



Origent Data Sciences and Cytokinetics Advance Collaboration Intended to Validate Predictive Analytics Model in ALS

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Research Aimed at Accelerating Conduct of Clinical Trials

VIENNA, Va. AND SOUTH SAN FRANCISCO, Calif., March 23, 2017 (GLOBE NEWSWIRE) -- Origent Data Sciences, Inc. (Origent) and Cytokinetics, Inc. (Nasdaq:CYTK) today announced the advancement of their research collaboration to prospectively validate Origent's computer model to predict the course of ALS (amyotrophic lateral sclerosis) disease progression using data from VITALITY-ALS, Cytokinetics' ongoing Phase 3 clinical trial of *tirasemtiv*. Funded by a grant from The ALS Association to Origent, this joint research program is designed to enable the first prospective validation of the predictive model in a clinical trial. Previously, the Origent models predicting both function and survival of ALS patients have been validated using the placebo arms of retrospective clinical trial datasets.

Because ALS disease progression is heterogeneous among patients, predicting an individual patient's course is difficult. This heterogeneity creates challenges for the design and conduct of clinical trials as inclusion of patients who progress at variable and unpredictable rates requires larger, longer and more expensive trials in order to observe a potential treatment effect of a therapeutic intervention. Origent's statistical models are designed to identify the patients whose symptoms are likely to progress quickly or slowly, potentially providing a methodology to address the complexity created by disease heterogeneity. Results from the first part of the research collaboration were presented at the 27th International Symposium on ALS/MND and showed that the Gradient Boosting Machine (GBM) algorithm was the optimal model to predict slow vital capacity (SVC) at times subsequent to baseline and that forced vital capacity (FVC) records could be used to predict SVC scores of ALS patients using this machine learning technique.



"Following the successful completion of the retrospective validation of our predictive models using baseline characteristics data from BENEFIT-ALS, the Phase 2 b trial of *tirasemtiv*, we look forward to taking this research collaboration to the next level and thank Cytokinetics for providing us access to the first real-time dataset for the prospective analysis of patients with ALS," said Dave Ennist, Chief Science Officer, Origent Data Sciences.

"The predictive power of the Origent computer model is encouraging, particularly the ability to predict slow vital capacity subsequent to baseline, as demonstrated in the first phase of the research," said Jinsy Andrews, M.D., Director of Neuromuscular Clinical Trials at Columbia University and Medical Monitor for VITALITY-ALS. "We are pleased to continue this groundbreaking collaboration which we hope may pave the way towards increased efficiencies in the conduct of clinical trials in patients with ALS."

About the Research Collaboration

Origent will seek to prospectively validate existing predictive models (including the ALSFRS-R, respiratory, gross, fine, and bulbar sub-scores, SVC and survival models) using baseline characteristics data from VITALITY-ALS, the ongoing Phase 3 clinical trial to assess the effects of *tirasemtiv* versus placebo on SVC and other measures of skeletal muscle strength in patients with ALS. *Tirasemtiv* is a fast skeletal troponin activator (FSTA) being developed by Cytokinetics for the potential treatment of patients with ALS. Using existing models in Origent's library, predictions will be made for each patient using only screening and baseline information from the placebo arm of the trial. Screening and baseline data of placebo patients will be provided following database lock and predictions will be made in the absence of access to the subsequent outcomes of the patients from the placebo arm of VITALITY-ALS. After the predictions are complete, clinical outcomes data from patients in the placebo arm of VITALITY-ALS will be made accessible to Origent for comparing actual placebo outcomes data to the previously escrowed predictions.

About Origent Data Sciences

Origent Data Sciences, Inc. is a spinoff of [Sentrana, Inc.](#), a pioneer in the field of Precision Sales and Marketing and winner of the *DREAM Phil Bowen ALS Prediction Prize4Life Challenge*. Since 2004, Sentrana has been a market leader in operationalizing new applications using predictive technologies. Similarly, Origent has become the market leader in patient-level predictive modeling for neurological conditions including ALS, and has developed many new applications to manage and reduce drug development risks through better foresight. Rather than considering a similar historic patient to act "the same" as a current patient, Origent treats and models each individual patient separately, predicting their behavior individually. By modeling patient-level dynamics rather than the characteristics of a population, Origent's tools uncover a deep level of insight that allows biostatisticians and researchers to gain clearer understanding and greater knowledge from their data. For additional information about Origent, visit www.origent.com.

