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ASIA EDITION

Cubist gets right to Astellas' ceftolozane

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Singapore: Cubist Pharmaceuticals and Astellas Pharma entered into an agreement under which Cubist will obtain the rights to ceftolozane in certain Asia Pacific and Middle East territories from Astellas. With the attainment of these rights, Cubist now owns worldwide rights to develop, manufacture, and commercialize ceftolozane/tazobactam.

Ceftolozane, in combination with tazobactam (ceftolozane/tazobactam or CXA 201), is currently being studied in two pivotal phase III trials as a potential first-line intravenous therapy for the treatment of complicated intra-abdominal infections (cIAI) and complicated urinary tract infections (cUTI) caused by certain Gram negative bacteria, including those caused by multi-drug resistant Pseudomonas aeruginosa.

Top-line data readouts from these two clinical trials are expected in the second-half of 2013. Cubist anticipates filing a New Drug Application (NDA) for ceftolozane/tazobactam in cUTI and cIAI approximately six months after announcing top-line results from the phase III trials. Cubist plans to begin phase III studies in nosocomial pneumonia around mid-year 2013.

The FDA granted a Qualified Infectious Disease Products (QIDP) designation for all three indications and granted fast track status for ceftolozane/tazobactam in cIAI. As a result of the QIDP designation, if ceftolozane/tazobactam is ultimately approved by the FDA, it would also receive a five-year extension of Hatch-Waxman exclusivity.

Cubist previously obtained the rights, outside of the Asia Pacific and Middle East territories, to develop and commercialize ceftolozane/tazobactam through its acquisition of Calixa Therapeutics in December 2009.

Under the terms of the agreement, Astellas will receive an upfront payment of $25 million, and sales of ceftolozane/tazobactam made in the newly-obtained territories will be counted towards the existing commercial milestone and royalty in terms of the original agreement. Cubist will fund the upfront payment with cash on hand.

"Today's agreement underscores our belief that ceftolozane/tazobactam has the potential to be an important therapy to combat certain serious Gram-negative bacterial infections," said Mr Michael Bonney, CEO, Cubist. "With ownership of the global rights to ceftolozane/tazobactam, Cubist is well positioned to continue advancing this promising product candidate and

capture the drug's full potential around the world, if it is approved."