OpGen Subsidiary Ares Genetics Announces Publication of Study Introducing Best Practice Techniques for AI-powered Prediction of Antibiotic Susceptibility Testing by Next-Generation Sequencing

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Study highlights best practice techniques for accurate antimicrobial resistance prediction from whole-genome sequencing data

Publication supports harmonization of the development of good machine learning practices as encouraged in recent FDA AI/ML Software as a Medical Device Action Plan

Work promotes robustness and facilitates translation of next-generation sequencing based antibiotic susceptibility testing into clinical practice

GAITHERSBURG, Md. and VIENNA, Austria, Feb. 16, 2021 (GLOBE NEWSWIRE) -- Ares Genetics GmbH (Vienna, Austria; "Ares Genetics"), a subsidiary of OpGen, Inc. (Nasdaq: OPGN, "OpGen"), announced today the publication of a peer-reviewed study introducing best practice techniques for prediction of antibiotic susceptibility testing (AST) results from whole-genome sequencing (WGS) data.

The work led by Ares Genetics and performed in collaboration with Prof. Thomas Rattei from the Division of Computational Systems Biology at the University of Vienna critically assessed different machine learning (ML) techniques for whole genome sequencing (WGS)-based AST on several thousand genome assemblies across more than 50 species/compound combinations collated from public databases. The publication describes the combination of different machine learning architectures for robust and accurate WGS-based AST.

The study addresses two out of five actions stipulated by the FDA in the recently issued Artificial Intelligence/Machine Learning (AI/ML)-Based Software as a Medical Device (SaMD) Action Plan. It aims at advancing good machine learning practices (GMLP) for WGS-based AST by describing best practice techniques for training and evaluation of predictive models, as well as introducing an optimized model architecture to reduce bias and promote robustness.

Dr. Arne Materna, CEO of Ares Genetics, commented, "The present study adds to Ares Genetics' publication record validating our approach to becoming a globally recognized leader in the development of AI-powered next generation sequencing or NGS-based solutions for infectious disease testing. Addressing the U.S. FDA action plan by developing good machine learning practice and robust algorithms will be key to moving our AI-powered solutions into clinical practice. Applying the proposed best practice techniques to our unique and curated ARESdb allowed us to further improve predictive performance of WGS-based AST even beyond the performance shown in our seminal multi-center evaluation study demonstrating feasibility of WGS-based AST for a broad selection of pathogen-drug combinations. In this context, we are currently also working with several leading clinical centers in the United States to further demonstrate the potential of accurate WGS-based AST in independent validation studies."

Oliver Schacht, President & CEO of OpGen added, "The Ares Technology platform is an integral part of OpGen's precision medicine offering and complements our commercial FDA-approved Unyvero platform as well as our Acuitas AMR Gene Panel for isolates for which we anticipate an upcoming FDA clearance decision. Following the successful integration of Ares Genetics into OpGen globally, we are focused on executing on our strategy to establish ourselves as industry leaders in the artificial intelligence and bioinformatics space."

About OpGen, Inc.

OpGen, Inc. (Gaithersburg, MD, USA) is a precision medicine company harnessing the power of molecular diagnostics and bioinformatics to help combat infectious disease. Along with subsidiaries Curetis GmbH and Ares Genetics GmbH, we are developing and commercializing molecular microbiology solutions helping to guide clinicians with more rapid and actionable information about life threatening infections to improve patient outcomes, and decrease the spread of infections caused by multidrug-resistant microorganisms, or MDROs. OpGen's product portfolio includes Unyvero, Acuitas AMR Gene Panel and Acuitas® Lighthouse, and the ARES Technology Platform including ARESdb, using NGS technology and AI-powered bioinformatics solutions for antibiotic response prediction.

For more information, please visit www.opgen.com.

Forward-Looking Statements by OpGen

This press release includes statements regarding the recently published benchmarking study on AI-powered prediction of antibiotic susceptibility. These statements and other statements regarding OpGen's Unyvero products, their commercialization and launch, future plans and goals constitute "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934 and are intended to qualify for the safe harbor from liability established by the Private Securities Litigation Reform Act of 1995. Such statements are subject to risks and uncertainties that are often difficult to predict, are beyond our control, and which may cause results to differ materially from expectations. Factors that could cause our results to differ materially from those described include, but are not limited to, our ability to successfully, timely and cost-effectively develop, seek and obtain regulatory clearance for and commercialize our product and services offerings, the rate of adoption of our products and services by hospitals and other healthcare providers, the fact that we may not effectively use proceeds from recent financings, including our November 2020 private placement, the realization of expected benefits of our business combination transaction with Curetis GmbH, the success of our commercialization efforts, the impact of COVID-19 on the Company's operations, financial results, and commercialization efforts as well as on capital markets and general economic conditions, the effect on our business of existing and new regulatory requirements, and other economic and competitive factors. For a discussion of the most significant risks and uncertainties associated with OpGen's business, please review our filings with the Securities and Exchange Commission. You are cautioned not to place undue reliance on these forward-looking statements, which are based on our expectations as of the date of this press release and speak only as of the date of this press release. We undertake no obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future events or otherwise.

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