OpGen Announces Prospective Clinical Data from Unyvero LRT BAL and Acuitas AMR Gene Panel for Isolates Data Presented at World Microbe Forum

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- Unyvero studies demonstrated potential for therapy adjustment in 42% to 53% of patients with results available 1 to 2 days faster

- Acuitas AMR Gene Panel for Isolates (RUO) studies demonstrate potential in infection control and prevention

GAITHERSBURG, Md., June 30, 2021 (GLOBE NEWSWIRE) -- OpGen, Inc. (Nasdaq: OPGN, "OpGen"), a precision medicine company harnessing the power of molecular diagnostics and bioinformatics to help combat infectious disease, today announced prospective clinical data on the Unyvero LRT BAL presented during a webinar held on June 29, 2021, and data presented at the virtual World Microbe Forum, June 20-24, 2021.

The webinar titled "One Academic Medical Center's Experience with the Unyvero Multiplex Platform for Testing Bronchoalveolar Lavage Fluids: Analytical and Clinical Assessment" studied patients in the intensive care unit (ICU) for whom bronchoalveolar lavage (BAL) specimen was ordered for diagnostic purpose and prospectively evaluated with the Unyvero LRT BAL panel in conjunction with quantitative bacterial culture and antimicrobial susceptibility testing (AST). Results from the Unyvero panel were communicated to the team of primary providers and the infectious disease pharmacist, who is a member of the antimicrobial stewardship program (ASP). The clinical impact of the Unyvero results on antibiotic stewardship and patient management were discussed and acted upon in real-time, enabling earlier adjustment of antimicrobial therapy in 53% of cases. De-escalation occurred in 33% of patients, and 20% of patients had an escalation. Changes in therapy occurred significantly faster with the Unyvero LRT BAL, on average 21 hours faster, compared to when conventional AST result was available.

Presented jointly by Dr. James W. Snyder, Professor of Pathology and Laboratory Medicine, University of Louisville, and Dr. Wes Hoffmann, Infectious Disease Pharmacist, University of Louisville Health System, Louisville, KY, they reported Unyvero results had 99.2% overall concordance for organism targets and 90% agreement for resistance genes when compared to bacterial quantitative culture and phenotypic susceptibility testing. In addition to the excellent concordance, Unyvero had more detections for organisms that are known causative agents of pneumonia such as *S. aureus*, *E. coli*, *K. pneumoniae*, *H. influenzae* and *Citrobacter* that were missed by culture.

Based on real-time clinical use of the Unyvero LRT BAL panel, they determined that the panel's *S. aureus* NPV is 97%, giving a solid indication that MRSA is not present causing the respiratory infection. By being able to de-escalate MRSA therapy, there are several major benefits, notably the mitigation of the potential for adverse vancomycin-induced nephrotoxicity and reducing the cost of drug as well as the cost of managing the administration of vancomycin. Similarly, they found the Unyvero panel *Pseudomonas* and *Acinetobacter* both have NPV of 98%, and often times it is unlikely that antipseudomonal therapy will help in those settings particularly extremely broad-spectrum agents like carbapenems. They concluded: "The negative predictive values (NPV) of the Unyvero LRT BAL panel can be extremely useful in reducing excess exposure to unnecessary antimicrobials, particular MRSA therapy and carbapenem and antipseudomonal therapy, and the panel can provide rapid and actionable results particularly if used in conjunction with an active antimicrobial stewardship program." A recording of this webinar can be accessed at OpGen.com.

