



Syndax and Nektar Therapeutics Announce Immuno-Oncology Clinical Trial Collaboration

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WALTHAM, Mass. and SAN FRANCISCO, May 30, 2018 /PRNewswire/ -- Syndax Pharmaceuticals, Inc. (Nasdaq: SNDX), a clinical stage biopharmaceutical company developing an innovative pipeline of cancer therapies, and Nektar Therapeutics (Nasdaq: NKTR) today announced a non-exclusive, clinical collaboration to evaluate the safety and efficacy of Nektar's NKTR-214, a CD122-biased agonist, in combination with entinostat, Syndax's oral, small molecule Class 1 specific HDAC inhibitor, in patients with metastatic melanoma who have previously progressed on treatment with an anti-PD-1 (programmed death receptor-1) agent.

Under the terms of the agreement, Syndax and Nektar will collaborate on a study to evaluate the combination. The Phase 1b portion of the trial aims to establish safety and a recommended dose for the combination regimen and will be followed by a Phase 2 portion designed to assess efficacy, as defined by objective response rate and durability of response. Progression free survival and overall survival will also be evaluated. Correlative biomarker analyses that aim to identify patients with enhanced responses to the combination, including analyses exploring the potential of elevated levels of classical peripheral blood monocytes, will be incorporated. Syndax will be responsible for conducting the Phase 1b/2 trial and the agreement includes a provision where the parties may extend the collaboration to include a pivotal trial based on mutual interest.

"We are excited to be working with Nektar as we build upon our strategy of establishing clinical collaborations to test novel combinations of entinostat with leading edge immune therapies," said Briggs W. Morrison, M.D., Chief Executive Officer of Syndax. "Previous Phase 2 data with entinostat and high dose IL-2 in renal cell cancer¹ and our promising preclinical data generated with NKTR-214, laid the scientific and clinical foundation for this collaboration. Working with Nektar allows us to increase the potential impact entinostat may have in the treatment of PD-1 refractory metastatic melanoma patients, and complements the [exciting data](#) we have seen when combining entinostat with KEYTRUDA[®] in a similar population."

In preclinical testing, the results of which were recently presented at the 2018 American Association of Cancer Research Annual Meeting², the combination of entinostat and NKTR-214 significantly inhibited tumor growth in tumor models of kidney and colon cancer. The anti-tumor activity of the combination was accompanied by a dramatic increase in the activation and cytotoxic activity of CD8+ T cells in the tumor, along with modulation of immune suppressor cells found in the tumor microenvironment.

"The combination of NKTR-214 and entinostat demonstrated a unique synergy in our preclinical models which warrants further study in the clinic," said Jonathan Zalevsky, Ph.D, Senior Vice President and Chief Scientific Officer of Nektar. "Importantly, we observed elevated levels of cytokine-positive tumor-infiltrating cytotoxic T cells following treatment with the combination. We believe this important preclinical finding could translate to improved tumor responses in patients who have become refractory to checkpoint inhibitors. We look forward to working with Syndax as this combination advances into the clinic."

Additional financial details and other terms of the agreement were not disclosed.

About Entinostat

Entinostat is a once-weekly, oral, small molecule, class I HDAC inhibitor currently being evaluated in a Phase 3 clinical trial in combination with exemestane for advanced hormone receptor positive, human epidermal growth factor receptor 2 negative breast cancer, an indication for which it has been granted Breakthrough Therapy Designation by the FDA. Entinostat has been shown to block the function of immune suppressive cells in the tumor microenvironment, and is being evaluated in combination with several approved PD-1/PD-L1 antagonists, including in ongoing Phase 1b/2 clinical trials combining entinostat with KEYTRUDA[®] from Merck & Co., Inc. for non-small cell lung cancer, melanoma and colorectal cancer; with TECENTRIQ[®] from Genentech, Inc. for triple negative breast cancer as well as advanced hormone receptor positive, human epidermal growth factor receptor 2 negative breast cancer; and with BAVENCIO[®] from Pfizer Inc. and Merck KGaA, Darmstadt, Germany, for ovarian cancer.

About NKTR-214

NKTR-214 is an experimental therapy designed to stimulate cancer-killing immune cells in the body by targeting CD122 specific receptors found on the surface of these immune cells, known as CD8+ effector T cells and Natural Killer (NK) cells. Growing these tumor-infiltrating lymphocytes (TILs) in vivo and replenishing the immune system is critically important as many patients battling cancer lack sufficient TIL populations to benefit from approved checkpoint inhibitor therapies. In preclinical studies, treatment with NKTR-214 resulted in a rapid expansion of these cells and mobilization into the tumor micro-environment. 1,2 NKTR-214 has an antibody-like dosing regimen similar to the existing checkpoint inhibitor class of approved medicines.

