

# Oncternal Therapeutics Hosting Key Opinion Leader Webinar on Hematological Malignancies and Prostate Cancer

January 20, 2022

- Session will include a discussion of the treatment landscape for Mantle Cell Lymphoma, including potential role of Zilovertamab, Oncternal's ROR1 antibody ready for Phase 3 in R/R MCL, with recent FDA agreement on study design
- The discussion will also cover perspectives on current and next generation treatments for patients with advanced prostate cancer, including potential role of ONCT-534, Oncternal's novel dual action androgen receptor inhibitor (DAARI)
- Webinar on Tuesday, January 25<sup>th</sup> from 2:30 4:30 pm (ET)

SAN DIEGO, Jan. 20, 2022 (GLOBE NEWSWIRE) -- Oncternal Therapeutics, Inc. (Nasdaq: ONCT), a clinical-stage biopharmaceutical company focused on the development of novel oncology therapies, today announced that it will host a key opinion leader (KOL) webinar on hematological malignancies and prostate cancer on Tuesday, January 25, 2022 from 2:30 - 4:30 pm (ET).

The webinar will feature a presentation by KOL Michael Wang, M.D., from the MD Anderson Cancer Center, who will discuss the current landscape and unmet medical need in the treatment of Mantle Cell Lymphoma (MCL). Oncternal's management will provide further details on the development of zilovertamab, the company's investigational anti-ROR1 monoclonal antibody, including the planned registrational Phase 3 superiority study ZILO-301, which is expected to be initiated in the first half of 2022, following the company's recently announced agreement with the U.S. Food and Drug Administration (FDA) regarding the study design and major details. Dr. Wang will serve as the U.S. Principal Investigator and Chairman of the Steering Committee for this study. Oncternal's management will also discuss the progress in the development of ONCT-808, its lead candidate of its autologous CAR-T program targeting ROR1-expressing malignancies.

A second KOL, Evan Yu, M.D., from the Fred Hutchinson Cancer Research Center, will provide perspectives on current standards of care and highlight the potential of next generation treatments for patients with advanced prostate cancer. Oncternal's management will present an overview of the preclinical data and development plans for ONCT-534, the lead candidate in its preclinical dual-action androgen receptor inhibitor (DAARI) program, a potential next-generation treatment option for patients with resistant prostate cancer.

A live question and answer session will follow the formal presentations. To register for the webinar, please click here.

Michael Wang, M.D. is Professor in the Department of Lymphoma and Myeloma at MD Anderson Cancer Center. Dr. Wang has published more than 250 peer-reviewed papers and has presented his work at meetings nationally and internationally. He is the current Director of Mantle Cell Lymphoma (MCL) Program of Excellence and Co-Director of Clinical Trials at MD Anderson. During the past 22 years, he has focused on preclinical and clinical research and established a MCL-SCID-hu mouse model, which is the first human primary MCL animal model for the study of the biology and treatment of MCL. Dr. Wang has pioneered the work to improve the treatment of patients with MCL, including the introduction of BTK inhibitors such as ibrutinib and acalabrutinib in the treatment algorithm, and has performed extensive work with CAR-T cells for the treatment of these patients. His work has been published in the most prestigious medical journals, such as the New England Journal of Medicine and the Lancet. He is currently the PI of the B-Cell Lymphoma Moon Shot Program at MD Anderson. Dr. Wang obtained his M.D. from Shandong Medical University and M.S. from Beijing University, Medical School. He completed his clinical training as a resident at Norwalk Hospital, Norwalk, Conn., and as a Fellow in Oncology and in Hematology.

Evan Ya-Wen Yu, M.D., is a medical oncologist who treats prostate, bladder, and testicular cancer patients at Seattle Cancer Care Alliance (SCCA), Fred Hutch's clinical care partner. In addition, Dr. Yu serves as the clinical research director of Genitourinary Medical Oncology at Seattle Cancer Care Alliance. Dr. Yu is also a professor of medical oncology at the University of Washington School of Medicine, a professor in clinical research at Fred Hutchinson Cancer Research Center, and medical director of clinical research support at Fred Hutchinson Cancer Research Consortium. As a physician-scientist, he provides a personalized-medicine approach to test novel therapies and discover unique cancer biomarkers. Dr. Yu also has a background in basic science; as a researcher, he studies the biological mechanisms of drug sensitivity and treatment resistance. In addition, his interests include cancer biomarkers, imaging (PET and MRI scans), and bone health. His overall goal is to discover novel biomarkers that can help quide treatment and aid in developing novel treatments for prostate cancer.

## **About Zilovertamab (formerly Cirmtuzumab)**

Zilovertamab is an investigational, potentially first-in-class monoclonal antibody targeting ROR1, or Receptor tyrosine kinase-like Orphan Receptor 1. Zilovertamab is currently being evaluated in a Phase 1b/2 clinical trial in combination with ibrutinib for the treatment of MCL or chronic lymphocytic leukemia (CLL), in a collaboration with the University of California San Diego (UC San Diego) School of Medicine and the California Institute for Regenerative Medicine (CIRM). In addition, Oncternal is supporting two investigator-sponsored studies being conducted at the UC San Diego School of Medicine: (i) a Phase 1b clinical trial of zilovertamab in combination with paclitaxel for the treatment of women with HER2-negative metastatic or locally advanced, unresectable breast cancer, and (ii) a Phase 2 clinical trial of zilovertamab in combination with venetoclax, a Bcl-2 inhibitor, in patients with relapsed/refractory CLL.

