OpGen Group Company Ares Genetics Demonstrates Feasibility of CLIA-compliant Next Generation Sequencing Workflow for Identification of Bacterial Pathogens and Antibiotic Resistance Markers

Accurate identification of antibiotic resistance markers based on the ARESdb QIAGEN CLC Module leveraging Ares Genetics' proprietary antibiotic resistance database

Pathogens correctly identified with 100% sensitivity and specificity, antibiotic resistance markers with >95% sensitivity and >99% specificity, respectively

Study paves the way for routine clinical diagnostic application of next-generation sequencing (NGS) in timely as well as accurate infectious disease testing and drug susceptibility prediction

VIENNA, Austria, and GAITHERSBURG, Md. U.S., August 11, 2020 -- Ares Genetics GmbH (Vienna, Austria; "Ares Genetics"), a subsidiary of OpGen, Inc. (Nasdaq: OPGN, "OpGen"), announced today the publication of a peer-reviewed study that demonstrates the feasibility of a highly accurate and reproducible sample-to-insight workflow for various clinical microbiology assays including the molecular identification of bacterial pathogens and their genetic markers of antibiotic resistance (Ref. 1).

The combined laboratory and bioinformatics workflow was developed following requirements of the U.S. Clinical Laboratory Improvement Act (CLIA) for laboratory-developed tests (LDTs). The bioinformatics analysis workflow leverages the QIAGEN CLC Microbial Genomics ARESdb Module for detection of antibiotic resistance (AMR) markers (Ref. 2). Powered by artificial intelligence, Ares Genetics' ARESdb is a comprehensive, global and continuously updated proprietary knowledgebase on AMR markers and their diagnostic relevance. Under a license from Ares Genetics, the QIAGEN CLC Microbial Genomics ARESdb Module provides users information about diagnostic performance parameters for individual AMR markers at antibiotic compound resolution and thereby addresses a key limitation of public AMR databases (Ref. 3).

The workflow was validated in a study focused on particularly challenging and clinically prevalent multi-drug resistant ESKAPE pathogens (*Enterococcus faecium, Staphylococcus aureus, Klebsiella pneumoniae, Acinetobacter baumannii, Pseudomonas aeruginosa, Enterobacter cloacae*) including the WHO priority 1 pathogens (Ref. 4). In this study, the workflow demonstrated >99% repeatability, reproducibility, and accuracy. Pathogens were correctly identified with 100% sensitivity and specificity, AMR markers with >95% sensitivity and >99% specificity, respectively.

Dr. Andreas Posch, CEO of Ares Genetics and corresponding author of the study, commented, "This study demonstrates that next-generation sequencing in combination with a standardized bioinformatics workflow and a curated interpretation database enables a wide array of clinical microbiology assays with the performance and quality that meet the high standards required for human diagnostic use. We are very pleased to reach this important milestone in our development of universal molecular diagnostic solutions for the timely detection of pathogens and accurate prediction of antibiotic susceptibility."

Ares Genetics currently offers NGS-based clinical microbiology assays for epidemiology, infection control and research via its AI-powered bioinformatics platform *ares-genetics.cloud* under the brand name ARESupa - Universal Pathogenome Assay. In a recently published multi-center study, Ares Genetics demonstrated that *ares-genetics.cloud* can also accurately predict antibiotic susceptibility based on complex DNA signatures that are interpreted by combining ARESdb with artificial intelligence (Ref. 5). The combination of high-resolution NGS and AI-powered data interpretation can enable accurate as well as comprehensive molecular antibiotic susceptibility testing and has the potential to provide information on antibiotic therapy response much faster than current culture-based approaches.

Dr. Andreas Posch added: "Highly standardized laboratory workflows like the one we realized in this study, are an important prerequisite for fast and reliable molecular solutions for pathogen identification and antibiotic susceptibility prediction in the clinical routine. They allow locally performed NGS analysis for expeditious turnaround times and cloud-based AI-powered data interpretation for clinical decision support. This enables new business models combining traditional IVD instrument and reagent business with SaaS business and hence paves the way for digital diagnostic companies like Ares Genetics."

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. 6). While on July 9th 2020, more than 20 leading biopharmaceutical companies announced the launch of the AMR Action Fund aiming to bring two to four new antibiotics to patients by 2030, a recent white paper by Ares Genetics highlights the urgent need for novel diagnostic approaches to allow for rapid identification of causative pathogens and their susceptibility to available antibiotic options, in order to guide appropriate treatment of patients while enabling prudent and informed use of existing or future new antibiotics (Ref. 7).

The studies by Ares Genetics were supported through funding provided by the Vienna Business Agency and the Austrian Research Promotion Agency.

References

1) Analytical performance validation of next-generation sequencing based clinical microbiology assays using a k-mer analysis workflow. Sarah Lepuschitz, Thomas Weinmaier, Katharina Mrazek, Stephan Beisken, Johannes Weinberger, Andreas E. Posch. 2020. Frontiers in Microbiology https://www.frontiersin.org/articles/10.3389/fmicb.2020.01883/full

2) The ARESdb Module (https://resources.qiagenbioinformatics.com/manuals/clcmgm/current/index.php?manual =ARES_Database.html) was released 2019 as part of the QIAGEN CLC Microbial Genomics Module (https://digitalinsights.qiagen.com/products-overview/discovery-insights-portfolio/analysis-and-visualization/qiagen-clc-microbial-genomics-module/)

within the QIAGEN CLC product line (https://digitalinsights.qiagen.com/products-overview/discovery-insights-portfolio/qiagen-clc-genomics/)

3) Large-scale assessment of antimicrobial resistance marker databases for genetic phenotype prediction: a systematic review. Norhan Mahfouz, Inês Ferreira, Stephan Beisken, Arndt von Haeseler, Andreas E. Posch. 2020. Journal of Antimicrobial Chemotherapy, https://doi.org/10.1093/jac/dkaa257

4) https://www.who.int/news-room/detail/27-02-2017-who-publishes-list-of-bacteria-for-which-new-antibiotics-are-urgently-needed

5) 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 58(7): e00273-20.

6) Tackling Drug-Resistant Infections Globally: Final Report and Recommendations. The Review on Antimicrobial Resistance 2016, chaired by Jim O'Neill https://amr-review.org/sites/default/files/160525_Final%20paper_with%20cover.pdf

7) https://uploads-ssl.webflow.com/5bbbb630dcca693cb5a8cb21/5f1154c7fa272f68241d147d_FightingAMRWithBetterDiagnostics_AresGenetics_2020.pdf

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 a validation study of next-generation sequencing based tests provided by OpGen's subsidiary, Ares Genetics GmbH. These statements and other statements regarding OpGen's 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 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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