



## **Cubist Obtains Remaining Rights to Ceftolozane from Astellas**

*Agreement Results in Cubist Owning Worldwide Rights to Ceftolozane/Tazobactam*

**Lexington, Mass. & Tokyo, Monday, March 11, 2013** – Cubist Pharmaceuticals, Inc. (NASDAQ: CBST) and Astellas Pharma Inc. (Tokyo: 4503) today announced that they entered into an agreement under which Cubist obtains 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 3 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 3 trials. Cubist plans to begin Phase 3 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 these Asia-Pacific and Middle East territories, to develop and commercialize ceftolozane/tazobactam through its acquisition of Calixa Therapeutics, Inc. 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 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 Michael Bonney, Chief Executive Officer of 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.”

Astellas hopes this transaction will lead to the contribution to patients through addressing their unmet medical needs.

### **About Cubist**

Cubist Pharmaceuticals, Inc. is a biopharmaceutical company focused on the research, development, and commercialization of pharmaceutical products that address significant unmet medical needs in the acute care environment. Cubist is headquartered in Lexington, Mass. Additional information can be found at Cubist’s web site at [www.cubist.com](http://www.cubist.com).

## **About Astellas**

Astellas Pharma Inc., located in Tokyo, Japan, is a pharmaceutical company dedicated to improving the health of people around the world through the provision of innovative and reliable pharmaceutical products. Astellas has approximately 17,000 employees worldwide. The organization is committed to becoming a global category leader in Urology, Immunology (including Transplantation) and Infectious Diseases, Oncology, Neuroscience and DM Complications and Kidney Diseases. For more information on Astellas Pharma Inc., please visit the company Website at [www.astellas.com/en](http://www.astellas.com/en).

### Cubist Safe Harbor Statement

*This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and other federal securities laws. Any statements contained herein which do not describe historical facts, including but not limited to, statements regarding: (i) a five year extension of Hatch-Waxman exclusivity if ceftolozane/tazobactam is ultimately approved by the FDA and (ii) the development, regulatory filing and review, including the expected timing of our Phase 3 clinical trials in nosocomial pneumonia, clinical trial data readouts and NDA filing for ceftolozane/tazobactam in cUTI and cIAI, and commercial and therapeutic potential of ceftolozane/tazobactam, are forward-looking statements which involve risks and uncertainties that could cause actual results to differ materially from those discussed in such forward-looking statements.*

*Such risks and uncertainties include, among others: clinical trials of ceftolozane/tazobactam may not be successful or initiated or conducted in a timely manner; we plan to rely, to a significant extent, on third party clinical research organizations, or CROs, to help us conduct clinical trials so the success and timing of these trials is dependent our ability to work with such CROs and their performance; technical difficulties or excessive costs relating to the manufacture or supply of ceftolozane/tazobactam; we plan to rely, to a significant extent, on third party contract manufacturers and suppliers to manufacture and supply ceftolozane/tazobactam on our behalf so our ability to obtain adequate supplies of ceftolozane/tazobactam is dependent on our ability to work with such third parties and on their performance; we may encounter other unanticipated or unexpected risks with respect to the development or manufacture of ceftolozane/tazobactam; our ability to successfully develop, gain marketing approval for and commercially launch ceftolozane/tazobactam for its planned indications and on the timelines that we expect and those additional factors discussed in our most recent annual report on Form 10-K filed with the Securities and Exchange Commission. We caution investors not to place considerable reliance on the forward-looking statements contained in this press release. These forward-looking statements speak only as of the date of this document, and we undertake no obligation to update or revise any of these statements.*

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