GangaGen Presents New Preclinical Data on P128 at ECCMID 2017 Showing Potent Bactericidal Activity Against MRSA and Other *Staphylococci*

-Novel ectolysin targets Staphylococcal infections, including drug resistant strains such as MRSA

-Rapidly kills Staph bacteria including antibiotic tolerant persister cells and those present in biofilms in all strains tested

-P128 shows efficacy alone and synergizes with standard of care antibiotics

UNITED STATES [22 APRIL 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 27th European Congress of Clinical Microbiology and Infectious Diseases (ECCMID) in Vienna, Austria. Four oral and poster presentations provide supporting data for P128 efficacy against S*taphylococcus* bacteria, including methicillin resistant S*taphylococcus aureus* (MRSA) and coagulase negative *Staphylococci* (CoNS).

P128 has demonstrated efficacy against all 120 strains of *S. aureus* tested *in vitro*. In these data, P128 demonstrated equal efficacy against CoNS species, which are increasingly recognized as causing serious disease. Recently CoNS, which account for a large number of hospital acquired bloodstream infections, have shown alarming resistance to drugs such as vancomycin, daptomycin and linezolid, making the need for new treatments urgent. Currently, there are no other lysins in development that have been reported to show rapid and comprehensive effect of P128 against all tested *Staphylococci* strains.

"The data on P128 stand out because they reveal the molecule's potential for difficult-to-treat infections, even against persister cells or when the bacteria are present in a biofilm. Notably, P128 demonstrated efficacy both alone and in combination with standard of care antibiotics suggesting that it can be developed in clinically meaningful settings where there is crucial unmet need," said **Aradhana Vipra, Head of Microbiology at GangaGen and co-author of the posters.** "P128 was also able to rapidly kill bacteria present in biofilms. These data sets, viewed comprehensively, support P128's overall profile and potent activity alone or in combination with commonly used drugs and make it a strong candidate for development to address serious infections."

Dr. T.S. Balganesh, President of GangaGen, continued: "The data presented this year at ECCMID continue to build on the body of scientific evidence demonstrating the unique characteristics of P128. These data are especially encouraging as we consider our future development plans for P128. On the basis of these robust data, we are prioritizing the development of P128 in systemic indications to address the growing threat of antibiotic resistance and dire outcomes for patients."

Oral presentation: Eradication of coagulase negative S*taphylococcal* biofilms by P128 alone and synergistic inhibition in combination with antibiotics

Key highlights:

- P128 is the first compound in development to report anti-biofilm activity *in vitro* alone and in combination with standard of care (SoC) antibiotics in multiple CoNS biofilm models, showing potent inhibition of bacterial growth even at low concentrations
- P128 shows synergistic or additive activity against CoNS biofilms when used in combination with current SoC antibiotics
- P128 rapidly eradicates biofilms from the surface of catheters

Poster presentation: Bactericidal activity of P128 on coagulase negative S*taphylococci* alone and in combination with antibiotics

Key highlights:

- P128 effectively kills multiple species and strains of CoNS including *S. epidermidis*, a known cause of difficult-to-treat device associated infections
- Time kill kinetics (TKK) data showed that P128 caused rapid loss of viability in all CoNS strains tested

- These results in CoNS are comparable to the results seen with P128 on MRSA strains

Poster presentation: *In vivo* synergy and efficacy of P128 in combination with standard of care antibiotics in methicillin resistant *Staphylococcus aureus* (MRSA) bacteremia
Key highlights:

- P128 was synergistic *in vivo* with the SoC antibiotics vancomycin and daptomycin in rodent models of MRSA bacteremia
- At least 80% of untreated mice succumbed to MRSA infection within 72 hours; P128 alone resulted in greater than 50% survival
- P128 in combination with vancomycin and daptomycin resulted in 85% and 88% survival, respectively; vancomycin and daptomycin alone each showed a 46% survival rate
- P128 and SoC antibiotics individually were effective at higher doses, but P128 demonstrated synergy with sub-MIC doses of antibiotics and significantly increased survival when used in combination

Poster presentation: Killing of persisters, stationary phase and starved cells of MRSA and coagulase negative S*taphylococci* by anti-S*taphylococcal* protein P128
Key highlights:

- Persisters, recognized as a major factor in recurrent and difficult-to-treat infections, are non-dividing cells that survive treatment by antibiotics and which show phenotypic resistance to antibiotics, but can revert to active growth when the antibiotic is removed
- P128 showed potent bactericidal activity on persister cells of MRSA or CoNS which were not killed by high concentrations of vancomycin or daptomycin.

Full details on the presentations, including electronic copies of the oral and poster presentations are available on the ECCMID website at http://www.eccmid.org/.

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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.