

Cylene Pharmaceuticals Initiates Phase I Trial With CX-4945 -Breakthrough First-in Class Inhibitor of CK2

SAN DIEGO, Jan. 5 /PRNewswire/ -- Cylene Pharmaceuticals announced today that it has initiated a Phase I clinical trial of its oral CK2 protein kinase inhibitor, CX-4945, in patients with advanced solid tumors, Castleman's disease, or multiple myeloma. The primary endpoints of the oral dose escalating trial are determination of safety, tolerance and PK properties of CX-4945 and to select the appropriate dose for Phase II trials. In addition, multiple mechanism-related pharmacodynamic biomarkers that were validated in preclinical studies will also be evaluated in the trial to assess the ability of CX-4945 to hit its target in patients.

CX-4945 is a first-in-class, orally administered small molecule anticancer agent that delivers highly selective and potent inhibition of CK2, a constitutively active protein kinase that is overexpressed in a wide range of cancers. CK2 drives the excessive proliferation phenotype of cancer cells through its potentiating role in key cell survival pathways and angiogenesis. CX-4945 demonstrates potent tumor regression activity in murine xenograft models, as well as favorable PK/ADMET and safety properties in preclinical studies.

"CX-4945 is a breakthrough molecule for Cylene," said Dr. William Rice, President and Chief Executive Officer of Cylene Pharmaceuticals. "CK2 overexpression drives key cell survival pathways and proliferation of cancer cells, but it has been notoriously difficult to inhibit because it has an unusual active site. CX-4945 represents the first potent and selective inhibitor of CK2 with a favorable safety profile and the ability to promote tumor regressions as a single agent in preclinical studies. We are delighted to have advanced CX-4945 into the clinic ahead of schedule, and we are thoughtfully planning our Phase II program in particular CK2 driven cancers."

In this Phase I trial, CX-4945 will be administered to patients orally twice a day, for three consecutive weeks of a four week cycle, over a range of doses. The primary objectives of the study will be to determine the maximum tolerated dose (MTD) and dose limiting toxicities (DLTs) of CX-4945, and to define the phase II dose. The secondary objectives are to characterize the pharmacokinetics, as well as observe for signs of anti-tumor activity via pharmacodynamic as well as radiographic assessments.

"CK2 is of central importance in driving cancer cell proliferation as well as in angiogenesis. As such, CX-4945 is a truly novel therapeutic, particularly against cancers and in other indications mediated by IL-6 and IL-8," added Dr. Daniel Von Hoff, Cylene's Co-Founder and Vice President, Medical Affairs.

About CX-4945, an oral CK2 protein kinase inhibitor

CX-4945 is a first-in-class small molecule that has been optimized to selectively inhibit CK2 activity. The CK2 protein kinase plays a multifunctional role in cell cycle regulation, signal transduction, transcriptional control, angiogenesis, apoptosis and inflammation. Because CK2

contributes to the cancer phenotype via multiple cellular events, CX-4945 has been designed with the objective of creating a multifunctional inhibitor by targeting a single protein and affecting potentially many cancers. CX-4945 demonstrates broad spectrum anti-proliferative activity against diverse cancer cell lines, and the data attribute the anti-tumor activity of CX-4945 to intracellular inhibition of the CK2 enzyme.

About Cylene Pharmaceuticals, Inc.

Cylene Pharmaceuticals is a biotech pharmaceutical company dedicated to the discovery, development and commercialization of targeted small-molecule drugs to treat life-threatening cancers. Cylene has created a diverse portfolio of product candidates, including novel inhibitors of cancer-linked serine/threonine protein kinases, as well as innovative nucleolus targeting agents (NTAs) that target the abnormal nucleolar functions of cancer cells and selectively kill cancer cells. More information can be found at <http://www.cylenepharma.com/> .

Cylene cautions you that statements included in this press release that are not a description of historical facts, including implied statements relating to future outcomes of clinical trials, may be forward-looking statements that are subject to risks and uncertainties. Actual results may differ materially from those set forth in this release due to the risks and uncertainties inherent in Cylene's business including, without limitation, risks related to difficulties or delays in, testing, obtaining regulatory approval for, producing and marketing its products; unexpected adverse side effects or inadequate therapeutic efficacy of its products that could delay or prevent product development or commercialization, the scope and validity of patent protection for its products; competition from other pharmaceutical or biotechnology companies; and its ability to obtain additional financing to support its operations. All forward-looking statements are qualified in their entirety by this cautionary statement and Cylene undertakes no obligation to revise or update this news release to reflect events or circumstances after the date hereof.