



## OpGen Subsidiary Curetis and BioVersys Sign Collaboration Agreement for Clinical Trial Support

October 25, 2022

- *Unyvero platform for rapid diagnostics to be used in Phase II clinical trial of BV100*
- *Focus on the detection of pneumonia patients infected with *Acinetobacter baumannii**

ROCKVILLE, Md. and BASEL, Switzerland, Oct. 25, 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, and BioVersys AG, a privately-held clinical stage, multi-asset Swiss pharmaceutical company focusing on research and development of small molecules for multidrug-resistant bacterial infections with applications in antimicrobial resistance (AMR) and targeted microbiome modulation, today announced the signing of a collaboration agreement for the deployment and use of the Unyvero platform in BioVersys' upcoming Phase II clinical trial of novel drug candidate BV100.

BV100 is a much-needed injectable formulation of rifabutin to treat serious infections caused by Carbapenem Resistant *Acinetobacter baumannii* (CRAB) in patients with ventilator-associated bacterial pneumonia (VABP), hospital-acquired bacterial pneumonia (HABP) and bloodstream infections (BSI). Today, mortality is typically around 50% in these patients and there are little to no effective and safe treatment options.

In the planned Phase II clinical trial, hospital sites will be using the Unyvero HPN for hospitalized pneumonia patients as a rapid diagnostic test to help optimize enrollment. Unyvero HPN allows the detection of not only *Acinetobacter baumannii* but a broad array of many pathogens as well as AMR markers that provides the broadest set of carbapenemase resistance markers available in an integrated pneumonia cartridge.

To ensure smooth and seamless operations, the Curetis team will train a team of trainers at BioVersys and their clinical research organization (CRO) for the Phase II trial. BioVersys will rent the Unyvero systems for the duration of the trial and will purchase the pneumonia cartridges and all consumables for the rapid diagnostics from Curetis. All data pertaining to the clinical trial will be owned by BioVersys and can be used in their future clinical development and regulatory submissions as needed.

Dr. Marc Gitzinger, Chief Executive Officer and founder of BioVersys commented: "Rapid diagnostics such as the Curetis Unyvero platform are increasingly becoming integral to clinical trials operational excellence in AMR, along with the urgent need to develop novel patient orientated solutions for the most difficult to treat infections. BioVersys is pleased to partner with Curetis, as we rapidly develop BV100 to address the unacceptably high CRAB mortality rate due to the lack of safe and efficacious treatment options for these patients."

Oliver Schacht, PhD, Chief Executive Officer of OpGen Inc. added: "The entire OpGen and Curetis team is excited to begin our collaboration with BioVersys and support their Phase II clinical trial of BV100 with our Unyvero platform. With Unyvero being the first to market CE IVD marked and FDA cleared sample to answer platform to offer a comprehensive and uniquely differentiated pneumonia panel and the broadest panel of AMR markers, we believe that there will be significant value added to patient selection and enrollment into the trial. It adds to the growing body of clinical evidence demonstrating the benefits of rapid pneumonia testing in hospitalized patients, also for pharmaceutical and biotech companies and their clinical trials."

### About BioVersys

BioVersys AG is a privately owned clinical stage Swiss pharmaceutical company focusing on research and development of small molecules acting on novel bacterial targets with applications in antimicrobial resistance (AMR) and targeted microbiome modulation. With the company's award-winning TRIC technology we can overcome resistance mechanisms, block virulence production and directly affect the pathogenesis of harmful bacteria towards the identification of new treatment options in the antimicrobial and microbiome fields. By this means, BioVersys addresses the high unmet medical need for new treatments against life-threatening resistant bacterial infections and bacteria-exacerbated chronic inflammatory microbiome disorders. Our most advanced research and development programs address nosocomial infections of *Acinetobacter baumannii* (BV100, Phase II-ready), and tuberculosis (BVL-GSK098, Phase II-ready) in collaboration with GlaxoSmithKline (GSK) and a consortium of the University of Lille. BioVersys is located in the Technologiepark in the biotech hub of Basel.

For more information, please visit [www.bioversys.com](http://www.bioversys.com).

**About OpGen, Inc.** OpGen, Inc. (Rockville, MD, U.S.A.) 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 current product portfolio includes Unyvero, Acuitas AMR Gene Panel, and the ARES Technology Platform including ARESdb, NGS technology and AI-powered bioinformatics solutions for antibiotic response prediction including ARESiss, ARESid, and AREScloud, as well as the Curetis CE-IVD-marked PCR-based SARS-CoV-2 test kit.

For more information, please visit [www.opgen.com](http://www.opgen.com).

### Forward-Looking Statements

This press release includes statements regarding the collaboration agreement entered into by OpGen's subsidiary Curetis GmbH and BioVersys AG for their BV100 phase II clinical trial. 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.

**OpGen:**

Oliver Schacht  
President and CEO  
[InvestorRelations@opgen.com](mailto:InvestorRelations@opgen.com)

**OpGen Press Contact:**

Matthew Bretzius  
**FischTank Marketing and PR**  
[matt@fischtankpr.com](mailto:matt@fischtankpr.com)

**OpGen Investor Contact:**

Alyssa Factor  
**Edison Group**  
[afactor@edisongroup.com](mailto:afactor@edisongroup.com)

**BioVersys contacts**

**Eliane Schmidt**  
Executive Assistant to CEO  
Tel. +41 61 633 22 50  
[info@bioversys.com](mailto:info@bioversys.com)



Source: OpGen, Inc.