OpGen Announces Publication of Results from Major Clinical Study Using Unyvero Hospitalized Pneumonia (HPN) Panel in the Lancet Respiratory Medicine

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- *208 patients enrolled in a prospective, randomized, controlled, multicenter, interventional trial*
- *Unyvero reduced the use of inappropriate antibiotic therapy by 45%, shortened inappropriate antibiotic therapy by 39 hours, and reduced overall antibiotic therapy duration by 22.5%*
- *Unyvero results combined with antibiotic stewardship are efficient and safe in decreasing time on inappropriate antibiotic therapy in hospitalized patients with pneumonia at risk for Gram-negative bacteria*

ROCKVILLE, Md., May 26, 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 major investigator-initiated, multicenter, randomized, controlled and interventional trial conducted at two tertiary care centers in Switzerland (University Hospital of Basel and Kantonsspital St. Gallen). The trial demonstrates that using Unyvero HPN panel in hospitalized pneumonia patients for the examination of bronchoalveolar lavage (BAL) in combination with antibiotic stewardship decreases the duration of inappropriate antibiotic therapy of hospitalized patients with pneumonia at risk for Gram-negative bacteria and supports antibiotic de-escalation in 66% of patients.

In this publication titled “Fast multiplex bacterial PCR of bronchoalveolar lavage for antibiotic stewardship in hospitalized patients with pneumonia at risk of Gram-negative bacterial infection (Flagship II): a multicentre, randomized controlled trial[1],” the authors assessed the clinical utility and impact of the Unyvero panel in hospitalized adult patients with suspicion of pneumonia, a clinical indication for bronchoscopy and at risk for infection with Gram-negative bacteria. The primary study endpoint was duration of inappropriate antibiotic therapy defined as the time in hours on inappropriate antibiotic therapy from bronchoscopy to discharge or up to 30 days after bronchoscopy. Secondary endpoints were time to clinical stability, length of hospital stay in days, mortality within 30 days, adverse events (safety), and diagnostic performance of the Unyvero panel assessed for BAL compared with conventional microbiological testing.

A total of 740 patients with pneumonia were screened; 208 eligible patients were randomized of whom 100 were assigned to the intervention group (also referred to as the PCR group); in this intervention group, the BAL specimen was analyzed by conventional culture as well as determination of Gram-negative bacteria using the Unyvero HPN panel; the other 108 patients were randomized to the control group where the BAL sample was analyzed solely by conventional microbiology culture. The Unyvero results for Gram-negative bacteria were disclosed to the attending physician treating the patients in the intervention group approximately 5 hours after bronchoscopy.

Several key findings emerged:

- The duration of inappropriate antibiotic treatment was decreased by 39 hours in the PCR group; Unyvero reduced the duration of inappropriate antibiotic therapy to 47 hours (vs. 86 hours in the control group), $p<0.0001$. The low P-value suggests a high statistical significance of this result.
- Inappropriate antibiotic therapy was reduced by 45% in the Unyvero group ($p<0.0001$).
- The overall duration of antibiotic therapy was 22.5% shorter in the Unyvero group.
- Patients treated in the Unyvero group had a three times higher probability of appropriate antibiotic therapy ($p<0.0001$).
- A reduction in the use of broad-spectrum antibiotics or decreasing the amount of antibiotics in the Unyvero group did not have any adverse effects on clinical stability, ICU admission, hospital readmission or 30-day mortality, compared to the control group.
- Gram-negative bacteria in BAL were detected more commonly by Unyvero than conventional microbiological culture in 39 patients vs. in 30 patients, respectively.

On diagnostic performance, the authors commented that “the accuracy of bacterial PCR is usually measured using culture as the reference standard, although microbiological culture is far from being an optimal gold standard due to its diagnostic performance.” In this study, they showed that Unyvero has a higher sensitivity than conventional microbiological culture when clinical syndrome or imaging is used as the reference standard.

The authors concluded that “this study is the first multicenter, randomized controlled trial showing that results from a multiplex bacterial PCR panel of bronchoalveolar lavage incorporated into antibiotic stewardship translate into less inappropriate antibiotic therapy. Accordingly, the duration of inappropriate antibiotic therapy was reduced in the PCR group with no compromise in clinical outcomes, including time to clinical stability, length of stay in the hospital, and mortality.”

Faranak Atrzadeh, OpGen’s Chief Marketing and Scientific Affairs Officer commented: “Pneumonia caused by Gram-negative bacteria is often associated with poor diagnosis and a high mortality rate. This multicenter, randomized, interventional study demonstrates the importance of rapid and accurate molecular diagnostics and the significant and actionable impact of the Unyvero hospitalized pneumonia panel on timely initiation of antibiotic therapy in patients with pneumonia.”

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 clinical 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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[1] https://www.thelancet.com/journals/lanres/article/PIIS2213-2600(22)00086-8/fulltext

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