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From discovery to preclinical study of N-Rephasin® SAL200: A novel antibacterial drug for multidrug-resistant *Staphylococci*-associated infections

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Statement of the Problem: Emergence and dispersal of multidrug-resistant *Staphylococcus aureus* (SA) (MRSA) are rapid and wide, necessitating an invention of novel class of MRSA-controlling effective antimicrobial drug that is not likely to induce a resistance. This presentation describes our 15 year-long experience in development of a bacteriophage-derived endolysin as promising new antibiotics.

Materials & Method: A bacteriophage SAP-1 specifically infecting SA was isolated from sewage water. Whole genome sequencing revealed typical genomic structure of lytic bacteriophage and identified putative peptidoglycan (PG) hydrolase gene encoding SAL-1 endolysin. The wild type SAL-1 with no extraneous amino acids was highly purified in compliance to a Good Manufacturing Practice (GMP) standard and further formulated to N-Rephasin® SAL200.

Findings: SAL200 showed to have unique modes of action: It potently and specifically killed planktonic and encapsulated SA as well as biofilm-producing SA cells, but not for other species. SAL200 exhibited strong bactericidal activity against more than 425 clinical isolates including 1 vancomycin-intermediate SA and 336 methicillin-resistant SA isolates. It directly bound to and lysed SA as quickly as within ten minutes and apparently did not induce an emergence of any resistant SA strains from 30-times repeated exposure at sub-lethal concentrations. Intravenous injection of SAL200 significantly prolonged survival of mice and reduced viable bacterial counts in MRSA infection mouse model. Further safety evaluation studies for rodents, dogs and monkeys showed neither death nor severe adverse events. Any abnormal findings-if any- were tolerable and transient.

Conclusion: The SAL200 specifically lysed SA strains including antibiotic-resistant SA strains *in vitro* and *in vivo* with excellent *in vivo* safety.

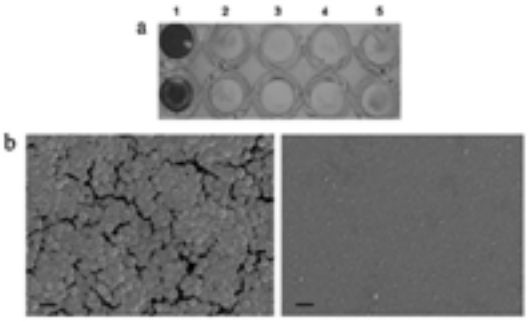

Fig. 1. Examination of the Staphylococcus aureus biofilm removal activity of SAL200. Biofilms of S. aureus SA1 were treated with SAL200 and biofilm removal was examined by (a) safranin staining and (b) scanning electron microscopy.

Biography

Myung-Soo Kang has earned his BS to PhD degrees from Department of Biology at Seoul National University, Korea. After his PhD, he did his Postdoctoral Research Fellowship at Department of Microbiology and Molecular Genetics, Harvard Medical School/Brigham and Women's Hospital. He then joined as a Professor and Faculty at Samsung Medical Center, Center for Future Medicine. Since 2016, he has been a Chief Scientist and Vice Director of Institute of iNtRON Biotechnology. He is interested in development of bacteriophages and phage –derived bio drugs for effectively controlling bacterial infections.

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