Onconova Therapeutics' ASH Poster To Focus on Narazaciclib in MCL

Nov 02, 2023

Preclinical data indicate that narazaciclib shows monotherapy and combination anti-tumor activity in ibrutinib-sensitive and resistant cells and xenograft models

NEWTOWN, Pa., Nov. 02, 2023 (GLOBE NEWSWIRE) -- Onconova Therapeutics, Inc. (NASDAQ: ONTX), ("Onconova" or "the Company"), a clinical-stage biopharmaceutical company focused on discovering and developing novel products for patients with cancer, today announced that Onconova and collaborators will present a preclinical poster related to its lead program, narazaciclib, at the 65th American Society for Hematology Annual Meeting & Exposition (ASH), taking place in San Diego, California from December 9 to 12, 2023.

"The poster that we and researchers from the Josep Carreras Leukaemia Research Institute in Barcelona, Spain are presenting at ASH 2023 shows that the study of narazaciclib, either as a single agent or in combination with ibrutinib, effectively controls tumor growth in preclinical models of mantle cell lymphoma (MCL), including those that are resistant to Bruton's tyrosine kinase inhibitors (BTKis), a mainstay of care for this aggressive and difficult to treat cancer. The experiments included a broad comparison of narazaciclib with three other approved cyclin-D-kinase inhibitors (CDKis), used in combination with several BTKis," said Steven Fruchtman, M.D., President and CEO of Onconova.

Dr. Fruchtman continued, "We were especially pleased by the broad translational data set that provided an understanding of narazaciclib's role in cell cycle blockade. These studies show that narazaciclib appears to act in the G1 phase of the cell cycle. Furthermore, the studies also indicate that the combination of narazaciclib and ibrutinib act in a synergistic way to achieve *in vitro* and *in vivo* anti-tumor activity in ibrutinib sensitive- and resistant -cells and xenograft models. Together, these data support the potential use of narazaciclib in MCL and other cyclin-dependent indications, and further inform our understanding of narazaciclib's mechanism of action as we advance the clinical program, led by the Phase 1/2a study in patients with low grade endometrioid endometrial cancer, an indication with a great unmet medical need."

Poster Presentation Information:

Title: Narazaciclib, a Differentiated CDK4/6 Antagonist, Prolongs Cell Cycle Arrest and Metabolomic Reprogramming, Enabling Restoration of Ibrutinib Sensitivity in Btki-Resistant Mantle Cell Lymphoma
Session Name: 605. Molecular Pharmacology and Drug Resistance: Lymphoid Neoplasms: Poster III
Session Date: Monday, December 11, 2023
Presentation Time: 6:00 PM - 8:00 PM PT
Location: San Diego Convention Center, Halls G-H
Poster Number: 4181
Presenters: Dr. Nuria Profitos-Peleja, Lymphoma Translational Group, Josep Carreras Leukaemia Research Institute, Barcelona, Spain

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.

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