Origent Data Sciences and Cytokinetics Present Analyses Demonstrating Baseline Data Predict Measures of Vital Capacity in Patients With ALS

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SOUTH SAN FRANCISCO, Calif., Dec. 07, 2016 (GLOBE NEWSWIRE) -- Origent Data Sciences, Inc. (Origent) and Cytokinetics, Inc. (Nasdaq:CYTK) today announced results from the first part of 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*. The poster, presented by David L. Ennist, Ph.D., MBA, Chief Science Officer, Origent Data Sciences and Jinsy A. Andrews, M.D., Director of Neuromuscular Clinical Trials, Columbia University, at the 27th International Symposium on ALS/MND in Dublin, Ireland, 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 slow vital capacity (SVC) scores of ALS patients using this machine learning technique.

"We are pleased to have completed this first-ever step toward using machine learning models for prospectively predicting ALS outcomes and disease progression in late-phase human clinical trials and look forward to continuing this important collaboration with Cytokinetics," said Dave Ennist, Chief Science Officer, Origent Data Sciences.

"These data bring us one step closer to prospectively validating the Origent predictive model using datasets from BENEFIT-ALS and VITALITY-ALS," said Jinsy Andrews, M.D., Director of Neuromuscular Clinical Trials, Columbia University and Medical Monitor for VITALITY-ALS. "We hope that predictive algorithms arising from this research collaboration may ultimately accelerate clinical trials in patients with ALS by using virtual control arms."

The objective of this phase of the research collaboration was to develop a model that uses baseline patient characteristics including the results of a screening visit to predict SVC at subsequent times using the PRO-ACT (Pooled Resource Open-Access ALS Clinical Trials) database, a platform that houses the largest ALS clinical trials dataset. The database was used to compare three different predictive models with the GBM algorithm proving to outperform other models in predicting SVC. Using the GBM model, the researchers demonstrated that 22 baseline characteristics including FVC could be used to train a model that predicts SVC at subsequent times. Additionally, the researchers showed that baseline FVC and SVC were highly correlated measures of vital capacity. Finally, the data identified and weighted the predictive value of several variables, demonstrating that FVC at baseline was the most important predictor of vital capacity at subsequent times in patients with ALS.

About the Research Partnership

Funded by Origent's receipt of a grant from The ALS Association, this joint research program is designed to enable the first prospective validation of predictive models 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. 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, Cytokinetics' completed Phase 2b trial of *tirasemtiv*, a 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 data to be 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. Founded in 2013, Origent has become the market leader in patient-level predictive modeling and has developed a number of 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 muscle troponin 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*, subject to an option held by Astellas Pharma Inc. Cytokinetics is also collaborating with Astellas to develop CK-2127107, a fast skeletal muscle activator, for the potential treatment of spinal muscular atrophy, chronic obstructive pulmonary disease and ALS. Cytokinetics is collaborating with Amgen Inc. to develop *omecamtiv mecarbil*, a novel cardiac muscle activator, for the potential treatment of heart failure. 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 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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