Key Publication of Clinical Study Demonstrates Unyvero Lower Respiratory Tract (LRT) Panel is Likely to Alter Antibiotic Management of Significant Numbers of Patients Presenting with Suspected Pneumonia

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- *Significant number of de-escalations (65.9%) could be made with high degree of clinical confidence when MRSA or Pseudomonas aeruginosa is not detected by the LRT Panel*
- *Unyvero LRT Panel had consistently a very high negative predictive value (97.9%)*
- *Unyvero LRT detected several key pathogens missed by culture that would have required specific antibiotic treatments*
- *The LRT Panel has the potential to lead to more effective antibiotic stewardship both in terms of regimen and duration*

GAITHERSBURG, Md., and HOLZGERLINGEN, Germany, Sept. 02, 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 the release of a new peer-reviewed publication that demonstrates the clinical utility of the Unyvero LRT panel and its potential impact on antibiotic use in hospitalized patients with suspected pneumonia compared to treatment directed based on microbiological culture results.

The study was led by investigators at Northwestern Memorial Hospital in Illinois and Beaumont Health in Michigan, who performed retrospective chart reviews on patients that had been enrolled at their respective institutions for the Unyvero LRT panel U.S. FDA clinical trial. The study was published in the *Journal of Diagnostic Microbiology & Infectious Disease* and found that the Unyvero LRT panel demonstrates consistently very high negative predictive value of 97.9%, allowing the potential for a significant number of de-escalations with a high degree of clinical confidence when MRSA or *Pseudomonas aeruginosa* are not reported by the LRT panel.

The study also demonstrates substantial advantages, including the ability of the Unyvero LRT panel to identify, in both bronchoalveolar lavage and endotracheal aspirate specimens, clinically important pathogens such as *Acinetobacter* spp., *Pneumocystis jirovecii* and *Stenotrophomonas maltophilia* missed by microbiological methods that would have required specific antibiotic treatments.

The study found strong, reliable performance of the Unyvero LRT panel on the enrolled patients:

- Antibiotics could have been narrowed in 65.9% of patients, of whom 69% had unnecessary MRSA coverage and 64% had unnecessary *Pseudomonas* coverage based on empiric antibiotic therapy.
- Antibiotics could have been broadened in 10.0% of cases.
- Antibiotics could have been optimized in 7.8% of patients through both de-escalation and expansion.
- In 3.1% of cases antibiotics could have been initiated.

In their publication titled "A Multiplex Polymerase Chain Reaction Assay for Antibiotic Stewardship in Suspected Pneumonia," the authors conclude that "The LRT Panel results could have changed the choice of antibiotic used in the majority of cases, potentially leading to more effective antibiotic stewardship both in terms of regimen and duration."

"Unyvero LRT is an important advancement in the diagnosis of lower respiratory tract infections such as pneumonia, and we are pleased to see robust data that demonstrates the clinical utility and the significant impact that Unyvero LRT panels can have on early diagnosis and proper choice of antibiotics – both of which are crucial for successful management of pneumonia, especially in urgent and difficult to treat cases," said Oliver Schacht, PhD, CEO of OpGen.

The Unyvero LRT and LRT BAL panels are FDA-cleared and detect 19 and 20 clinically relevant pathogens, respectively, and each detect 10 antibiotic resistance markers in less than five hours directly from native lower respiratory specimen with only around two minutes of hands-on time, compared to routine bacterial cultures that can take up to several days for confirmatory pathogen identification and antimicrobial susceptibility testing results. Unyvero LRT BAL is the only FDA-cleared lower respiratory tract infection panel that includes *Pneumocystis jirovecii,* a causative agent of Pneumocystis pneumonia (PJP) and a key fungal pathogen often found in immunocompromised patients that can be difficult to diagnose.

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 its 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 potential impact on antibiotic therapy regimen and clinical utility of the Unyvero LRT and LRT BAL cartridges. 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 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 realization of expected benefits of our business combination transaction with Curetis GmbH, 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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