



Kolltan Pharmaceuticals Provides Update on Clinical Pipeline, Corporate Developments and Near-Term Milestones

- ***First cancer patient treated with KTN0158, a novel KIT-targeting antibody, following FDA acceptance of Investigational New Drug (IND) application; Phase 1 clinical trial expected to generate clinical data in 2016 followed by combination studies with targeted agents (TKIs) and T-cell checkpoint inhibitor drugs***
- ***KTN3379, targeting ErbB3 (HER3), continues to enroll patients in three Phase 1b clinical trials; presentation of data from these studies and initiation of first Phase 2 clinical trial planned for 2016***

NEW HAVEN, Conn.—January 8, 2016—Kolltan Pharmaceuticals, Inc., a privately held clinical-stage company focused on the discovery and development of novel antibody-based drugs targeting receptor tyrosine kinases (RTKs) for use in oncology and immunology, today announced corporate developments, progress of the Company’s lead development programs and research pipeline and upcoming milestones. Based on significant progress achieved in 2015, the Company now has two clinical stage development programs in oncology, KTN3379 and KTN0158, and is advancing a research pipeline focused on the TAM family of RTKs (Tyr_o3, Axl and MerTK) for potential use in oncology, inflammation and autoimmunity. KTN3379, targeting ErbB3, is currently being evaluated in three Phase 1b clinical trials for the treatment of solid tumors with data showing early signs of efficacy, and the Company plans to initiate a Phase 2 clinical trial in 2016. KTN0158, targeting KIT, is currently in a Phase 1 clinical trial for the treatment of gastro-intestinal stromal tumors (GIST) and other KIT expressing tumors. The Company’s important corporate developments in 2015 include the expansion of its executive management team, the issuance of a key patent and multiple notices of allowances related to its antibody portfolio, modification of an agreement with MedImmune to ensure control of future development and commercial activities for KTN3379 as well as to arrange for additional KTN3379 drug supply for Phase 2 clinical trials, and ongoing partnering discussions related to the TAM program.

The Company reported today that KTN0158 has been administered to the first cancer patient in a Phase 1 clinical trial following the acceptance by the U.S. Food and Drug Administration (FDA) of an IND application for KTN0158. KTN0158 is a potential first-in-class, humanized anti-KIT monoclonal antibody drug candidate discovered at Kolltan using structural insights obtained from the laboratory of Dr. Joseph Schlessinger at Yale University. In preclinical studies, KTN0158 has exhibited highly potent and selective inhibition of KIT expressed on cancer cells and mast cells, supporting its potential use in the treatment of cancers and other mast cell-related disorders. KTN0158 is the second clinical-stage program for Kolltan and is currently in an open-

label, dose-escalating Phase 1 clinical trial focused on cancer patients with gastrointestinal stromal tumors (GIST) and other tumors expressing KIT. In 2015, the Company presented preclinical data supporting the potential use of KTN0158 in cancer through its direct impact on KIT as an oncogenic driver and through its immunomodulatory effects on mast cells and myeloid-derived suppressor cells (MDSCs), thereby potentially augmenting the effectiveness of T-cell checkpoint inhibitors. The Company expects that favorable safety, pharmacokinetic, pharmacodynamic and early tumor response data later this year would support expanded clinical trials of KTN0158 in cancer patients as a monotherapy and in combination with TKIs (tyrosine kinase inhibitors) and T-cell checkpoint inhibitor drugs.

In addition, the Company announced that KTN3379, a potential best-in-class antibody targeting ErbB3 (HER3), continues to enroll patients in three active Phase 1b clinical trials that are evaluating the safety and efficacy of KTN3379 in combination with several targeted therapies in cancer patients with lung, breast, gastric, colorectal, thyroid, and head and neck cancer. Data from these ongoing studies are expected to be presented at medical conferences during 2016. Kolltan also announced that the U.S. Patent Office has granted U.S. Patent No. 9,220,775, which contains claims for composition of matter and uses relating to KTN3379. This patent will expire in November 2032, not including any patent term extensions.

Lastly, Kolltan announced that active discovery efforts are underway for the TAM research program to identify antibodies that can modulate the TAM family of RTKs (Tyro3, Axl and MerTK). The TAM receptors are expressed on macrophages and dendritic cells and have been implicated as drug targets for oncology, inflammation, and autoimmunity. The Company is evaluating potential partnerships for the TAM program.

