OpGen Products in Development to Address “Urgent Threat” Pathogens Highlighted in New CDC Report on Antibiotic Resistance Threats

November 19, 2019

GAITHERSBURG, Md., Nov. 19, 2019 (GLOBE NEWSWIRE) -- OpGen, Inc. (Nasdaq: OPGN) announced today that the Center for Disease Control (CDC) has released updated data increasing the number of deaths in the United States (U.S.) from antibiotic-resistant bacteria and fungi, and highlighting the continuing threat of rising antibiotic resistance. According to the CDC, these pathogens cause more than 2.8 million infections and 35,000 deaths in the U.S. each year. That means, on average, someone in the United States gets an antibiotic-resistant infection every 11 seconds, and every 15 minutes, someone dies[1]. OpGen’s products have been developed to help combat these growing threats. The Acuitas® AMR Gene Panel test, currently in development, is designed to help identify drug-resistant pathogens directly from urine as an aid in the diagnosis of urinary tract infections in under three hours. The Acuitas® Lighthouse Software, also in development, is currently being tested in a state-wide initiative to help quickly identify and track urgent threat pathogens.

Evan Jones, Chairman and CEO of OpGen, commented, “We applaud the CDC for continuing to focus on the growing challenge of antimicrobial resistant (AMR) pathogens. This new report highlights that there were nearly twice as many annual deaths as the CDC originally reported in 2013, which is why we are encouraged that our Acuitas® products can help address these rising threats.”

The Acuitas® AMR Gene Panel (Urine) test is being developed for patients at risk for complicated urinary tract infections (cUTI) and is designed to test for up to five pathogens and up to 47 antimicrobial (AMR) genes. When paired with the Acuitas® Lighthouse Software, OpGen believes the test will be able to help improve management of the more than one million patients in the United States with cUTI. Specifically, the Acuitas® AMR Gene Panel (Urine) test, in combination with the Acuitas® Lighthouse Software, both in development, can help test for and identify major concerns for hospital patients, including Carbapenem-Resistant Enterobacteriaceae (CRE), Multidrug-Resistant (MDR) *Pseudomonas Aeruginosa,* and Extended-Spectrum Beta-Lactamase (ESBL) Producing Enterobacteriaceae.

OpGen is conducting clinical trials in 2019 to support a submission for the direct-from-urine Acuitas AMR Gene Panel (Urine) test and for the Acuitas Lighthouse Software for antibiotic resistance prediction for the management of antimicrobial resistance data in healthcare institutions. Earlier this year, clinical trials were conducted for establishing the performance of the Acuitas AMR Gene Panel for use with bacterial isolates. Data obtained from the clinical trials were submitted in a 510(k) submission which is currently under review by the U.S. Food and Drug Administration (FDA).

About Carbapenem-Resistant Enterobacteriaceae (CRE), Multidrug-Resistant (MDR) *Pseudomonas Aeruginosa*

CRE are a major concern for patients in healthcare facilities. Some bacteria in this family are resistant to nearly all antibiotics, leaving more toxic or less effective treatment options. The 13,000 cases in hospitalized patients in the US in 2017[1] demonstrate the need for tests such as the Acuitas® AMR Gene Panel (Isolates) and tools such as the Acuitas® Lighthouse software for the management of antimicrobial resistance data. *Pseudomonas Aeruginosa* causes many types of healthcare associated infections, including pneumonia, bloodstream infections, urinary tract infections, and surgical site infections. The 32,600 estimated cases in hospitalized patients in 2017 resulted in 2,700 estimated deaths.

About Extended-Spectrum Beta-Lactamase (ESBL) Producing Enterobacteriaceae

ESBL-producing Enterobacteriaceae (a family of different types of bacteria) are a concern in healthcare settings and the community. They can spread rapidly and cause or complicate infections in healthy people. Annual cases have increased 33% since 2012 to 197,400 with 9,100 deaths[1]. ESBL *E. Coli* have been increasing rapidly in cUTI patients highlighting the growing need for rapid, accurate detection and decision-making technology.

About OpGen

OpGen, Inc. is a precision medicine company harnessing the power of molecular diagnostics and informatics to help combat infectious disease. We are developing molecular information products and services for global healthcare settings, helping to guide clinicians with more rapid and actionable information about life threatening infections, improve patient outcomes, and decrease the spread of infections caused by multidrug-resistant microorganisms, or MDROs.

Our molecular diagnostics and informatics products, product candidates and services combine our Acuitas molecular diagnostics and Acuitas Lighthouse informatics platform for use with our proprietary, curated MDRO knowledgebase. We are working to deliver our products and services, some in development, to a global network of customers and partners. The Acuitas AMR Gene Panel (RUO) is intended for Research Use Only and is not for use in diagnostic procedures. The Acuitas Lighthouse Software is not distributed commercially for antibiotic resistance prediction and is not for use in diagnostic procedures. For more information, please visit www.opgen.com.

Forward-Looking Statements

This press release includes statements relating to updated CDC data highlighting the continued threat of rising antibiotic resistance and OpGen’s products in development to help address such threat. 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, advance our current and planned 510(k) clearance submissions with the FDA, and continue our activities under the New York State Infectious Disease Digital Health Initiative.

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 (SEC). 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.

[1] CDC. Antibiotic Resistance Threats in the United States, 2019. Atlanta, GA: U.S. Department of Health and Human Services, CDC; 2019.

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Source: OpGen, Inc.