About Syndax Pharmaceuticals, Inc.

Syndax, headquartered in Waltham, Massachusetts, is a biopharmaceutical company developing an innovative pipeline of cancer therapies at various stages of clinical and pre-clinical development. The company's mission is to develop agents that extend and improve the lives of cancer patients. For more information, please visit www.syndax.com and follow us on Twitter and LinkedIn.

About Nektar Therapeutics

Nektar Therapeutics is a biopharmaceutical company with a robust, wholly-owned R&D pipeline of investigational medicines in oncology, immunology and pain as well as a portfolio of approved partnered medicines. Nektar is headquartered in San Francisco, California, with additional operations in Huntsville, Alabama and Hyderabad, India. Further information about the company and its drug development programs and capabilities may be found online at <http://www.nektar.com>.

Citations

¹ [Pili R., et al. \(2017\) Clin. Cancer Res., 23\(23\) 7199-7208.](#)

² [Wang L., et al. \(2018, April\). AACR, Chicago, IL.](#)

Syndax's Cautionary Note on Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Words such as "may," "will," "expect," "plan," "anticipate," "estimate," "intend," "believe" and similar expressions (as well as other words or expressions referencing future events, conditions or circumstances) are intended to identify forward-looking statements. These forward-looking statements are based on Syndax's expectations and assumptions as of the date of this press release. Each of these forward-looking statements involves risks and uncertainties. Actual results may differ materially from these forward-looking statements. Forward-looking statements contained in this press release include, but are not limited to, statements about the progress, timing, clinical development and scope of clinical trials and the reporting of clinical data for Syndax's product candidates, and the potential use of our product candidates to treat various cancer indications. Many factors may cause differences between current expectations and actual results including unexpected safety or efficacy data observed during preclinical or clinical studies, clinical trial site activation or enrollment rates that are lower than expected, changes in expected or existing competition, changes in the regulatory environment, failure of Syndax's collaborators to support or advance collaborations or product candidates and unexpected litigation or other disputes. Other factors that may cause Syndax's actual results to differ from those expressed or implied in the forward-looking statements in this press release are discussed in Syndax's filings with the U.S. Securities and Exchange Commission, including the "Risk Factors" sections contained therein. Except as required by law, Syndax assumes no obligation to update any forward-looking statements contained herein to reflect any change in expectations, even as new information becomes available.

Nektar's Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements which can be identified by words such as: "will," "believe," "aim," "expect," "designed" and similar references to future periods. Examples of forward-looking statements include, among others, statements we make regarding the therapeutic potential NKTR-214 in combination with entinostat, the enrollment of future clinical trials, and outcomes from clinical and preclinical studies of our new drug candidates. Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based only on our current beliefs, expectations and assumptions regarding the future of our business, future plans and strategies, anticipated events and trends, and other future conditions. Because forward-looking statements relate to the future, they are subject to inherent uncertainties, risks and changes in circumstances that are difficult to predict and many of which are outside of our control. Our actual results may differ materially from those indicated in the forward-looking statements. Therefore, you should not rely on any of these forward-looking statements. Important factors that could cause our actual results to differ materially from those indicated in the forward-looking statements include, among others: (i) our statements regarding the therapeutic potential of NKTR-214 are based on pre-clinical and clinical findings and observations; (ii) NKTR-214 is in early-stage clinical development and there are substantial risks that can unexpectedly occur for numerous reasons including negative safety and efficacy findings in the ongoing clinical studies notwithstanding positive findings obtained in prior studies; (iii) our statements regarding the therapeutic potential of NKTR-214 are based on preclinical findings and early observations in clinical studies; (iv) scientific discovery of new medical breakthroughs is an inherently uncertain process and the future success of potential new drug candidates (such as NKTR-214) alone or in combination with entinostat is therefore very uncertain and unpredictable; (v) the timing of the commencement or end of clinical trials and the availability of clinical data may be delayed or unsuccessful due to regulatory issues, slower than anticipated patient enrollment, manufacturing challenges, changing standards of care, evolving regulatory requirements, clinical trial design, clinical outcomes, competitive factors, or delay or failure in ultimately obtaining regulatory approval in one or more important markets; (vi) patents may not issue from our patent applications for our drug candidates, patents that have issued may not be enforceable, or additional intellectual property licenses from third parties may be required; and (vii) certain other important risks and uncertainties set forth in Nektar's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on May 10, 2018. Any forward-looking statement made by us in this press release is based only on information currently available to us and speaks only as of the date on which it is made. We undertake no obligation to update any forward-looking statement, whether written or oral, that may be made from time to time, whether as a result of new information, future developments or otherwise.

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