



OpGen Subsidiary Ares Genetics Demonstrates Feasibility and Potential of Next Generation Sequencing Based Antibiotic Susceptibility Testing in Multi-Center Study

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Peer-reviewed study evaluated performance of AI-powered bioinformatics cloud platform, ares-genetics.cloud, for NGS-based antibiotic susceptibility testing on 12 pathogenic bacterial species and 21 antibiotic drugs

NGS-based testing reached 100% agreement with reference culture-based testing for 32 pathogen-drug pairs and 89% across all 129 pathogen-drug combinations evaluated

The comprehensive study on NGS-based antibiotic susceptibility testing was based on 620 isolates from more than 2,000 patients collected at nine medical centers across the U.S.

VIENNA, Austria and GAITHERSBURG, Md., April 16, 2020 (GLOBE NEWSWIRE) -- OpGen, Inc. (Nasdaq: OPGN, "OpGen"), a precision medicine company harnessing the power of molecular diagnostics and bioinformatics to help combat infectious disease, announced today that a study on the feasibility and potential of antibiotic susceptibility testing and bacterial pathogen identification using next-generation sequencing (NGS) [has been pre-published in the Journal of Clinical Microbiology](#). The study was performed by its newly acquired subsidiaries Ares Genetics GmbH and Curetis GmbH, and scientists at the Max Perutz Labs (Austria), a joint venture of the University of Vienna and the Medical University of Vienna, and the Mayo Clinic (Rochester, MN, U.S.A.).

The article titled, "*Species Identification and Antibiotic Resistance Prediction by Analysis of Whole Genome Sequence Data Using ARESdb - An Analysis of Isolates from the Unyvero Lower Respiratory Tract Infection Trial*" (Ref. 1) reports on a study evaluating the performance of pathogen identification and antibiotic susceptibility testing based on whole genome DNA sequencing (WGS) using Ares Genetics' AI-powered cloud-based bioinformatics platform ares-genetics.cloud and its underlying reference database, ARESdb.

WGS-predicted susceptibility to antibiotics showed 89% categorical agreement with the current reference method of broth microdilution susceptibility testing across a total of 129 pathogen-drug pairs analyzed. Categorical agreement exceeded 90% in 78, and reached 100% in 32 pathogen-drug pairs. For the taxonomic identification of the isolated bacterial pathogens, WGS showed 99% and 93% concordance with the MALDI-ToF reference method at the genus and species levels, respectively.

The study evaluating the AI-powered ares-genetics.cloud platform and the underlying ARESdb reference database included 12 pathogenic bacterial species and 21 antibiotic compounds covering common lower respiratory tract pathogens and is likely one of the most comprehensive peer-reviewed reports on the performance of WGS in predicting susceptibility to antibiotics in a multi-center U.S. trial.

Dr. Andreas Posch, CEO of Ares Genetics and senior author of the study, commented, "This multi-center study clearly demonstrates the feasibility and potential of next-generation sequencing based antibiotic susceptibility testing using our AI-powered cloud platform. Already today, we are offering cloud-based data interpretation and next-generation sequencing services for research use which we intend to roll out more broadly based on these validating results. Equally important, we learned through the study how to optimize our reference database, ARESdb, and improve our predictive models to further advance to applications in clinical practice."

In this study, the investigators analyzed WGS data of a total of 620 bacterial strains isolated from more than 2,000 clinical samples collected from patients with suspected lower respiratory tract infections at nine hospitals across the U.S. The samples were originally collected for a U.S.-FDA study for the validation of the now FDA-cleared Unyvero LRT syndromic multiplex PCR panel by Curetis. Species identity of the isolated pathogens and their susceptibility to antibiotics were analyzed using MALDI-ToF and broth microdilution, respectively, as best-in-class reference methods according to current practice.

The WGS data analysis was performed using Ares Genetics' proprietary database, ARESdb, with state-of-the-art open-source tools and public data. At the time of the study, ARESdb comprised of curated genotype-phenotype data for approximately 35,000 bacterial strains. To date, ARESdb has further grown containing matched whole-genome sequencing and antibiotic susceptibility data for more than 50,000 bacterial strains and more than 100 antibiotics.

Microbial infections and antibiotic resistance have become major healthcare challenges with rapidly spreading antimicrobial resistance estimated to have caused 700,000 deaths globally in 2016, a number that is projected to dramatically increase to 10 million deaths annually by 2050 if no countermeasures are taken (Ref. 2). At the same time, few novel antibiotics are in development and prominent pharmaceutical companies have cut back their R&D efforts in the infectious diseases space. In the absence of novel treatment options, we believe novel diagnostic approaches to allow for rapid identification of causative pathogens and their susceptibility to available treatment options are urgently needed to guide appropriate therapy of patients while enabling prudent and informed use of antibiotics.

The study was supported through funding provided by the Austrian Research Promotion Agency and the Vienna Business Agency.

References

1. Species Identification and Antibiotic Resistance Prediction by Analysis of Whole Genome Sequence Data Using ARESdb - An Analysis of Isolates from the Unyvero Lower Respiratory Tract Infection Trial. Ines Ferreira, Stephan Beisken, Lukas Lueftinger, Thomas Weinmaier, Matthias Klein, Johannes Bacher, Robin Patel, Arndt von Haeseler and Andreas E. Posch. 2020. Journal of Clinical Microbiology, DOI: 10.1128/JCM.00273-20
2. The Review on Antimicrobial Resistance. 2016. Tackling Drug-Resistant Infections Globally: Final Report and

Recommendations. The Review on Antimicrobial Resistance, chaired by Jim O'Neill, Wellcome Trust & HM Gove

For further information, please register on the Ares Genetics cloud platform:

<https://ares-genetics.cloud/>

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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 our 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 Panels 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

This press release includes statements regarding the development of diagnostic tests by subsidiaries of OpGen. Such statements 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 success of our commercialization efforts, 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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