

# Origent Data Sciences and Cytokinetics Announce Research Collaboration on Predictive Analytics Model in ALS

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## **Origent Receives ALS Association Grant to Enable Research Partnership**

SOUTH SAN FRANCISCO, Calif., March 31, 2016 (GLOBE NEWSWIRE) -- Origent Data Sciences, Inc. (Origent) and Cytokinetics, Inc. (Nasdaq:CYTK) today announced a research collaboration to refine and prospectively validate an Origent computer model to predict the course of ALS disease progression leveraging data from Cytokinetics' clinical trials of *tirasemtiv*. Funded by Origent's receipt of a grant from The ALS Association, this joint research program will enable the first prospective validation of the predictive model in a clinical trial setting. Previously, the Origent models predicting both function and survival of ALS patients have been validated using internal and retrospective external datasets.

ALS disease progression is extremely heterogeneous among patients. While the average life expectancy of a patient living with ALS is 3-5 years after diagnosis, many patients survive only a few months, while still others live with the disease for decades. This heterogeneity of progression creates significant challenges for clinical trial design and conduct, as patients who progress at highly variable rates may confound traditional statistical analyses, and require larger, longer and more expensive trials. Origent's statistical models are designed to identify the patients whose symptoms are likely to

progress quickly or slowly, thereby reducing the statistical complexities created by this disease heterogeneity.

“We are extremely grateful to The ALS Association for this generous grant and to Cytokinetics for the opportunity to access their robust clinical trial data,” said Dave Ennist, Chief Science Officer, Origent Data Sciences. “If validated, the models we have developed will be submitted to the FDA and may enable more nimble, cost-effective execution of ALS clinical trials, resulting in a potentially quicker path to new medicines.”

“This unique collaboration between Origent Data Sciences, Cytokinetics and The ALS Association reflects another step in our collective efforts to accelerate the clinical trial process and make new medicines available to people with ALS in desperate need of new therapeutic options,” said Jinsy Andrews, M.D., Cytokinetics’ Senior Director Clinical Research and Development and Head of Neuromuscular Therapeutics. “We are pleased to join with Origent to potentially validate their predictive model using datasets from BENEFIT-ALS and VITALITY-ALS which we hope may then facilitate the use of this novel technology to positively impact the design and conduct of future ALS clinical trials.”

“We are extremely excited to see this collaboration get underway,” said ALS Association Chief Scientist Lucie Bruijn, Ph.D., M.B.A. “This tool has the potential to accelerate clinical trials for ALS and the Cytokinetics’ Phase 3 trial provides an excellent opportunity to validate the disease progression algorithm.”

### **About the Research Partnership**

Origent will first seek to confirm the retrospective external validation of the existing predictive models (including the ALSFRS-R, respiratory, gross, fine, and bulbar sub-scores, slow vital capacity (SVC) and survival models) using baseline characteristics data from BENEFIT-ALS, the completed Phase 2b trial of *tirasemtiv*, Cytokinetics’ fast skeletal muscle activator which is being developed for the potential treatment of ALS. If these retrospective validations are confirmed, Origent plans to prospectively validate the models with the data provided by Cytokinetics following the completion of VITALITY-ALS, an ongoing Phase 3 clinical trial designed to assess the effects of *tirasemtiv* versus placebo on SVC and other measures of skeletal muscle strength in patients with ALS.

### **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 C 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](http://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 muscle activator, for the potential treatment of 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 for the potential treatment of ALS. Cytokinetics retains the right to develop and commercialize *tirasemtiv*. Cytokinetics is collaborating with Amgen Inc. to develop *omecamtiv mecarbil*, a novel cardiac muscle activator, for the potential treatment of heart failure. Cytokinetics is collaborating with Astellas Pharma Inc. to develop CK-2127107, a fast skeletal muscle activator, for the potential treatment of spinal muscular atrophy. Amgen holds an exclusive license worldwide to develop and commercialize *omecamtiv mecarbil* and Astellas holds an exclusive license worldwide to develop and commercialize CK-2127107. Both licenses are subject to Cytokinetics' specified development and commercialization participation rights. For additional information about Cytokinetics, visit [www.cytokinetics.com](http://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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