CLEAVE
BIOSCIENCES

Cleave Biosciences Receives Orphan Designation from FDA for CB-5083 for Treatment of Multiple Myeloma

Burlingame, Calif. – Monday, July 13, 2015 – Cleave Biosciences today announced that its lead drug candidate, CB-5083, has been granted Orphan Drug Designation by the U.S. Food and Drug Administration (FDA) for the treatment of multiple myeloma. CB-5083 is a first-in-class, oral inhibitor of p97, a critical enzyme that controls various aspects of protein homeostasis. Cleave is currently evaluating CB-5083 in two Phase 1 studies including one in patients with multiple myeloma, and one in patients with solid tumor malignancies.

"The Orphan designation for CB-5083 recognizes its potential as a new therapeutic option for patients with multiple myeloma," said Laura Shawver, Ph.D., chief executive officer of Cleave Biosciences. "Targeting protein homeostasis is a validated therapeutic approach for the treatment of patients with multiple myeloma and we're making great progress in our data-rich Phase 1 trial to evaluate the safety of CB-5083 and further understand cancers' dependency on the p97 pathway for growth and survival."

Orphan designation is granted by the FDA Office of Orphan Products Development to novel drugs or biologics that treat a rare disease or condition affecting fewer than 200,000 patients in the U.S. The designation for CB-5083 for the treatment of multiple myeloma provides Cleave the ability to apply for tax credits for certain clinical research costs, the ability to apply for annual grant funding, clinical trial design assistance, and waiver of Prescription Drug User Fee Act filing fees, as well as seven years of U.S. marketing exclusivity once the drug is approved.

Cleave's ongoing studies include an open-label, Phase 1 dose escalation/dose expansion trial to evaluate the safety, pharmacokinetics, pharmacodynamics and anti-tumor activity of CB-5083 in multiple myeloma patients who have relapsed/refractory or refractory disease after receiving two or more lines of therapy, including an immunomodulatory agent (IMiD) and a proteasome inhibitor. Cleave expects to enroll up to 60 patients at multiple U.S. cancer centers that are part of the Multiple Myeloma Research Consortium. More information about the trial, including enrolling centers, is available by visiting www.clinicaltrials.gov (ID # NCT02223598) or www.cleavebio.com.

About Multiple Myeloma

Multiple myeloma, also known as myeloma, is a hematologic cancer, or cancer of the blood, that develops in the plasma cells in bone marrow. It is the second most common blood cancer, after non-Hodgkin's lymphoma. The National Cancer Institute estimates that in the U.S., approximately 90,000 people are living with multiple myeloma and more than 26,000 new cases will be diagnosed this year. Worldwide, nearly 230,000 people are living with the disease and approximately 114,000 new cases are diagnosed annually.

About Cleave Biosciences

Biopharmaceutical company Cleave Biosciences is a pioneer in the discovery and development of drugs that target protein homeostasis systems and have the potential to transform the treatment of people with difficult to treat solid tumors and hematologic malignancies. The company is privately held and located in Burlingame, California. For additional information, visit www.cleavebio.com.

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