# OpGen Announces Results from Successful Webinar on Bacterial Pneumonia Co-infections in COVID-19 Patients

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*Experts presented the results of their Unyvero studies and demonstrated:*

- *Distinguishing those COVID-19 ICU patients with bacterial superinfection early and accurately is crucial for patient management and antibiotic stewardship*

- *Unyvero detected bacterial pathogens up to 7 days earlier and would have enabled prompt and appropriate targeted antibiotics in 41.3% of cases and reduced time to appropriate therapy by 25.7 hours*

GAITHERSBURG, Md., April 12, 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 the results from the highly attended webinar titled "Pneumonia Diagnosis: Bacterial Superinfection in COVID-19 Patients", where two infectious disease experts presented their independent study results from the Unyvero Hospitalized Pneumonia (HPN) and Unyvero Lower Respiratory (LRT BAL) panels, respectively. Their studies demonstrated that syndromic testing of lower respiratory specimens with Unyvero HPN and LRT BAL panels can improve patient care and time to appropriate targeted antibiotic therapy in COVID-19 pneumonia patients, as well as in a non-COVID-19 population with suspicion of pneumonia, including *Pneumocystis jirovecii* Pneumonia (PJP).

Professor and Senior Consultant Physician Christian Giske (MD, PhD), at the Department of Laboratory Medicine, Karolinska Institutet, Stockholm, Sweden, discussed "Diagnosing bacterial pneumonia in COVID-19" in his presentation, and highlighted several important findings from his study and key advantages of the Unyvero HPN panel compared with conventional bacterial culture:

- Unyvero demonstrated higher diagnostic yield (25.3% more detections) than bacterial culture, including several key pathogens of concern such as *S. aureus*, *P. aeruginosa*, *S. marcescens*, *H. influenzae*, *K. oxytoca*, *S. maltophilia*. Notably, *S. maltophilia* was called out as an important target on the Unyvero panel because of its intrinsic resistance against many of the standard antibiotics.
- Analysis of chart reviews of patients that had multiple lower respiratory cultures ordered during the course of their hospital stay revealed two clinically important cohorts:
    - In Group 1, culture and Unyvero HPN results were 100% concordant on the first and all subsequent samples that had been ordered. The findings in this cohort demonstrated that Unyvero HPN would enable significantly more rapid detection of pathogens not covered by empiric therapy due to intrinsic resistance, i.e. *S. maltophilia*, or multidrug resistant organisms (MDROs), i.e. carbapenem-producers, within 5 hours vs. 2.5 days by culture.
    - In Group 2, Unyvero HPN detected bacterial pathogens up to 7 days earlier in patient samples that were initially negative by culture but subsequent cultures ordered during hospital stay were confirmed as positive for the same pathogen at a much later stage. As a consequence of lack of finding any microbial etiology by culture, this group of patients were exposed to longer duration of empirical antibiotic treatment. This group also had longer hospital length of stay (LOS), longer ICU LOS and longer VAP duration, which could have been shorter if antibiotics could have been tailored and targeted earlier. "The potential impact of Unyvero HPN in this group could be significantly greater than in Group 1," stated Prof. Giske, as he presented several clinical cases of patients with ongoing infection where culture exhibited intermittent detection of pathogen(s) impacted by antibiotics across serial sampling while Unyvero HPN demonstrated consistent and steady detection of these pathogen(s). Prof. Giske pointed out that similar findings were reported[1] by Pickens et al. where chart reviews were performed on 4 culture-negative *Acinetobacter* cases that Unyvero had reported positive for *Acinetobacter*, and subsequent cultures grew *Acinetobacter*. In these cases, empiric therapy did not adequately cover for *Acinetobacter* and all four patients died.

Prof. Giske concluded his presentation with the following remarks: 1) distinguishing those COVID-19 ICU patients with bacterial superinfection early and accurately is crucial for patient management and antibiotic stewardship; 2) Excellent NPV of 99.8% allows for a reduction in unnecessary antibiotics use; 3) Unyvero reduces diagnostic turnaround time to about 5 hours (vs. an average of 2.5 days for final culture results), and it can easily fit into a 24/7 lab workflow; and 4) Unyvero provides clinicians earlier data to inform antimicrobial decisions, especially in critically ill COVID-19 patients.

The second presentation focused on a number of clinical cases from the Unyvero LRT BAL study that exemplify the performance characteristics and potential clinical impact of this Unyvero panel in pneumonia diagnostic algorithms, presented by Drew Bell (PhD), Medical and Public Health Microbiology Fellow at Indiana University School of Medicine, Indianapolis, IN. The patient population in this study (n=63) included pneumonia: Community-Acquired Pneumonia (CAP, 27), Hospital-Acquired Pneumonia (HAP, 14), Ventilator-Associated Pneumonia (VAP, 8), Aspiration Pneumonia (1), as well as non-pneumonia (13) patients. Results of Unyvero LRT BAL were compared to conventional microbiological methods

including bacterial culture for pathogen identification and antimicrobial susceptibility testing, as well as microscopic examination for PJP.

Analysis of retrospective chart reviews performed on these patients revealed that, based on conventional microbiological results, 41% were undertreated, 19% were overtreated, while only 25% were appropriately treated and 16% were appropriate without antibiotic treatment. In contrast, the study demonstrated that using the Unyvero LRT BAL panel would have enabled prompt and appropriate targeted antibiotic therapy in 41.3% of cases, including escalations (i.e. detection of *S. aureus* and *mec*A 11 to 18 hours earlier than culture), and de-escalations (i.e. detection of *M. catarrhalis*, which would have enabled de-escalation from piperacillin/tazobactam and azithromycin to amoxicillin clavulanate in just 5 hours), and reduced time to appropriate therapy by 25.7 hours.

This presentation also called out the fact 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. Clinical cases were presented which demonstrated the rapid and reliable detection of *Pneumocystis jirovecii* using the Unyvero LRT BAL panel in just 5 hours with only about 2 minutes of hands-on time.

Key comments and concluding remarks from Dr. Bell were that, “Implementing rapid molecular testing for lower respiratory specimen assessment algorithms can lead to faster identification and decrease time to appropriate escalation and de-escalation of antibiotic therapies. The Unyvero LRT BAL panel includes fastidious organisms, as well as organisms that are difficult to culture or completely unculturable, and the minimal amount of hands-on time is a big benefit.” In addition, he noted that “the Unyvero LRT BAL panel provides a notable improvement in diagnosis of PJP.”

A recording of this webinar can be accessed at OpGen.com.

**About Unyvero HPN and LRT BAL**

The Unyvero Hospitalized Pneumonia (HPN) panel detects 21 clinically relevant pathogens and 19 antibiotic resistance markers in less than five hours directly from native specimens 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. In the U.S., the Unyvero LRT and LRT BAL panels for rapid detection of lower respiratory tract infections such as pneumonia are FDA-cleared for tracheal aspirate samples and bronchoalveolar lavage fluids, respectively. Unyvero HPN and LRT BAL are the only syndromic multiplex PCR panels for lower respiratory tract infections that also include *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 studies conducted by independent infectious disease professionals presented at a recent webinar on OpGen’s Unyvero HPN and Unyvero LRT BAL panels 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, February 2021, and March 2021 financings, 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://www.atsjournals.org/doi/abs/10.1164/ajrccm-conference.2018.197.1_MeetingAbstracts.A7770

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