

Kenta Biotech Obtains FDA Orphan Drug Designation for Human Monoclonal Antibody against Pseudomonas Pneumonia

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Kenta Biotech Ltd. announced today the United States Food and Drug Administration (FDA) has granted „Orphan Drug“ designation to Kenta Biotech’s fully human monoclonal antibody KBPA 101, for the treatment of nosocomial pneumonia caused by serotype O11 *Pseudomonas aeruginosa*.

KBPA101 is the first fully human monoclonal antibody in development against serotype O11 *Pseudomonas aeruginosa* pneumonia. In animal models, a single dose of KBPA 101 demonstrated rapid clearance of the pseudomonas lung-infection after a lethal challenge with pseudomonas bacteria.

The compound has already successfully completed Phase I in healthy volunteers. There were no serious adverse events and the drug was well tolerated, showing a favourable risk/benefit profile.

The efficacy and safety of KPBA 101 is currently being investigated in patients with ventilator-associated pneumonia caused by *Pseudomonas serotype* O11.

In July 2006, KBPA 101 has already received Orphan Drug designation from the European Commission.

"Receiving FDA „Orphan Drug“ designation is another important milestone for Kenta Biotech“ Violetta Georgescu-Kyburz, CEO of Kenta Biotech, commented on the notice. "The support of the FDA will allow us to advance this promising compound as safely and quickly as possible into patients with life-threatening pseudomonas-pneumonia".

About Pseudomonas Pneumonia

In spite of preventive measures and current medical treatment (mostly antibiotic therapy, alone or in combination), pneumonia caused by *Pseudomonas aeruginosa* can be life-threatening, particularly in mechanically ventilated patients. The infection-related mortality can be as high as 40%. Even with high dose antibiotics hospital-acquired pneumonia remains the leading cause of mortality and morbidity in nosocomial (hospital-acquired) infections.

Pseudomonas aeruginosa shows a high intrinsic resistance to antibiotics and has the ability to acquire adaptive resistance to antibiotics during a single course of therapy. In order to decrease morbidity and mortality it is therefore important to specifically target the virulent bacteria effectively. KBPA 101 is a promising new treatment option for *Pseudomonas aeruginosa* pneumonia because of its unique mode of action: KBPA101 binds to *Pseudomonas aeruginosa* bacteria and independent from the microbiological sensitivity of antibiotics kills the bacteria. It is expected that KBPA 101 will represent a significant progress in the treatment of life-threatening *Pseudomonas aeruginosa* pneumonia.

About Orphan Drug Act (ODA)

The FDA's US Orphan Drug Act is intended to assist and encourage companies to develop safe and effective therapies for the treatment of rare diseases and disorders. Orphan Drug designation is awarded to compounds that offer potential therapeutic value in the treatment of rare diseases, defined as those affecting fewer than 200,000 Americans. This designation provides companies with several benefits during the course of orphan drug development, such as guidance in study design, assistance from the FDA in guiding the drug through the regulatory approval process, tax credits related to clinical trial expenses and a possible exemption from the FDA-user fee. The designation also provides the opportunity for KBPA 101 to obtain market exclusivity for seven years from the drug's approval date.

About Kenta

Kenta Biotech Ltd is a biopharmaceutical company headquartered in Berne, Switzerland. The company is focusing on the development of innovative, life-saving treatment options against serious hospital infections. Kenta Biotech is specialised in the discovery and research of fully human monoclonal antibodies for the prevention and treatment of serious bacterial and viral infection. These antibodies will enable physicians to more effectively combat life-threatening infections. KBPA101, its lead-product, is currently in Phase II. In addition, Kenta Biotech is conducting drug discovery programs in infectious disease and other disease areas.

For additional information please visit our website www.kentabiotech.com or contact us

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