physician prescribed treatment response rate of 70.2% (95% CI: 66.0%, 74.2%). Cellworks Singula™ exhibited 97.1% sensitivity (95% CI: 94.8%, 98.6%) and 68.0% specificity (95% CI: 59.8%, 75.5%). Cellworks Singula™ was also an independent predictor for OS (HR = 2.080, p < 0.0001) after adjusting for patient age (p = 0.0018) and physician prescribed treatment (p = 0.0011). For all 100 true negatives, Cellworks Singula™ generated alternative standard of care therapy selections with predicted clinical response.
myCare-009-02 Clinical Study

An independent cohort of 146 MDS patients aged 28 to 89 years (median age 69) and treated with physician prescribed therapy were randomly selected for this prospective retrospective study. Patient ‘omics data from PubMed and The Cancer Genome Atlas (TCGA) was used for the study. The accuracy of Cellworks Singula™ therapy response predictions was compared to the accuracy of prescribed therapies and clinical outcomes. Accuracy comparisons were enabled using McNemar’s test to account for the correlation between Cellworks Singula™ and physician recommendations. Multivariate logistic regression modeled complete response (CR) as a function of patient age, physician prescribed treatment and Cellworks Singula™ against non-response (NR).

Study results show Cellworks Singula™ is a superior predictor for complete response (CR) in MDS patients (McNemar’s $\chi^2 = 42.0, p < 0.0001$) with an overall predictive accuracy of 73.3% (Exact 95% CI: 65.3%, 80.2%) relative to physician prescribed treatment, compared to a physician prescribed treatment response rate of 37.7% (95% CI: 30.0%, 46.1%). In the study, Cellworks Singula™ exhibited 90.9% sensitivity (95% CI: 80.0%, 97.0%) and 62.6% specificity (95% CI: 51.8%, 72.6%). In multivariate regression analysis, Singula™ ($p < 0.0001$) remained an independent predictor for CR after adjusting for patient age ($p = 0.0759$) and PPT ($p = 0.0496$).

“We are committed to advancing Personalized Medicine,” said Yatin Mundkur, CEO of Cellworks. “Oncologists seek the ability to consistently prescribe cancer treatments with a high level of confidence that the chosen therapy will produce a response for an individual patient. Cellworks multi-omics biosimulation makes it possible to accurately predict whether a patient will respond to specific therapies. This Personalized Medicine knowledge can improve patient outcomes, reduce payer costs and ultimately save lives.”

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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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