“The past year has been a period of exceptional accomplishment at Kolltan, and our company is excited and energized as we continue to progress our oncology and immunology portfolio, including our most advanced product candidates in the clinic, KTN3379 and KTN0158,” said Gerald McMahan, Ph.D., President and Chief Executive Officer of Kolltan. “Last year, Dr. Ronald A. Peck joined Kolltan as Chief Medical Officer and Senior Vice President, Clinical Development, and his expertise in immuno-oncology is particularly useful as we evaluate KTN0158 as both an anti-tumor drug candidate as well as an immuno-oncology drug candidate to potentiate T-cell checkpoint inhibitor drugs. Our lead program, KTN3379, continues to enroll patients and generate data supporting our plan to initiate a Phase 2 clinical trial in 2016. This antibody has a novel mechanism of action which has been recently published and is protected by an issued composition of matter patent from the U.S. patent office. In addition, our immunology portfolio continues to expand as we now have identified our first prototype antibodies targeting the TAM receptors.”

Recent Highlights and Upcoming Milestones

In 2015, Kolltan reported substantial progress in its R&D pipeline, including the Company’s clinical-stage programs, KTN3379 and KTN0158.

KTN3379

- In October 2015, Kolltan announced interim Phase 1b safety and efficacy data for KTN3379 showing evidence of sustained tumor shrinkage in several late-stage cancer patients.
 - Confirmed responses include an ongoing complete response in a patient with head and neck cancer treated with KTN3379 plus cetuximab who had progressed on prior cetuximab therapy, partial responses in two patients with BRAF-mutant non small cell lung cancer (NSCLC) treated with KTN3379 plus vemurafenib, one of which had previously progressed during treatment with another BRAF inhibitor, and a patient with BRAF-mutant colorectal cancer treated with KTN3379 plus vemurafenib who had durable stable disease.
 - Based on these initial efficacy signals, Kolltan expanded its KTN3379 program with two new clinical trials: (1) a Phase 1b study in thyroid cancer evaluating the treatment of patients with radioactive iodine refractory BRAF-mutated cancers with a combination of KTN3379 and vemurafenib, and (2) a clinical study evaluating tumor biomarker responses to KTN3379 in newly diagnosed patients with head and neck cancers who are treated with KTN3379 prior to their surgical resection.
- At the recent AACR-NCI-EORTC International Conference held in November 2015, the Company presented preclinical findings showing that KTN3379 reverses ErbB3-mediated resistance of BRAF and MEK inhibitors in BRAF-mutated thyroid cancer and melanoma. These preclinical findings support Kolltan's ongoing Phase 1b clinical trials in BRAF-mutant tumors and the recently initiated clinical trial in thyroid cancer.
- At the AACR Conference held in April 2015, the Company presented preclinical findings showing that KTN3379 and cetuximab as a dual ErbB blockade yields enhanced anti-tumor activity in head and neck cancer by inhibiting parallel signaling pathways, AKT and ERK. The Company also presented data showing that there is a high prevalence of neuregulin overexpression in head and neck cancer.
- Based on the encouraging clinical findings to date and the supportive preclinical data, the Company is planning to initiate Phase 2 clinical trials of KTN3379 in 2016 with an initial focus in head and neck cancer. In addition, Kolltan is exploring partnerships to combine KTN3379 with other targeted therapies for several tumor types where ErbB3 may play a role to drive tumor growth.
- In October 2015, the Proceedings of the National Academy of Sciences published a seminal article* by Dr. Joseph Schlessinger, his laboratory, and Kolltan scientists that describes how KTN3379 binds to ErbB3, leading to a mechanism of action (MOA) that is materially different from other approaches for antibody targeting. The data reveal that KTN3379 effectively locks ErbB3 in an inactive conformation by binding to a unique epitope, which may contribute to the antibody's high potency and dual MOA, a differentiating feature of KTN3379 compared to other known anti-ErbB3 antibodies. This published research exemplifies the quality and productiveness of Kolltan's broad

collaboration with Yale, including the world-class crystallography efforts in Dr. Schlessinger's lab that have contributed, and continue to contribute, to antibody discovery and differentiation at Kolltan.

* (Proc Natl Acad Sci U S A. 2015 Oct 27;112(43):13225-30. doi: 10.1073/pnas.1518361112. Epub 2015 Oct 12.)

- In 2015, we modified our agreement with MedImmune to ensure Kolltan's control of KTN3379 and its future development, which means that Kolltan can progress this product candidate forward independently or with potential corporate partners. As part of this agreement, MedImmune agreed to manufacture certain additional amounts of KTN3379, which will contribute to further advancement of Kolltan's program and the transition into planned Phase 2 clinical trials.