About Cytokinetics

Cytokinetics is a late-stage biopharmaceutical company focused on discovering, developing and commercializing first-in-class muscle activators as potential treatments for debilitating diseases in which muscle performance is compromised and/or declining. As a leader in muscle biology and the mechanics of muscle performance, the company is developing small molecule drug candidates specifically engineered to increase muscle function and contractility. Cytokinetics' lead drug candidate is *tirasemtiv*, a fast skeletal troponin activator (FSTA). *Tirasemtiv* is the subject of VITALITY-ALS, an international Phase 3 clinical trial in patients with ALS. *Tirasemtiv* has been granted orphan drug designation and fast track status by the U.S. Food and Drug Administration and orphan medicinal product designation by the European Medicines Agency. Cytokinetics is preparing for the potential commercialization of *tirasemtiv* in North America and Europe and has granted an option to Astellas for development and commercialization in other countries. Cytokinetics is collaborating with Astellas to develop CK-2127107, a next-generation fast skeletal muscle activator. CK-2127107 is the subject of two ongoing Phase 2 clinical trials enrolling patients with spinal muscular atrophy and chronic obstructive pulmonary disease. Cytokinetics is collaborating with Amgen Inc. to develop *omecamtiv mecarbil*, a novel cardiac muscle activator. *Omecamtiv mecarbil* is the subject of GALACTIC-HF, an international Phase 3 clinical trial in patients with heart failure. Amgen holds an exclusive worldwide license to develop and commercialize *omecamtiv mecarbil* with a sublicense held by Servier for commercialization in Europe and certain other countries. Astellas holds an exclusive

worldwide license to develop and commercialize CK-2127107. Licenses held by Amgen and Astellas are subject to Cytokinetics' specified co-development and co-commercialization rights. For additional information about Cytokinetics, visit www.cytokinetics.com.

Cytokinetics Forward-Looking Statements

This press release contains forward-looking statements for purposes of the Private Securities Litigation Reform Act of 1995 (the "Act"). Cytokinetics disclaims any intent or obligation to update these forward-looking statements, and claims the protection of the Act's Safe Harbor for forward-looking statements. Examples of such statements include, but are not limited to, statements relating to Cytokinetics' and its partners' research and development activities, including Cytokinetics' and Origent's predictive analytics research and the ability to validate Origent's predictive technology; the initiation, conduct, design, enrollment, progress, continuation, completion and results of clinical trials; the significance and utility of preclinical study and clinical trial results, the expected availability of clinical trial results, planned interactions with regulatory authorities and the outcomes of such interactions; and the significance and utility of Origent's predictive modeling. Such statements are based on management's current expectations, but actual results may differ materially due to various risks and uncertainties, including, but not limited to the U.S. Food and Drug Administration (FDA) or foreign regulatory agencies may not accept the utility of predictive modeling, including its utility in clinical trial design; the FDA or foreign regulatory agencies may delay or limit Cytokinetics' or its partners' ability to conduct clinical trials; and Cytokinetics may incur unanticipated research and development and other costs or be unable to obtain additional financing necessary to conduct development of its products. For further information regarding these and other risks related to Cytokinetics' business, investors should consult Cytokinetics' filings with the Securities and Exchange Commission. Forward-looking statements are not guarantees of future performance, and Cytokinetics' actual results of operations, financial condition and liquidity, and the development of the industry in which it operates, may differ materially from the forward-looking statements contained in this press release. Any forward-looking statements that Cytokinetics makes in this press release speak only as of the date of this press release. Cytokinetics assumes no obligation to update its forward-looking statements whether as a result of new information, future events or otherwise, after the date of this press release.

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