GangaGen Presents New Preclinical Data on P128 Showing Broad Efficacy Against Drug-Resistant Bacteria at ASM Microbe 2017

-GangaGen's novel ectolysin, P128, shows robust efficacy against multiple drug-resistant strains of S. aureus and coagulase-negative Staphylococci

-P128 shows in vivo efficacy in rescuing animals from fatal MRSA bacteremia

-P128 shows synergistic efficacy with standard of care antibiotics against antibiotic-resistant strains

UNITED STATES,2 JUNE 2017 – GangaGen Inc., a biotechnology company developing novel therapeutic proteins for infectious diseases, today announces new preclinical data on P128, a phage-derived ectolysin that targets S*taphylococcus* bacteria. The data were presented at the American Society for Microbiology's ASM Microbe 2017 conference, taking place 1-5 June 2017 in New Orleans, Louisiana. Three poster presentations build further support for P128 efficacy against S*taphylococcus* bacteria, including strains showing resistance to frequently prescribed antibiotics such as daptomycin.

"Our growing body of positive preclinical research deepens our understanding of the potential of P128 alone or in combination with standard of care antibiotics to enhance the outcomes for patients with hard-to-treat systemic infections," said **Dr. T.S. Balganesh, President of GangaGen.** "P128 showed activity against *S. aureus* resistant to methicillin, daptomycin, vancomycin, and linezolid, commonly prescribed antibiotics for which resistance is a serious clinical concern. P128 is the only product in its class to report this breadth of efficacy against these key drug-resistant *S. aureus* strains as well as efficacy on daptomycin-resistant *S. epidermidis*, a coagulase-negative *Staphylococcus* (CoNS) species with known involvement in hard-to-treat biofilm infections. Additionally, these data showed that P128 reverses antibiotic resistance when used in combination with low doses of antibiotics to treat infections in which the antibiotics alone are not effective due to drug resistance. We are very encouraged by these data and are prioritizing work towards a clinical program for P128 against systemic *Staphylococcus* infections."

Bharathi Sriram, Vice President of Research and Development at GangaGen, continued: "We are excited about the breadth and consistency of *in vitro* and *in vivo* data on P128 showing rapid impact against these serious bacterial infections. Without exception, P128 has proven to be effective on *Staphylococcus* bacteria, including on drug-resistant strains and biofilm models. Further, P128 has demonstrated potent efficacy in rescuing animals from fatal MRSA bacteremia."

Poster Title: Reversal of Drug Resistant Phenotype of *Staphylococcus* Clinical Strains by Synergistic Action of P128 and Antibiotics
Date and time: 2 June 2017, 12:45-14:45 EST
Key Highlights:

- The addition of P128 to sub-therapeutic doses of vancomycin, linezolid, daptomycin, or ciprofloxacin could effectively inhibit the growth of clinically relevant *S. aureus* strains which were individually resistant to these drugs
- P128 showed synergistic bactericidal activity in combination with standard of care antibiotics, irrespective of antibiotic class, resulting in reversal of drug resistant phenotype
- In a mouse model of MRSA bacteremia, 81% of mice treated with P128 in combination with oxacillin survived, compared to 31% and 50% survival of mice treated with sub-therapeutic doses of oxacillin or P128 alone, respectively
- The results and impact on drug-resistant strains of *S. aureus* and *S. epidermidis* were replicated in biofilm models, recognized as having an important role in recalcitrant disease

Poster Title: Preclinical Studies of Anti-*Staphylococcal* Ectolysin P128 for Potential Systemic Hypersensitivity and Evaluation of Efficacy in *Staphylococcus aureus* Bacteremia with Renal Abscesses in Rats
Date and time: 2 June 2017, 12:45-14:45 EST

Key Highlights:

- No Type I or Type III systemic hypersensitivity was seen in animals upon re-exposure to P128 at all three dose levels tested (0.6, 6.0 and 12.0 mg/kg)
- Intravenous administration of doses of P128 as high as 12.0 mg/kg did not result in toxicity
- P128 was effective in lowering a high bacterial count in the kidneys, preventing renal abscess formation in the animals
- P128 rescued animals from fatal systemic MRSA infection

Poster Title: Pharmacokinetics and Efficacy of P128 in a Mouse Model of Systemic Methicillin Resistant *Staphylococcus aureus* (MRSA) Infection
Date and time: 2 June 2017, 12:45-14:45 EST
Key Highlights:

- P128 showed rapid antibacterial activity after a single intravenous dose in neutropenic mice, with maximum bactericidal effect within 30 minutes of administration
- P128 showed dose-dependent antibacterial activity following single IV bolus doses at 10, 30 and 60 mg/kg
- Animals treated with 30 or 60 mg/kg doses showed a decrease in circulating colony-forming units (CFU) of at least two orders of magnitude compared to untreated animals (10^4 – 10^6CFU/ml compared to 10^7 – 10^8 CFU/ml in untreated animals)
- P128 showed potential as standalone therapy or combination with standard of care antibiotics due to the rapid killing of MRSA bacteria

Copies of the posters containing the relevant information are available on the GangaGen website.

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About P128

P128 is an ectolysin, a proprietary phage-derived protein with a novel mechanism of action that allows it to rapidly and specifically kill *Staphylococcus* bacteria, including drug resistant strains such as methicillin-resistant *Staphylococcus aureus* (MRSA) and coagulase-negative *Staphylococci* (CoNS). Due to its novel mode of action, no naturally occurring resistance to P128 has been detected. To date, P128 has been shown *in vitro* to effectively kill over 120 strains of *S. aureus*, representing more than 3,000 isolates, and has demonstrated a similar level of efficacy against CoNS, which are associated with serious device-associated infections in hospitals. P128 is also active against *Staphylococci* in biofilms. The unique mechanism of P128 allows it to kill the bacterium without needing to enter the cell, allowing it to act rapidly and to kill bacteria present in biofilms. P128's specificity allows it to kill *Staphylococcus* bacteria without disrupting beneficial bacterial flora.

About GangaGen, Inc.

GangaGen, Inc. is a biotechnology company focused on developing novel therapeutic proteins targeting infectious diseases in areas of high unmet need such as MRSA and other drug resistant bacteria. GangaGen is based in the United States with research facilities in Bangalore, India. For more information, please visit www.gangagen.com.