KTN0158

- Kolltan announced key preclinical data related to KTN0158, a potential first-in-class antibody targeting KIT, at three major conferences – the European Society for Medical Oncology (ESMO) Cancer Conference (September 2015), the Society for Immunotherapy of Cancer (SITC) Conference (November 2015), and the AACR-NCI-EORTC International Conference (November 2015).
- As presented at ESMO, KTN0158 showed substantial tumor shrinkage in a preclinical study in dogs with spontaneous mast cell tumors. Tumor shrinkage was observed at every dose level in all 12 dogs after one or two doses and in tumors with and without activating KIT receptor mutations. The Company expects that KTN0158 will be developed as a monotherapy for 95% of human GIST where KIT is thought to play an important role. The Company also believes KTN0158 may be used in combination with small-molecule approaches to the KIT target in tumors that are limited by mutations and resistance.
- At the SITC conference, Kolltan reported research demonstrating the potential of anti-KIT antibody therapy to modulate immuno-oncology. Preclinical findings showed that inhibition of KIT with anti-KIT antibodies resulted in a marked decrease in myeloid-derived suppressor cells (MDSCs) in the tumor microenvironment. Additional preclinical data demonstrated that targeting KIT with an antibody enhanced the anti-tumor activity of T-cell checkpoint antibody-based inhibitors. This second feature provides support for clinical trials in several tumor types where blockade by T-cell targeting checkpoint inhibitor antibodies has shown clinical benefit. These combination trials are expected to follow the ongoing Phase 1 clinical trial that was recently initiated and is enrolling patients.
- Based on the preclinical data announced recently and generated since the beginning of 2015, Kolltan plans to aggressively pursue multiple potential pathways to the market, including (1) KTN0158 as a single agent in oncology (e.g., GIST) and in combination with targeted agents; (2) KTN0158 in combination with T-cell checkpoint inhibitors (e.g., anti-

CTLA4 and/or anti-PD1/PD-L1 drugs), and (3) KTN1058 in mast cell-related diseases, such as neurofibromatosis 1 (NF1) and other diseases with significant medical needs.

TAM RTK Research

- In 2015, the Company initiated an antibody discovery effort for the TAM family of RTKs that act as rheostats of the immune system. This differentiated family of targets has attractive therapeutic potential across many diseases, including autoimmune and inflammatory disease areas (by stimulating the receptors) and immuno-oncology and anti-viral areas (by inhibiting the receptors). Kolltan has exclusive relationships with the pioneers and thought leaders in the TAM field, including Dr. Greg Lemke of the Salk Institute for Biological Studies and Drs. Schlessinger, Rothlin, and Rimm at Yale University. The Company is currently engaged in discussions to partner the TAM program to discover and develop novel therapeutics for oncology, chronic inflammatory diseases, and autoimmunity.

Corporate Update

- The U.S. and European Patent Offices have issued notices of allowance in companion patent applications related to Dr. Schlessinger's discovery regarding inhibition of the KIT receptor. Kolltan has an exclusive license to these applications from Yale, which forms the founding IP of Kolltan. Kolltan applied Dr. Schlessinger's novel insights about the x-ray crystallographic structure of the KIT receptor employing structure based design and identified an antibody (KTN0158) that has a unique way of inhibiting the function of KIT through binding to the domain that is near the cell membrane and blocking dimerization.
- In August 2015, the Company hired Dr. Ronald A. Peck as Chief Medical Officer and Senior Vice President, Clinical Development. Dr. Peck's exceptional track record and experience in oncology clinical development and his accomplishments in immuno-oncology will contribute to the evaluation of Kolltan's antibody therapeutics in oncology and other immune-related disorders. Dr. Peck has over 15 years of extensive drug development expertise in oncology and other areas. Prior to joining Kolltan, Dr. Peck held roles of increasing responsibility at Bristol-Myers Squibb Company since 2000, where he contributed to the successful development of multiple therapeutic drug products. Notably, Dr. Peck led the clinical development program for IXEMPRA® (ixabepilone), and he served most recently as Vice President, Global Development Lead for YERVOY® (ipilimumab), playing a key role in the approval and commercialization of this drug in all indications.

