



Oncternal Expands Leadership Team with Appointment of Frank Hsu, M.D., as Chief Medical Officer, and Rajesh Krishnan, Ph.D., as Senior VP CMC and Manufacturing

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SAN DIEGO--(BUSINESS WIRE)--Aug. 28, 2019-- Oncternal Therapeutics, Inc. (Nasdaq: ONCT), a clinical-stage biotechnology company developing potential first-in-class product candidates for cancers with critical unmet medical needs, today announced the appointment of Frank Hsu, M.D., as Chief Medical Officer, and Rajesh Krishnan, Ph.D., as Senior Vice President, Chemistry, Manufacturing and Controls (CMC) and Manufacturing.

Dr. Hsu brings to Oncternal extensive experience in cancer drug development, most recently from Immune Design Corporation, where he served as Vice President and Head of Oncology, responsible for development and execution of the company's clinical programs, supporting preclinical and business efforts. Dr. Krishnan brings a wealth of experience in manufacturing, process development, technology transfer and technical operations, most recently from Dynavax Technologies Corporation, where he served as Vice President, Process Development and Manufacturing Sciences.

"I am very excited to announce these two key executive appointments. Frank Hsu's arrival reflects the growing importance of clinical drug development at Oncternal," said James Breitmeyer, M.D., Ph.D., Oncternal's President and CEO. "We believe that Frank's wealth of expertise in oncology drug development and regulatory approval, his deep academic oncology background and proven ability to collaborate and lead teams make him an ideal fit for Oncternal as we advance our pipeline of potential first-in-class targeted therapies. Raj Krishnan's appointment also reflects Oncternal's commitment to advancing its diverse targeted therapeutic candidates. Raj has extensive experience and a proven track record of innovation and success in cross-functional CMC programs involving biologic and small molecule product candidates. We believe that the addition of these two outstanding professionals to the Oncternal executive team will be instrumental as we continue to advance our lead clinical product candidate, cirmtuzumab, along with our clinical TK216 product candidate and our preclinical ROR1 targeted CAR-T program."

Dr. Hsu stated, "This is an exciting time at Oncternal, with its diversified clinical pipeline targeting emerging cancer biology and multiple indications, including both hematological and solid tumor programs. I look forward to working with the talented individuals at Oncternal to execute the Company's clinical development programs."

"I am delighted to have the opportunity to bring my extensive experience with process development and manufacturing of both biologic and small molecule product candidates to Oncternal," said Dr. Krishnan.

Dr. Hsu has held positions of increasing responsibility in both biotech and academic settings. From 2013 through 2018, he served as Vice President and Head of Oncology at Immune Design Corporation prior to its acquisition by Merck Co., Inc., where he was responsible for development of several immuno-oncology programs. From 2012 until 2013, Dr. Hsu served as Chief Medical Officer at Zyngenia, Inc., where he was responsible for development of its multivalent protein therapeutics. From 2002 through 2012, he served as Senior Medical Director at Genzyme Corporation prior to its acquisition by Sanofi, S.A. Previously, Dr. Hsu was a faculty member at Yale University, serving as an Assistant Professor of Medicine in the Section of Oncology and co-Director/Director of the Immunology Research Program of the Yale Cancer Center. Dr. Hsu holds a B.S. degree in biology from Stanford University, and an M.D. degree from Harvard Medical School and the Health Science and Technology Program at the Massachusetts Institute of Technology. He completed his internship/residency in Internal Medicine at the University of California, San Francisco and his oncology training at Stanford University.

Dr. Krishnan has experience across a range of CMC and manufacturing technologies for U.S. and international manufacturing sites, involving both internal and partnered programs. From 2018 until 2019, he served as Vice President, Process Development and Manufacturing Sciences at Dynavax Technologies Corporation, where he led manufacturing, drug process development, process validation and technology transfer efforts for commercial and clinical development programs. From 2012 through 2017, Dr. Krishnan served in several positions at Gilead Sciences, Inc., most recently as Head, Biologics Drug Substance Process Development. Previously, he served in positions of increasing responsibility at Merck & Co., Inc., Amgen Inc. and Pfizer from 2000 through 2012. Dr. Krishnan holds a B.S.E. degree in chemical engineering from Princeton University, an M.S. degree in chemical engineering from the University of California, Davis, and a Ph.D. degree in Biochemical Engineering from the University of California, Davis.

