OpGen Announces Data from Prospective Randomized Controlled Multicenter Clinical Study Using the Unyvero HPN Panel for Hospitalized Patients with Suspicion of Pneumonia

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- Unyvero reduced the use of inappropriate antibiotic therapy by 45.1%

- Unyvero shortened inappropriate antibiotic therapy by 39 hours, and reduced overall antibiotic therapy duration by 22.54%

- 3 x higher probability of avoiding inappropriate antibiotic therapy in the patient group diagnosed by Unyvero

- 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., Sept. 15, 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 clinical data from an investigator-initiated and driven prospective randomized controlled multicenter study. Data on the Unyvero HPN was presented at the virtual European Respiratory Society (ERS) conference on September 7, 2021, and subsequently presented during a webinar held on September 14, 2021.

The webinar titled "Multiplex Bacterial PCR in Bronchoalveolar Lavage (BAL) - Does It Impact Inappropriate Antibiotic Use?" described the study which assessed the clinical utility and impact of the Unyvero panel in hospitalized adult patients with suspicion of pneumonia and a clinical indication for bronchoscopy and at risk for infection with Gram-negative bacteria. The primary study endpoint was duration of inappropriate antibiotic therapy.

740 patients were screened, of which 208 eligible patients underwent randomization; 100 patients were randomized to the intervention group (also referred to as the PCR group; BAL was analyzed by conventional culture as well as determination of Gram-negative bacteria using the Unyvero HPN panel), and 108 patients were randomized to the control group (BAL was analyzed solely by conventional culture). Within 4 hours after bronchoscopy Unyvero results were available and shared with the attending physician treating the patients in the intervention group.

Pulmonary physician Prof. Daiana Stolz, MD, MPH, FCCP, FERS, University Hospital Basel, Switzerland, presented a summary of the study results based on the primary endpoint and findings from several other measured metrics:

- Inappropriate antibiotic treatment was significantly shorter in the PCR group – Unyvero decreased the average duration of inappropriate antibiotic therapy from 86 hours in the control group to 47 hours in the PCR intervention group; the low P-value $p<0.0001$ suggests the robustness and high statistical significance.
- Inappropriate antibiotic therapy was reduced by 45.1% in the PCR group.
- Duration of antibiotic therapy altogether was reduced by 22.5% in the PCR group.
- Probability of avoiding inappropriate antibiotic therapy was 3 times higher in the patient group that was diagnosed by Unyvero.
- Clinical stability, including reaching clinical stability and/or being discharged, time to clinical stability or discharge, length of hospital stay, ICU admission, and 30-day mortality were assessed to determine if decreasing the amount of antibiotics or reduction in use of broad-spectrum antibiotics in the intervention group worsened patient outcomes, and the findings suggested that there was no significant difference in the two randomized groups.
- In terms of diagnostic performance, Gram-negative rods in BAL were detected more commonly by Unyvero PCR than conventional culture – 45 bacteria in 39 patients vs. 32 bacteria in 33 patients, respectively.

The study concluded that "The results of Unyvero combined with antibiotic stewardship is efficient and safe in decreasing time on inappropriate antibiotic therapy in hospitalized patients with pneumonia at risk for Gram-negative rods."

Faranak Atrzadeh, OpGen's Chief Marketing and Scientific Affairs Officer commented: "This multicenter randomized interventional study clearly demonstrates the clinical utility and actionable impact of the Unyvero HPN panel. Unyvero is a rapid and culture-independent comprehensive diagnostic tool to help with detection of lower respiratory tract bacterial infections or co-infections earlier in the hospital journey of severely ill group of patients in whom rapid and accurate detection is particularly critical to enable prompt and appropriate targeted antibiotic therapy to maximize treatment benefit, reducing adverse side effects and antibiotic resistance. We are excited about this data and the impact that the Unyvero lower respiratory panels together with antibiotic stewardship can make in daily clinical practice and in the management of these patients."

A recording of this webinar will be available at OpGen.com.

About Unyvero Lower Respiratory Tract 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 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

This press release includes statements regarding the clinical utility of the Unyvero Hospitalized Pneumonia panel based on the results of studies conducted by independent infectious disease professionals. 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, 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 our 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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