Results from 1,400 Patient Sample Multicenter Study Published: Unyvero LRT BAL Panel Provides Accurate Detection in Bronchoalveolar Lavage Fluid, Allowing Enhanced Diagnosis of Lower Respiratory Tract Infections

December 17, 2020

- *Early diagnosis and proper choice of antimicrobials are crucial for successful management of pneumonia*
- *Study demonstrates Unyvero LRT BAL provides accurate detection of common agents of bacterial pneumonia and of Pneumocystis jirovecii in ~4.5 hours*
- *Performance data, comprehensive coverage and fast time to result of this panel suggest significant clinical value for choosing appropriate antibiotics and for antibiotic stewardship*

GAITHERSBURG, Md. and HOLZGERLINGEN, Germany, Dec. 17, 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, today announced the release of a new peer-reviewed publication that demonstrates that the Unyvero LRT BAL panel accurately detects 19 bacteria alongside *Pneumocystis jirovecii* and 10 antibiotic resistance genes directly from bronchoalveolar lavage fluid, allowing enhanced diagnosis of lower respiratory tract infections.

Performance of the Unyvero LRT BAL was evaluated against standard of care (SoC) microbiological testing, using 1,016 prospectively collected and 392 archived specimens from 11 clinical trial sites in the United States. The results of this FDA clinical study have now been published in the *Journal of Clinical Microbiology* and found that the Unyvero LRT BAL panel provides accurate detection of common agents of bacterial pneumonia and of *Pneumocystis jirovecii* with an overall high negative predictive value of 97.2% for pathogen detection on a per sample basis, potentially allowing for de-escalation of antibiotics. The overall positive percent agreement (PPA) and negative percent agreement (NPA) with culture for detection and identification of bacteria that grow in routine cultures were 93.4% and 98.3%, respectively, consistent with the Unyvero LRT performance that has been published recently by Mackenzie E. Collins and colleagues[1].

Furthermore, the PPA and NPA for detection of *P. jirovecii* were 100.0% (5/5) and 99.0% (99/100), respectively, for the prospective study arm for the subset of samples routinely tested by SoC methods. Nucleic acid amplification testing is a recommended approach for *P. jirovecii*, and the Unyvero LRT BAL is the only FDA-cleared lower respiratory tract panel that offers this testing. Detection with the Unyvero LRT BAL panel may be indicative of *P. jirovecii* pneumonia (PCP) that would otherwise remain undiscovered if only routinely ordered SoC tests are applied, especially in case of non-HIV patients. As the potential for PCP is often not even considered in such patients and may be rare, routine testing for *P. jirovecii*, provided by the Unyvero panel, may be beneficial, in particular for patients where the cause of pneumonia may be difficult to determine.

The study also demonstrates that Unyvero LRT BAL significantly increased the positivity rate of diagnostic testing. It enabled the identification of additional, clinically relevant pathogens such as *Acinetobacter* spp., *Staphylococcus aureus* and *Pseudomonas aeruginosa* in 21.7% of prospectively collected specimens that were missed by microbiological methods. The sensitivity and fast time to result of this panel suggest significant clinical value for choosing appropriate antibiotics and for antibiotic stewardship.

In their publication titled "Multicenter Evaluation of the Unyvero Platform for Testing Bronchoalveolar Lavage Fluid[2]," the authors note that "while BAL is considered an excellent specimen for the assessment of lower respiratory tract infections such as pneumonia, it aids in identifying causative organisms in only 50-70% of cases, with these values varying with both the type of pneumonia and the patient population." Culture yield can be low, especially in the context of prior antibiotic therapy. Infections with bacteria that do not grow in routine cultures, such as *Legionella* species or *Mycoplasma pneumoniae*, are often missed if specific testing is not performed. The Unyvero panel detects the most common species observed in hospital-acquired and ventilator-associated pneumonia patients in addition to *M. pneumoniae*, *Chlamydia pneumoniae*, *Legionella pneumophila*, and *Pneumocystis jirovecii*, as well as ten resistance markers, in less than 5 hours. The authors conclude that "Diagnosis of the etiology of pneumonia in clinical practice is challenging. The Unyvero LRT BAL gives the clinicians more data to guide them in their treatment choices."

A recent paper[3] looking at the potential for the Unyvero LRT panel to guide antibiotic therapy found that it could have changed management of 87.6% of all patients, including the possibility of antibiotic de-escalation in at least 66% or escalation in 10% of the cases.

"Unyvero Lower Respiratory Tract panels provide early information on the potential causative pathogens and their associated resistance markers, allowing faster antibiotic therapy decisions with coverage for the most prevalent bacteria and *Pneumocystis jirovecii* causing lower respiratory tract infections such as pneumonia. We are pleased to see compelling data on performance characteristics that demonstrates the diagnostic utility of Unyvero LRT BAL. Microbiological confirmation of severe pneumonia is a crucial step for tailoring antibiotic therapy but culture results often take several days. Unyvero LRT panels are culture-independent and provide the speed and sensitivity that may achieve more reliable identification of causative agents than culture, allowing clinicians to make more informed decisions about antibiotics use," said Faranak Atrzadeh, Chief Marketing and Scientific Affairs Officer of OpGen.

The Unyvero LRT and LRT BAL products are FDA-cleared multiplex PCR panels that allow rapid and comprehensive detection of 19 and 20 clinically relevant pathogens, respectively. They 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 also includes *Pneumocystis jirovecii,* a causative agent of *Pneumocystis* pneumonia (PCP) 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 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 a recent study of the Unyvero LRT-BAL panel. 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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[1] https://jcm.asm.org/content/jcm/58/5/e02013-19.full.pdf
[2] https://jcm.asm.org/content/early/2020/12/15/JCM.02497-20.abstract
[3] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7428672/

Source: OpGen, Inc.