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CrystalGenomics antibiotic gives positive results in trial

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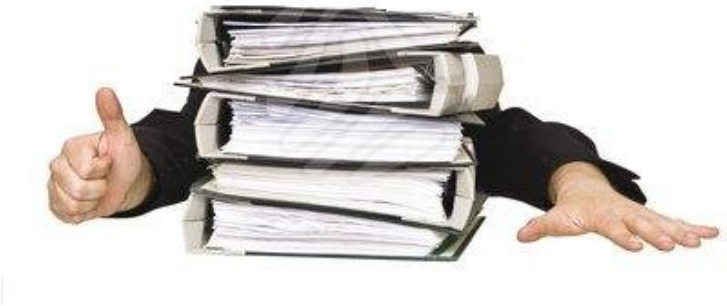
CrystalGenomics antibiotic for MRSA gives positive results in clinical trial



Singapore: CrystalGenomics, a clinical stage biopharmaceutical company headquartered in Korea, has received the draft of the clinical study report from the recently completed phase IIa study of CG400549, a first-in-class antibiotic candidate for Methicillin-resistant Staphylococcus aureus (MRSA).

This study was the first human efficacy study for CG400549 and was an open-label, exploratory study to evaluate the safety, pharmacokinetics, and efficacy of 960 mg of CG400549 orally administered, once daily for 10 to 14 days, in subjects with complicated acute bacterial skin & skin structure infections (cABSSSI) caused by MRSA. All subjects received active treatment of CG400549 and there were no active comparators in the study. The primary efficacy parameter was evaluated at the Early Clinical Evaluation (ECE) point, between 48-72 hours of treatment initiation per new FDA recommendations.

Antibacterial resistance is a serious global health issue. Infections caused by antibiotic-resistant Staphylococcus aureus, such as MRSA, has been increasing significantly and a 2007 report on "Emerging Infectious Diseases", a publication from the Center for Disease Control and Prevention (CDC), estimated that the number of MRSA infections in hospitals doubled nationwide, from 127,000 in 1999 to 278,000 in 2005. Annual deaths from MRSA increased from 11,000 to more than 19,500 during that same span.

The top-line data revealed that at the ECE visit, 90.9 percent of subjects were considered to be stable or improving in the investigator's assessment, meeting the primary efficacy endpoint of the study. The study also met its secondary endpoints.

In terms of safety, there were no deaths, serious adverse events or discontinuations due to adverse events and most of the adverse events were considered unrelated to the study drug. Also, there were no abnormal findings on vital signs, ECG, or physical examination that suggested safety risks for the use of CG400549.

Dr Joong Myung Cho, president & CEO, CrystalGenomics, stated, "We are very pleased with the results from our first human efficacy study as no one else has yet to confirm human efficacy with FabI inhibitors as an antibiotic agent. Based on currently available data, the biggest advantages of CG400549 over the Standard of Care (SOC) anti-MRSA therapeutics are its novel

drug target, new chemical class, and once-a-day formulation. However, if we can show that the safety profile of our drug is better than the SOC such as linezolid and vancomycin, CG400549 may become an excellent alternative for those patients who are restricted from using SOC due to safety concerns."