About Oncternal Therapeutics

Oncternal Therapeutics is a clinical-stage biopharmaceutical company focused on developing a diverse pipeline of product candidates for the treatment of cancers with critical unmet medical need. Oncternal focuses drug development on promising yet untapped biological pathways implicated in cancer generation and progression. The pipeline includes its lead clinical program, [cirmtuzumab](#), a monoclonal antibody designed to inhibit the ROR1 receptor that is being evaluated in a Phase 1/2 clinical trial in combination with ibrutinib for the treatment of chronic lymphocytic leukemia (CLL) and mantle cell lymphoma (MCL), and [TK216](#), a small-molecule compound that is designed to inhibit E26 transformation specific (ETS) family oncoproteins, which is being evaluated in a Phase 1 clinical trial alone and in combination with vincristine as a treatment for Ewing sarcoma, a rare pediatric cancer. In addition, Oncternal has a [CAR-T program targeting ROR1](#), which is currently in preclinical development as a potential treatment for hematologic cancers and solid tumors. More information is available at www.oncternal.com.

- In August 2019, Oncternal announced it has opened for enrollment its randomized Phase 2 study of cirmtuzumab, a ROR1-targeted monoclonal antibody, combined with ibrutinib in patients with CLL. The decision to open the Phase 2 portion of the Company's ongoing Phase 1/2 CIRLL (Cirmtuzumab and Ibrutinib targeting ROR1 for Leukemia and Lymphoma) clinical trial was triggered by favorable outcomes from the Part 1 dose-finding and Part 2 dose-confirming cohorts of the clinical trial, including an observed interim objective response rate (ORR) of 100% for the first nine CLL patients with evaluable data receiving the recommended dosing regimen who have completed 12 weeks of cirmtuzumab

plus ibrutinib treatment in Part 2. The Company continues to see a well-tolerated safety profile consistent with that seen with ibrutinib treatment alone.

- In June 2019, Oncternal presented interim data from its ongoing Phase 1/2 study of cirmtuzumab in combination with ibrutinib at the 2019 American Society of Clinical Oncology (ASCO) Annual Meeting – the largest oncology conference of the year. Results from the first 12 patients with CLL treated in the Part 1 dose-finding portion of the Phase 1 study showed an observed interim ORR of 91.7% for the combination of cirmtuzumab plus ibrutinib, including three patients with clinical or confirmed complete responses, and a well-tolerated safety profile consistent with that seen for ibrutinib treatment alone.
- Oncternal also disclosed at the ASCO meeting that six patients with MCL had been treated in a separate cohort of the CIRLL study. One patient with MCL who had relapsed following an allogeneic stem cell transplant experienced a confirmed complete response (CR) after 3 months of cirmtuzumab plus ibrutinib treatment, including complete resolution of a large mediastinal mass. This CR appears to be durable, and has been confirmed after 6, 9 and 11 months of cirmtuzumab plus ibrutinib treatment.

Forward-Looking Information

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 the Company’s current beliefs and expectations. Forward-looking statements include statements regarding Oncternal’s expectations regarding its ability to advance its lead clinical product candidate, cirmtuzumab, along with its TK216 clinical product candidate and preclinical ROR1 targeted CAR-T program. The inclusion of forward-looking statements should not be regarded as a representation by Oncternal that any of its plans will be achieved. Actual results may differ from those set forth in this release due to the risks and uncertainties inherent in Oncternal’s business, including, without limitation: uncertainties inherent in the clinical development process and in obtaining regulatory approval of cirmtuzumab, TK216 and Oncternal’s other product candidates, including potential delays in the commencement, enrollment and completion of clinical trials; Oncternal’s dependence on the success of cirmtuzumab, TK216 and its other product development programs; the risk that interim results of a clinical trial do not necessarily predict future or 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, and as more patient data become available; the risk that unforeseen adverse reactions or side effects may occur in the course of developing and testing product candidates such as cirmtuzumab, TK216 and Oncternal’s other product candidates; the Company’s reliance on third parties for the manufacture of its product candidates and the risk that sufficient quantities of such product candidates may not be available to perform clinical studies or at an acceptable cost, which could delay, prevent or impair Oncternal’s development efforts; Oncternal’s limited operating history and the fact that it has incurred significant losses, and expects to continue to incur significant losses for the foreseeable future; risks related to the inability of Oncternal to obtain sufficient additional capital to continue to advance the development of cirmtuzumab, TK216 and its other product candidates; and other risks described in Oncternal’s prior press releases as well as in public periodic filings with the U.S. Securities & 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 forward-looking 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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