About KTN3379

KTN3379 is a human monoclonal antibody designed to block the activity of ErbB3 (HER3), a receptor tyrosine kinase (RTK) that belongs to the epidermal growth factor receptor, or EGFR,

family. ErbB3 is believed to be an important receptor regulating cancer cell growth and survival. ErbB3 is expressed in many cancers, including head and neck, breast, lung, gastric, and melanoma. While there are several successful currently marketed products targeting two members of the EGFR family, there are none that directly target ErbB3. In cancer, ErbB3 activation can be driven by its ligand, neuregulin, or in its absence, through overexpression of its co-receptor ErbB2 (HER2). KTN3379 binds in a unique way to ErbB3 that results in the locking of ErbB3 in an inactive conformation that blocks kinase activation and ligand binding. In addition, KTN3379 has an engineered Fc domain to prevent antibody-mediated clearance leading to serum half-life extension.

Kolltan is conducting multiple clinical trials evaluating KTN3379 in the treatment of solid tumors. These trials include an ongoing Phase 1b multi-center, open-label, dose escalation clinical trial of KTN3379 in patients with solid tumors, with expansion cohorts testing KTN3379 in combination with cetuximab, erlotinib, vemurafenib, or trastuzumab. In addition, the Company is conducting a Phase 1b clinical trial in thyroid cancer, evaluating the treatment of patients with radioactive iodine refractory BRAF-mutated cancers with a combination of KTN3379 and vemurafenib. A third clinical trial is evaluating tissue responses to KTN3379 in newly diagnosed patients with head and neck cancers who are treated with KTN3379 prior to their surgical resection.

About KTN0158

KTN0158 is a proprietary, humanized monoclonal antibody designed using structure-based approaches to block the activation of KIT, an RTK that is expressed on many cancers and mast cells. Kolltan applied novel insights about the x-ray crystallographic structure of the KIT receptor to identify a unique way to inhibit the function of KIT through binding to the domain that is near the cell membrane and blocking dimerization. This targeting of KIT proximal to the membrane is a novel approach compared to targeting ligand binding and led to Kolltan's discovery of KTN0158.

There are currently no KIT-targeting antibodies on the market for any disease indication. In oncology, KIT is expressed in tumors such as GIST, melanoma, AML, SCLC, and others. Additionally, KIT is expressed in immune suppressive cells in the tumor microenvironment and thus, may provide a novel combination treatment for immuno-oncology. There are several KIT-targeting small molecule drugs approved for use in GIST where mutant KIT is present. However, no KIT-targeting drugs are approved for non-GIST tumor types, and treatment of GIST tumors does not always lead to long-term clinical benefit due to resistance, including secondary mutations that overcome small-molecule drug approaches.

The Company believes KTN0158 as a monoclonal antibody is particularly suited to block KIT dimerization and inhibit activation and signaling of the receptor and therefore result in potent and selective inhibition of both wild-type and some mutant KIT forms. Kolltan filed an IND with the FDA for KTN0158 in late 2015 and has recently initiated a Phase 1 study for the treatment of GIST and other KIT-expressing tumors. A second IND filing for KTN0158 is anticipated in 2017

for neurofibromatosis 1 (NF1). KIT and mast cells have been associated with the etiology of NF1, an orphan disease afflicting approximately 100,000 individuals in the U.S.

About Kolltan

Kolltan, a privately held clinical-stage company, is focused on the discovery and development of novel, antibody-based drugs targeting RTKs for the treatment of cancer and other diseases with significant unmet need. Kolltan's founders and members of its management team have deep expertise and a proven track record in drug discovery, development, and commercialization of innovative therapeutics, including drugs targeting RTKs. Kolltan is working in close collaboration with the laboratory of Kolltan Co-Founder, Dr. Joseph Schlessinger, as well as the Yale University medical and scientific community. The Company has a broad and novel oncology and immunology portfolio of therapeutic biologics targeting multiple RTKs that are advancing in the clinic and are expected to generate multiple near-term milestones. Kolltan's most advanced product candidates include KTN3379, a human monoclonal antibody designed to block the activity of ErbB3 which is in several Phase 1b clinical trials in solid tumors, and KTN0158, a humanized monoclonal antibody designed to block the activation of KIT, which is being developed as a potential therapy for cancer and mast cell-related diseases and is in a Phase 1 study for cancer where KIT has been implicated as a tumor driver. Kolltan plans to initiate additional trials for its lead development programs, including a Phase 2 clinical trial for KTN3379 in 2016 and Phase 1 combination trials for KTN0158 with other targeted agents and T-cell checkpoint inhibitors.

Forward Looking Statements Disclosure

Any statements in this news release about future expectations, plans and prospects for Kolltan constitute forward-looking statements. Actual results may differ materially from those indicated by such forward-looking statements as a result of a variety of important factors. Kolltan anticipates that subsequent events and developments may cause its views to change. However, while Kolltan may elect to update these forward-looking statements in the future, Kolltan specifically disclaims any obligation to do so.

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