At the World Microbe Forum 2021, an iposter titled "Clinical Evaluation of a Multiplex Molecular Diagnostic Lower Respiratory Tract Panel for Bronchoalveolar Lavage Specimens" by Drew Bell et al. of Indiana University School of Medicine, Indianapolis, IN, reported that the Unyvero LRT BAL provided a basis for appropriate escalation and de-escalation of antibiotic therapies in 42% of cases, reducing time to appropriate therapy by 31 hours. They evaluated the efficacy and potential clinical impact of the Unyvero LRT BAL panel compared to conventional microbiological methods in 70 patients, including: Community-Acquired Pneumonia (CAP, 30), Hospital-Acquired Pneumonia (HAP, 15), Ventilator-Associated Pneumonia (VAP, 8), Aspiration Pneumonia (1), as well as non-pneumonia (16) patients. Analysis of retrospective chart reviews performed on these patients revealed that, based on conventional microbiological results, 38% were undertreated, 20% were overtreated, while only 23% were appropriately treated and 19% were appropriate without antibiotic treatment. The Unyvero LRT BAL results would have provided a basis to change antibiotic therapies to a more appropriate regimen faster, with 29% of cases having cause of escalation of therapy, 13% of cases having cause for de-escalation, and in 27% of cases antibiotic treatment would not have been indicated (vs. 19% based on culture results) which would have reduced unnecessary antibiotics in 8% of cases. Particularly of interest to this study were the inclusion of 9 patients that were determined to have *Pneumocystis jirovecii* pneumonia (PJI) via microscopy, and for whom Unyvero LRT BAL results demonstrated complete agreement with the diagnosis of PJP. In addition, Unyvero detected *Pneumocystis jirovecii* in a patient that was not conventionally diagnosed with PJP; however, further chart review demonstrated that the patient was newly diagnosed with HIV and was treated empirically with trimethoprim-sulfamethoxazole. It is important to note that *Pneumocystis jirovecii* is a non-culturable fungus, and in the absence of PCR testing, PJP diagnosis relies on microscopic examination of trophic forms or cysts, which is laborious and insensitive. The Unyvero LRT BAL panel includes rapid and reliable detection of *Pneumocystis jirovecii* in just 5 hours with only about 2 minutes of hands-on time.

During the Rapid Fire session of the World Microbe Forum 2021, Dr. Cory Hale, Infectious Disease Clinical Pharmacist, Penn State Health Milton S. Hershey Medical Center, Hershey, PA, presented on Unyvero LRT, titled "Antimicrobial Stewardship Opportunities Using Results from a Multiplex Molecular Lower Respiratory Tract Panel as Compared to Conventional Culture." Their data characterized the potential impact of Unyvero LRT on antibiotic therapy in patients being treated for pneumonia and retrospective chart reviews were performed in 92 of these patients (39 tracheal aspirates, 53 sputum specimens), including 51 (55.4%) critically ill ICU patients and 39 (42.4%) pediatric patients. They reported complete agreement between Unyvero LRT and culture results in 50% of cases, and in 45.7% of cases Unyvero yielded more information than culture, with *Stenotrophomonas maltophilia*, *Pseudomonas aeruginosa* and *Staphylococcus aureus* among the top 3 most frequently detected pathogens by Unyvero. Overall, antibiotic changes would potentially have been made in 31 (33.7%) of the patients based on the Unyvero panel results (13.0% de-escalations, 23.9% escalation of therapy). They concluded that "Decreased turnaround time of results provided by the Unyvero LRT could provide targeted coverage sooner and should be coupled with an antibiotic stewardship program to ensure antibiotic coverage is optimal and necessary."

In addition, two posters on the Acuitas AMR Gene Panel for Isolates were presented at this conference by Wadsworth Center, New York State

Department of Health (NYSDOH), Albany, NY, and their participating sites. Titled “Combating Antimicrobial Resistance in New York State with Public Health Partnerships,” this poster highlighted the collaboration project between the Wadsworth Center (WC) and OpGen, Inc. as part of the New York State Life Sciences Initiative, to demonstrate the benefit of a rapid molecular diagnostic assay in identifying relatedness of antimicrobial resistant (AR) organisms indicative of outbreaks or transmission. To assess this, all carbapenemase-producing carbapenem-resistant organisms (CP-CRO) culture isolates were run on the Acuitas AMR Gene Panel for Isolates and results were compared to whole-genome sequencing (WGS) performed at WC. The project included three pilot sites, Northwell Health, NYU Langone and Mount Sinai who submitted CRO isolates. The results demonstrated that the Acuitas AMR Gene Panel in conjunction with the Acuitas Lighthouse Software is a promising new test that may be used as a front-line tool in clinical settings for cluster detection and implementation of infection control. The second poster, titled “Comparative Analysis of a Carbapenemase-producing *Klebsiella pneumoniae* Outbreak in a New York State Healthcare Facility using Multiple Typing Methods” investigated a large outbreak of carbapenemase-producing carbapenem-resistant Enterobacteriaceae (CP-CRE) at a healthcare facility detected through the AR Laboratory Network using multiple molecular epidemiology typing methods, and concluded that the Acuitas AMR Gene Panel produced highly concordant results with WGS, and that these findings can be used to improve infection control practices in this and other facilities.

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 results of studies conducted by independent infectious disease professionals presented at a recent webinar and at the 2021 World Microbe Forum on OpGen’s Unyvero LRT BAL panel as well as the Acuitas AMR Gene Panel for Isolates (RUO) and their potential clinical benefits. 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, February 2021 Registered Direct and March 2021 warrant exercise and exchange, 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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