OpGen Receives Regulatory Approval to Market Pathogen Identification Products in Colombia

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Approval gives OpGen its first commercial product in the region; paves way for broader expansion into South American markets

GAITHERSBURG, Md., Dec. 04, 2018 (GLOBE NEWSWIRE) -- OpGen, Inc. (Nasdaq: OPGN) announced today it has received approval from the Instituto Nacional de Vigilancia de Medicamentos y Alimentos (INVIMA), Colombia's regulatory authority for food, drugs, and medical devices, to market its rapid pathogen identification products in the country.

Earlier this year OpGenestablished a subsidiary, OpGen Colombia, SAS, to commercialize the Company's precision medicine products in Colombia and more broadly through South America. The approval of QuickFISH®, which is already cleared by the U.S. Food & Drug Administration and identifies pathogens in 20 minutes in positive blood culture, is a significant milestone for the Company's expansion into the Latin American markets.

"We are proud to receive regulatory approval from INVIMA to begin the sale of our suite of QuickFISH pathogen identification products in Colombia," said Evan Jones, CEO, OpGen, Inc. "This milestone represents a significant step for the Company as we seek to support our growth initiative in South America, and will serve as a market indicator for further expansion and commercialization of our Acuitas® antibiotic resistance detection product offerings."

The approval follows a successful study using QuickFISH. The study was conducted with Maria Virginia Villegas, M.D, M.Sc., of Universidad El Bosque, the Bacteria Resistance and Hospital Epidemiology, Centro Internacional de Entrenamiento e Investigaciones Medicas (CIDEIM), Cali, Colombia and four Colombian acute care hospitals. OpGen received positive feedback from the hospitals and the study results, which demonstrated a 57% improvement in survival rate and reductions in antibiotic usage for patients tested with the rapid diagnostic test, were presented at ASM Microbe 2018. Publication of the study is expected in 2019.

OpGen continues its Center for Disease Control (CDC) funded collaboration to develop clinical support tools for antimicrobial stewardship and infection control for low and middle-income countries. Evaluation of the new software is underway in Colombia.

About OpGen

OpGen, Inc. is harnessing the power of informatics and genomic analysis to provide complete solutions for patient, hospital, and network-wide infection prevention and treatment. For more information, please visit www.opgen.com.

Forward-Looking Statements

This press release includes statements relating to OpGen's plans to commercialize its rapid pathogen identification products in Latin American markets, starting in Colombia. 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 success of our commercialization efforts, 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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