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Tolero and MannKind Sign Collaboration and License Agreement to Develop and Commercialize Novel BTK Inhibitors for Hematological Malignancies and Inflammatory Diseases

April 30, 2012 4:00 AM EDT

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SALT LAKE CITY & VALENCIA, Calif.--(BUSINESS WIRE)--Apr. 30, 2012-- Tolero Pharmaceuticals, a biopharmaceutical company focused on the discovery and development of novel therapeutics to treat cancer and other serious human diseases, and MannKind Corporation (Nasdaq: MNKD), focused on discovering, developing and commercializing therapeutic products for diabetes and cancer, today announced a license agreement granting Tolero exclusive worldwide rights to develop and commercialize compounds from MannKind's novel BTK (Bruton's tyrosine kinase) program, which are currently being developed for the treatment of hematological malignancies and inflammatory diseases.

Under the terms of the agreement, Tolero will pay MannKind upfront and milestone payments linked to the development, approval and commercialization of products, for total potential upfront and milestone payments of approximately \$130 million. MannKind will also receive tiered royalties on sales of products and a percentage of sublicensing revenue. In addition, MannKind has an option to re-acquire the rights to the program at pre-specified terms until 60 days after the conclusion of the first Phase 1 study. If MannKind exercises this option, then MannKind would assume responsibility for developing and commercializing products and Tolero would become entitled to receive the milestone payments, royalties and sublicensing revenues specified in the agreement.

"We are really excited about this opportunity and pleased to be working with an experienced drug development team at MannKind that is passionate about moving this program forward. BTK currently represents one of the most exciting therapeutic targets in oncology, and we feel that our collaborative approach to targeting BTK may uncover some novel utilities not yet fully realized," said Dallin Anderson, Chairman and President of Tolero.

Dr. David Bearss, Founder of Tolero, added, "BTK has already been demonstrated to be a validated clinical target in multiple disease settings. We believe that MannKind has developed a series of novel compounds with unique mechanisms of action that may lead to important treatments for cancer and autoimmune diseases, such as rheumatoid arthritis. We are excited to be a strategic partner with MannKind."

About Tolero Pharmaceuticals

Tolero is a biopharmaceutical company dedicated to the discovery and development of novel therapeutics to treat and cure cancer and other life-threatening diseases. Tolero has used its innovative drug development platform to create a diverse portfolio of drug candidates targeting several cancer-associated cellular pathways. Tolero Pharmaceuticals is a privately held company founded in 2011 and headquartered in Salt Lake City, Utah.

About MannKind Corporation

MannKind Corporation (Nasdaq: MNKD) focuses on the discovery, development and commercialization of therapeutic products for patients with diseases such as diabetes and cancer. Its lead product candidate, AFREZZA®, is in late stage clinical investigation for the treatment of adults with type 1 or type 2 diabetes for the control of hyperglycemia. MannKind maintains a website at http://www.mannkindcorp.com to which MannKind regularly posts copies of its press releases as well as additional information about MannKind. Interested persons can subscribe on the MannKind website to e-mail alerts that are sent automatically when MannKind issues press releases, files its reports with the Securities and Exchange Commission or posts certain other information to the website.

This press release contains forward-looking statements, including statements regarding our expectations and beliefs regarding the collaboration and license agreement with Tolero, that involve risks and uncertainties. Words such as "believes," "anticipates," "plans," "expects," "intends," "will," "goal," "potential" and similar expressions are intended to identify forward-looking statements. These forward-looking statements are based upon our current expectations. Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of these risks and uncertainties, which include, without limitation, risks regarding reliance on Tolero to develop and commercialize products from the BTK program, including risks that Tolero may not devote sufficient efforts to those activities, whether due to lack adequate financial or other resources, a strategic decision to focus on other initiatives or otherwise, and risks that the agreement with Tolero may be terminated, as well as risks associated with the progress, timing and results of clinical trials, difficulties or delays in seeking or obtaining regulatory approval, competition from other pharmaceutical or biotechnology companies, and other risks detailed in our filings with the Securities and Exchange Commission, including its annual report on Form 10-K for the year ended December 31, 2011. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this press release. All forward-looking statements are qualified in their entirety by this cautionary statement, and we undertake no obligation to revise or update any forward-looking statements to reflect events or circumstances after the date of this press release.

Source: MannKind Corporation and Tolero Pharmaceuticals

For Tolero Pharmaceuticals: Dallin Anderson Chairman and President (801) 285-7570 danderson@toleropharma.com or For MannKind Corporation: Matthew Pfeffer Chief Financial Officer (661) 775-5300 mpfeffer@mannkindcorp.com