



ONCONOVA THERAPEUTICS

Promising Preclinical Narazaciclib Data Presented at MCL Meeting

Oct 19, 2023

*Data for Mantle cell lymphoma (MCL) presented in Ireland on Oct. 7, 2023
Additional studies support broad potential, especially in cyclin-dependent cancers*

NEWTOWN, Pa., Oct. 19, 2023 (GLOBE NEWSWIRE) -- Onconova Therapeutics, Inc. (NASDAQ: ONTX), ("Onconova", the "Company"), a clinical-stage biopharmaceutical company focused on discovering and developing novel products for patients with cancer, today announced that one of the Company's scientific collaborators, Gaël Roué, Ph.D., from the Josep Carreras Leukaemia Research Institute, Spain, made a podium presentation during the European MCL Network Annual Meeting in Dublin, Ireland on October 7, 2023 regarding promising ongoing preclinical studies of narazaciclib, in combination with ibrutinib and other targeted therapies used in the treatment for mantle cell lymphoma.

"Mantle cell lymphoma (MCL) is an aggressive and devastating disease, marked by frequent relapses and poor prognosis. The biology of MCL is very interesting to Onconova because of the link to cyclin D1 (CD1) overexpression. Onconova's proprietary multi-kinase inhibitor, narazaciclib, has nanomolar potency across a range of targets including CD1. We believe this molecular feature could make MCL amenable to treatment combinations that include narazaciclib," said Steven Fruchtman, M.D., President and CEO of Onconova. "Dr. Roué's recent work expands the dataset regarding the potential use of narazaciclib in combination with ibrutinib and other targeted therapies in sensitive and resistant MCL cell lines. Together, these data provide a foundation of support for using narazaciclib in MCL and other cyclin-dependent indications. We look forward to incorporating these important findings into the development plan for narazaciclib as we advance the clinical program, led by the Phase 1/2a study in patients with LGEEC."

Onconova plans to provide an update on the Phase 1/2a clinical program with narazaciclib in patients with low grade endometrioid endometrial cancer (LGEEC), including topline safety, pharmacology data, and selection of a recommended Phase 2 dose, in Q4 2023.

Data featured in the presentation in Dublin and in a prior presentation at the American Association for Cancer Research (AACR) Annual Meeting in April of 2023 outlined promising results from preclinical studies that compared combinations of narazaciclib and other approved CDK4/6 inhibitors with ibrutinib and other next-generation BTK inhibitors to assess potential treatment synergies. Data from the combination of narazaciclib and ibrutinib showed significant synergistic anti-tumor activity in both sensitive and ibrutinib-resistant MCL models.

About Onconova Therapeutics, Inc.

Onconova Therapeutics is a clinical-stage biopharmaceutical company focused on discovering and developing novel products for patients with cancer. The Company's product candidates, narazaciclib and rigosertib, are proprietary targeted anti-cancer agents designed to disrupt specific cellular pathways that are important for cancer cell proliferation.

Narazaciclib, Onconova's novel, multi-kinase inhibitor (formerly ON 123300), is being evaluated in a Phase 1/2 combination trial with the estrogen blocker letrozole, in advanced endometrial cancer ([NCT05705505](#)). Based on preclinical and clinical studies of CDK 4/6 inhibitors, Onconova believes narazaciclib has broad potential and is also evaluating opportunities for combination studies with narazaciclib and letrozole in additional indications, including breast cancer.

Rigosertib is being studied in an investigator-sponsored trial strategy to evaluate the product candidate in multiple indications, including a dose-escalation and expansion Phase 1/2a study of oral rigosertib in combination with nivolumab in patients with KRAS+ non-small cell lung cancer ([NCT04263090](#)), a Phase 2 program evaluating oral or IV rigosertib monotherapy in advanced squamous cell carcinoma complicating recessive dystrophic epidermolysis bullosa (RDEB-associated SCC) ([NCT03786237](#), [NCT04177498](#)), and a Phase 2 trial evaluating rigosertib in combination with pembrolizumab in patients with metastatic melanoma ([NCT05764395](#)).

For more information, please visit www.onconova.com.

Forward Looking Statements

Some of the statements in this release are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, Section 21E of the Securities Exchange Act of 1934, as amended, and the Private Securities Litigation Reform Act of 1995, and involve risks and uncertainties. These statements relate to Onconova's expectations regarding its clinical development and trials, its product candidates, its business and financial position. Onconova has attempted to identify forward-looking statements by terminology including "believes," "estimates," "anticipates," "expects," "plans," "intends," "may," "could," "might," "will," "should," "preliminary," "encouraging," "approximately" or other words that convey uncertainty of future events or outcomes. Although Onconova believes that the expectations reflected in such forward-looking statements are reasonable as of the date made, expectations may prove to have been materially different from the results expressed or implied by such forward looking statements. These statements are only predictions and involve known and unknown risks, uncertainties, and other factors, including the success and timing of Onconova's clinical trials, investigator-initiated trials and regulatory agency and institutional review board approvals of protocols, Onconova's collaborations, market conditions and those discussed under the heading "Risk Factors" in Onconova's most recent Annual Report on Form 10-K and quarterly reports on Form 10-Q. Any forward-looking statements contained in this release speak only as of its date. Onconova undertakes no obligation to update any forward-looking statements contained in this release to reflect events or circumstances occurring after its date or to reflect the occurrence of unanticipated events.

Company Contact:

Mark Guerin
Onconova Therapeutics, Inc.
267-759-3680
ir@onconova.us
<https://www.onconova.com/contact/>

Investor Contact:

Bruce Mackle
LifeSci Advisors, LLC
646-889-1200
bmackle@lifesciadvisors.com