OpGen Announces Publication of Results of Unyvero Hospitalized Pneumonia (HPN) Panel for Detection of Bacterial Respiratory Tract Pathogens from Serial Specimens Collected from Hospitalized COVID-19 Patients

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- *Results were published in the European Journal of Clinical Microbiology & Infectious Diseases*
- *Serial specimen analysis confirms correct detection of pathogens by Unyvero HPN*
- *Additional pathogens detected by Unyvero HPN confirmed in many instances by culture positivity for the same microorganism in another sample obtained from the same patient*
- *This observation highlights the ability of Unyvero HPN in detecting potential pneumonia pathogens earlier than culture*

ROCKVILLE, Md., June 22, 2022 (GLOBE NEWSWIRE) -- OpGen, Inc. (Nasdaq: OPGN, “OpGen” or “the Company”), 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 journal publication from a study conducted at Karolinska University Hospital (KUH), Solna, Stockholm, Sweden. The publication highlights the ability of the Unyvero Hospitalized Pneumonia panel in detecting potential pneumonia pathogens earlier than culture or very early during an infection.

The performance characteristics of the Unyvero Hospitalized Pneumonia panel, in comparison with microbiological culture for detection of bacterial pathogens from lower respiratory tract samples obtained from critically ill COVID-19 patients, were recently published[1] by the investigators at Karolinska Institute. The study results demonstrated that Unyvero HPN provides a higher diagnostic yield than bacterial culture. This enables reliable and rapid diagnosis of pathogens of concern in these patients directly from native lower respiratory tract samples, and provides identification of bacterial co-infections in hospitalized patients with COVID-19 pneumonia in just five hours.

In their new publication titled “Evaluation of a pneumonia multiplex PCR panel for detection of bacterial respiratory tract pathogens from serial specimens collected from hospitalized COVID-19 patients[2]”, the investigators conducted a follow-up study aimed to examine the concordant and discrepant results comparing the Unyvero HPN and culture results for detection of microorganisms from serial specimens collected from the same patient.

Sixty-nine samples obtained from 27 adult subjects (fifteen patients with two, nine patients with three, and three patients with four samples collected on separate days) admitted in the intensive care unit with COVID-19 were included. Data was categorized based on full concordance (results from Unyvero were identical for the presence or absence of one or more pathogens by culture), concordance by correlation (Unyvero was positive for a pathogen that was negative by culture from the same sample but was positive by culture in a previous or a subsequent sample from the same patient within ±7 days), partial concordance (Unyvero detected the same pathogens that were detected by culture plus additional pathogen(s) that were not detected by culture and failed achieving concordance by correlation), discordance (an on-panel pathogen was culture positive but was not detected by Unyvero; discordant results were also considered when a sample had only one pathogen detected by Unyvero but was not detected by culture), concordance and discordance (samples that were positive for more than one pathogen by Unyvero but was not detected by culture; one pathogen was concordant by correlation by culture in a previous or a subsequent sample from the same patient within ±7 days, the other pathogen was not detected by culture).

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[1] https://link.springer.com/content/pdf/10.1007/s10096-021-04194-6.pdf

[2] https://link.springer.com/content/pdf/10.1007/s10096-022-04466-9.pdf

Results were analyzed in two ways: The first evaluation (Evaluation I) was performed in a typical manner for a comparative study where Unyvero results were compared with culture results per subject. The second evaluation (Evaluation II) explored interpretation of Unyvero false positive results which were then corroborated by culture from a different sample taken at a later or at an earlier time point from the same patient. In this approach, all Unyvero false positives results were considered true positives, if culture confirmed this result for any other sample (collected at an earlier or later time point) from the same subject. The latter approach highlights an important point because published literature reports sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPV) comparisons with the assumption that conventional microbiologic techniques are 100% sensitive and specific when in fact microbiological culture is acknowledged to be far from being an optimal gold standard due to its diagnostic performance[3].

Several key findings emerged in this study:

- Unyvero detected at least one additional pathogen in 20/69 (29%) of the samples tested.
- The additional pathogens detected by Unyvero in 12/20 (60%) samples were detected by culture from a previous or a subsequent sample collected (± 7 days) and tested from the same subject in six samples each.
- This observation emphasizes the ability of the Unyvero panel in detecting a potential pneumonia pathogen earlier than culture or very early during an infection.

The investigators reported that Unyvero detected an additional pathogen from at least one sample collected from 14/27 (52%) patients. Among these 14 patients, 10 of them had exposure to antibiotics before the collection of samples for culture and it is plausible that the exposure to the antibiotics had a negative influence on the yield of the cultures from these samples. The authors conclude that “The additional pathogens detected by Unyvero HPN from a given lower respiratory tract sample could be confirmed in many instances by culture positivity for the same microorganism from a

previous or a subsequent sample obtained from the same subject. This observation underscores the ability of the Unyvero HPN in detecting a potential pneumonia pathogen earlier than culture and/or very early during infection."

Faranak Atrzadeh, OpGen's Chief Marketing and Scientific Affairs Officer commented: "The findings in this study highlight the accurate and reliable performance of the Unyvero Pneumonia panel and its diagnostic and clinical utility in detecting bacterial pneumonia earlier to enable more prompt and appropriate antibiotic treatment."

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[3] https://www.thelancet.com/journals/lanres/article/PIIS2213-2600(22)00086-8/fulltext

About Unyvero Lower Respiratory Tract and Hospitalized Pneumonia Panels
The Unyvero Hospitalized Pneumonia (HPN) panel detects 21 clinically relevant pathogens and 17 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. (Rockville, MD, USA) is a precision medicine company harnessing the power of molecular diagnostics and bioinformatics to help combat infectious disease. Along with our 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 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
This press release includes statements regarding the publication of results of a recent study of the Unyvero Hospitalized Pneumonia panel. 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, the success of our commercialization efforts, 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, the continued realization of expected benefits of our business combination transaction with Curetis GmbH, the continued impact of COVID-19 on the Company's operations, financial results, and commercialization efforts as well as on capital markets and general economic conditions, our ability to satisfy debt obligations under our loan with the European Investment Bank, the effect of the military action in Russia and Ukraine on our distributors, collaborators and service providers, our liquidity and working capital requirements, 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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