ROR1 is a potentially attractive target for cancer therapy because it is an onco-embryonic antigen – not usually expressed on adult cells, and its expression confers a survival and fitness advantage when reactivated and expressed by tumor cells. Researchers at the UC San Diego School of Medicine discovered that targeting a critical epitope on ROR1 was key to specifically targeting ROR1 expressing tumors. This led to the development of zilovertamab, that binds this critical epitope of ROR1, which is highly expressed on many different cancers but not on normal tissues. Preclinical data showed that when zilovertamab bound to ROR1, it blocked Wnt5a signaling, inhibited tumor cell proliferation, migration and survival, and induced

differentiation of the tumor cells. The FDA has granted Orphan Drug Designations to zilovertamab for the treatment of patients with MCL and CLL/small lymphocytic lymphoma. Zilovertamab is in clinical development and has not been approved by the FDA for any indication.

#### **About Oncternal Therapeutics**

Oncternal Therapeutics is a clinical-stage biopharmaceutical company focused on the development of novel oncology therapies for the treatment of cancers with critical unmet medical need. Oncternal focuses drug development on promising, yet untapped biological pathways implicated in cancer generation or progression. The clinical pipeline includes <u>zilovertamab</u> (formerly cirmtuzumab) an investigational monoclonal antibody designed to inhibit the ROR1 pathway, a type I tyrosine kinase-like orphan receptor, that is being evaluated in a Phase 1b/2 clinical trial in combination with ibrutinib for the treatment of patients with mantle cell lymphoma (MCL) and chronic lymphocytic leukemia (CLL) and in an investigator-sponsored, Phase 1b clinical trial in combination with paclitaxel for the treatment of women with HER2-negative metastatic or locally advanced, unresectable breast cancer, as well as a Phase 2 clinical trial of zilovertamab in combination with venetoclax, a Bcl-2 inhibitor, in patients with relapsed/refractory CLL. Oncternal is also developing <u>ONCT-808</u>, a chimeric antigen receptor T cell (CAR-T) therapy that targets ROR1, which is currently in preclinical development as a potential treatment for hematologic cancers and solid tumors. The clinical pipeline also includes <u>ONCT-216</u> (formerly TK216), an investigational targeted small-molecule inhibitor of the ETS family of oncoproteins, that is being evaluated in a Phase 1/2 clinical trial for patients with Ewing sarcoma alone and in combination with vincristine chemotherapy. The early-stage pipeline includes <u>ONCT-534</u> (formerly GTX-534), a dual-action androgen receptor inhibitor, that is in pre-clinical development as a potential treatment for castration resistant prostate cancer and other androgen-receptor dependent diseases. More information is available at <a href="https://oncternal.com/">https://oncternal.com/</a>.

### Forward-Looking Information [Chase]

Oncternal cautions you that statements included in this press release that are not a description of historical facts are forward-looking statements. In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "expect," "plan," "anticipate," "could," "intend," "target," "project," "contemplates," "believes," "estimates," "predicts," "potential" or "continue" or the negatives of these terms or other similar expressions. These statements are based on Oncternal's current beliefs and expectations. Forward-looking statements include statements regarding the potential for zilovertamab in combination with ibrutinib to treat MCL or CLL; the potential that ZILO-301 can serve as a registrational clinical trial; and the expected initiation of the ZILO-301 study. Forward-looking statements are subject to risks and uncertainties inherent in Oncternal's business, including risks associated with the clinical development and process for obtaining regulatory approval of Oncternal's product candidates, such as potential delays in the commencement, enrollment and completion of clinical trials; we have not conducted head-to-head studies of zilovertamab in combination with ibrutinib compared to ibrutinib monotherapy and data from separate studies may not be directly comparable due to the differences in study protocols, conditions and patient populations; the risk that interim results of a clinical trial do not predict final results and that one or more of the clinical outcomes may materially change as patient enrollment continues, following more comprehensive reviews of the data, as follow-up on the outcome of any particular patient continues, and as more patient data become available; later developments with the FDA may be inconsistent with the minutes from the completed end of Phase 2 meeting, including that the proposed ZILO-301 trial may not support registration of zilovertamab in combination with ibrutinib which is a review issue with the FDA upon submission of a BLA; and other risks described in Oncternal's filings with the U.S. Securities and Exchange Commission. All forward-looking statements in this press release are current only as of the date hereof and, except as required by applicable law, Oncternal undertakes no obligation to revise or update any forward-looking statement, or to make any other forwardlooking statements, whether as a result of new information, future events or otherwise. All forward-looking statements are qualified in their entirety by this cautionary statement. This caution is made under the safe harbor provisions of the Private Securities Litigation Reform Act of 1995.

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