



aRigen, Inc.

Press Release

aRigen, Japanese Bioventure Company, Announces Start of US Clinical Study of Novel Anti-Staph Antibiotic By Catalyst (CRO)

aRigen initiates clinical development activities in the United States

San Antonio, Texas--(BUSINESS WIRE)—September 21, 2004--aRigen Inc. (aRigen) a privately held, bioventure company headquartered in Tokyo, Japan announced initiation of their Phase I, single dose study of WAP 8294A2 (WAP). WAP has a unique mechanism of action and potent antimicrobial efficacy against methicillin-resistant *Staphylococcus aureus* (MRSA) and other drug resistant strains.

This double-blind, randomized, study is the first human study with WAP, and is designed to provide information on the safety and tolerability, and pharmacokinetic profile of the compound as an intravenous infusion. According to Gensuke Tokoro, CEO of aRigen, " This first clinical test is an important milestone for our company and demonstrates our ability to develop novel anti-infective compounds outside of Japan that can meet FDA requirements for clinical development. The data from this study will be assessed in order to guide future development." The study is being conducted at Healthcare Discoveries Inc. of San Antonio, Texas, a subsidiary of Catalyst Pharma Group, Inc.

About WAP-8294A2 (WAP)

WAP is a novel depsipeptide antibiotic, which has high potency against *Staphylococcus aureus* (*staph*), a type of bacteria commonly found on the surface of the skin. WAP appears to achieve bactericidal activity by selective interaction with phospholipids in the target cell membrane, resulting in membrane damage and subsequent bacterial cell death. WAP was originally discovered by Wakamoto Pharmaceutical Co. of Japan. All rights for future development of WAP have been assigned to aRigen. Potential indications for future development plans include uncomplicated and complicated skin and superficial skin structure infections, septicemia, endocarditis, and osteomyelitis due to staphylococcus.

About Staphylococcus Aureus (Staph)

According to the Centers for Disease Control (CDC), "*Staphylococcus aureus*, often referred to simply as "staph," are bacteria commonly carried on the skin or in the nose of healthy people. Occasionally, staph can cause an infection; staph bacteria are one of the most common causes of skin infections in the United States." Staph also causes serious infections (such as surgical wound infections and pneumonia). Over the past 50 years, treatment of these infections has become more difficult because staph has become resistant to various antibiotics, including the commonly used penicillin-related antibiotics.

About aRigen Inc.

aRigen acquires and develops under valued assets from Japanese pharmaceutical firms, public research institutes and universities. In a few short years, aRigen has acquired a large product portfolio, with several products rapidly advancing into clinical development.

About Catalyst Pharma Group (CPG)

CPG provides contiguous and integrated clinical development programs from IND to NDA for Japanese pharmaceutical and biotech companies interested in entering the US market. CPG has three subsidiaries, Catalyst Pharmaceutical Research LLC, a premier clinical research organization (CRO), and Healthcare Discoveries Inc., a high-quality 50+ bed Phase 1 unit and Adept LTD, a UK based project management team.

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