



November 13, 2012

## **Colby and MannKind Sign License and Joint Development Agreement to Develop and Commercialize Cancer Immunotherapy Products**

SAN JOSE, Calif. & VALENCIA, Calif.--(BUSINESS WIRE)--Nov. 13, 2012-- Colby Pharmaceutical Company and MannKind Corporation (Nasdaq: MNKD) today announced a license agreement granting Colby exclusive worldwide rights to develop and commercialize disease-specific antigen compounds and intra-lymph node delivery technologies from MannKind's novel MKC1106 active immunotherapy programs, which are currently being developed for the treatment of melanoma, prostate, hematological disorders and other human cancers.

Intra-lymph node injections (ILNI, vaccine inoculation directly into the normal lymph node with ultrasound image guided standard syringes) of cancer vaccine antigens have been reproducibly shown to generate much more potent therapeutic T-cell responses, when compared to cancer vaccine antigen immunizations using traditional intra-muscular or sub-cutaneous injections of the same cancer vaccine antigens in animals. In a Phase 1 human melanoma study of MKC1106-MT, the most advanced ILNI regimen from this program, repeat intra-lymph nodal injection for administration of the therapeutic antigens was well-tolerated and generated strong immune responses, clearly meeting the primary endpoints.

Under the terms of the agreement, Colby will pay MannKind upfront and milestone payments linked to the development, approval and commercialization of products, with upfront and potential milestone payments of approximately \$140 million total. MannKind will also receive tiered royalties on sales of products.

"We are very keen on this opportunity and in continuing to work with the experienced drug development team at MannKind," said David Zarling, Ph.D., MBA, Chief Executive Officer of Colby. "MannKind has amassed an extensive and thorough active immunotherapy patent portfolio. We fully appreciate and understand that ILNI generates remarkably superior immune responses that also can be adjuvanted, and our organizations share a passion to advance the current MKC1106 clinical melanoma, prostate and other programs. We will also evaluate ILNI for potential synergy with our lead adjuvant, JVRS-100, a cationic lipid-based immune activator of both innate and adaptive immunity. ILNI and JVRS-100 both represent compelling new therapeutic approaches. We have good reason to believe that our collaboration will uncover other more optimal cancer vaccine modalities and synergies with novel adjuvants not yet realized by others working on cancer vaccines and immune activation. We believe that MannKind's ILNI and our new immune activators, like JVRS-100 or JVRS-200, or other adjuvants, will prove to be important for rational cancer immunotherapies."

### **About Colby Pharmaceutical Company**

Colby is a privately held company located at 5941 Optical Court, San Jose, CA 95138. Colby is developing new oral small molecule signal transduction modulator drugs and immune modulator biopharmaceuticals for cancer, chronic inflammation, pain, infectious diseases, and neurodegenerative or metabolic diseases. Colby is going after the indications for the very sick patients for which there are such poor alternatives – i.e., melanoma, acute myelogenous leukemia, cancer radio-chemo-mitigation or mucositis, and cancer patient vaccination by ILNI. Colby's lead small molecule and biologic drug candidates are new molecular entities which have unique mechanisms of action and are in newly discovered pathways for molecular targeted therapies to treat or cure patients with hard to treat infections, inflammation, malignancies and pain, with minimal toxicities and side effects. The company encourages inquiries to [dzarling@colbypharmaceuticals.com](mailto:dzarling@colbypharmaceuticals.com) regarding potential investment, partnering, and/or licensing opportunities

### **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 license agreement with Colby, which 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 Colby to develop and commercialize immunotherapy products, including risks that Colby 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 Colby 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

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