CORONADO INITIATES PHASE 1/2 TRIAL OF CNDO-109 ACTIVATED ALLOGENEIC NATURAL KILLER CELLS IN ACUTE MYELOID LEUKEMIA

Burlington, MA – November 28, 2012 – Coronado Biosciences, Inc. (NASDAQ: CNDO), a biopharmaceutical company focused on the development of novel immunotherapy biologic agents for the treatment of autoimmune diseases and cancer, announced today the initiation of a phase 1/2 dose escalation trial of allogeneic natural killer (NK) cells activated by the Company’s CNDO-109 in patients in first complete remission (CR1) from acute myeloid leukemia (AML), and who are deemed high-risk for relapse.

"Over 70% of AML patients who achieve a first complete remission will relapse, and it remains a significant unmet medical need. In an investigator-initiated phase 1 trial reported late last year, a number of patients experienced a longer complete remission after receiving CNDO-109 activated NK cells than their previous complete remission, so we are pleased to advance the clinical development of this novel immunotherapy," said Dr. Bobby W. Sandage, Jr., Coronado’s President and CEO. “Earlier this year, we received Orphan Drug Designation from the FDA for CNDO-109 for the treatment of AML and we were recently granted our first U.S. patent covering CNDO-109.”

The phase 1/2 trial is a multi-center, open-label, single-dose, dose-escalating clinical study designed to examine the safety of CNDO-109 activated allogeneic NK cells, as well as the relapse-free survival and overall survival in adult patients with AML. Up to 36 patients who are in CR1 from AML at the time of enrollment, and who are at high-risk for relapse, will be infused with a preparatory regimen of cyclophosphamide and fludarabine followed by a single dose of allogeneic NK cells activated by CNDO-109. Additional study details can be found at clinicaltrials.gov.

AML is one of the most deadly and most common types of acute leukemia in adults. There are over 30,000 cases worldwide, primarily afflicting elderly and relapsed and refractory populations. Once diagnosed with AML, patients typically receive induction and consolidation chemotherapy, with the majority achieving complete remission. However, about 70-80% of patients who achieve first complete remission will relapse, and the overall five year survival rate is less than 25%.

About CNDO-109

CNDO-109 is a novel biologic that primes natural killer (NK) cells without the need for cytokine (IL-2) treatment that is being evaluated for the treatment of hematological cancers, including acute myeloid leukemia (AML) and multiple myeloma, and may have additional applications in solid tumors. NK cells possess potent activity against a wide range of hematologic and solid malignancies, but require activation by IL-2, which can cause many serious side effects. Instead, CNDO-109 activated NK cells can be activated by CNDO-109 in the absence of IL-2. CNDO-109 activated NK cells have shown early efficacy in an investigator-initiated Phase 1 clinical trial in patients with AML and demonstrated preclinical activity in multiple myeloma, breast cancer, prostate cancer and ovarian cancer.
The core NK activation technology was developed in the laboratory of Dr. Mark Lowdell, Director of Cellular Therapy & Biobanking at Royal Free Hampstead NHS Trust and Assistant Professor and Senior Lecturer in Hematology at University College London. Coronado acquired the exclusive worldwide rights to develop and market CNDO-109 from the University College London Business PLC.

About Coronado Biosciences

Coronado Biosciences is engaged in the development of novel immunotherapy biologic agents. The company’s two principal pharmaceutical product candidates in clinical development are: TSO (Trichuris suis ova or CNDO-201), a biologic for the treatment of autoimmune diseases, such as Crohn’s disease, ulcerative colitis and multiple sclerosis; and CNDO-109, a biologic that activates natural killer (NK) cells, for the treatment of acute myeloid leukemia (AML), multiple myeloma and solid tumors. For more information, please visit www.coronadobiosciences.com.

Forward-Looking Statements

This press release may contain "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Such statements include, but are not limited to, any statements relating to the company’s product development programs and any other statements that are not historical facts. Forward-looking statements are based on management’s current expectations and are subject to risks and uncertainties that could negatively affect our business, operating results, financial condition and stock price. Factors that could cause actual results to differ materially from those currently anticipated risks relating to the results of research and development activities, uncertainties relating to preclinical and clinical testing, financing and strategic agreements and relationships, the early stage of products under development, our need for substantial additional funds, government regulation, patent and intellectual property matters; our dependence on third party suppliers and competition, as well as other risks described in our SEC filings. We expressly disclaim any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in our expectations or any changes in events, conditions or circumstances on which any such statement is based, except as required by law.

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