

# Global Phase 3 Study of IMC-1121B in Metastatic Breast Cancer Commences

NEW YORK--(BUSINESS WIRE)--Aug 13, 2008 - ImClone Systems Incorporated (NASDAQ: IMCL), a global leader in the development and commercialization of novel antibodies to treat cancer, today announced that the first patient has been treated in a global Phase 3 clinical trial of IMC-1121B, its anti-vascular endothelial growth factor receptor-2 (VEGFR-2) IgG1 monoclonal antibody, in women with metastatic breast cancer.

"Since the growth of breast cancer is dependent on VEGFR-2 activation, IMC-1121B presents a unique opportunity to optimize this therapeutic approach as IMC-1121B uniquely binds to the VEGFR-2 receptor itself, thereby blocking many VEGF ligands from activating it," said Eric K.

Rowinsky, M.D., Executive Vice President and Chief Medical Officer of ImClone. "Unlike bevacizumab that targets only a single ligand, and unlike small molecule drugs that target many unrelated receptors, IMC-1121B specifically targets only VEGFR-2. This clinical trial will help us understand whether this approach produces greater activity with fewer side effects."

In April 2008, ImClone announced the establishment of an agreement with the U.S. Food and Drug Administration (FDA) under a Special

Protocol Assessment (SPA) for this trial. The SPA is a written agreement between the trial's sponsor and the FDA regarding the design and size of the Phase 3 trial to be used in generating the primary clinical data necessary to support approval of an efficacy claim in conjunction with the submission of a new drug application (NDA) or biologics licensing application (BLA).

Pursuant to the SPA, this Phase 3 trial is a randomized, double-blind, placebo-controlled trial of IMC-1121B plus docetaxel in women with unresectable locally-recurrent or metastatic breast cancer who have not received prior chemotherapy in the locally-recurrent or metastatic setting. The trial, which is being conducted under the auspices of the Cancer International Research Group, doing business as Translational Research in Oncology (TRIO), is expected to enroll approximately 1,100 patients who will be randomized (2:1) to receive either IMC-1121B plus docetaxel or placebo plus docetaxel. The primary endpoint of the trial is progression-free survival. The trial will be conducted at more than 200 sites throughout the world.

"This trial of IMC-1121B highlights the efforts of TRIO to bring promising new therapies to women with breast cancer, which remains the most frequently diagnosed cancer among women today," said John Mackey, M.D., FRCPC, Professor of Oncology at the University of Alberta, and Principal Investigator of the study. "Our efforts also demonstrate TRIO's commitment to transforming our understanding of cancer biology into clinical trials by testing compounds, like IMC-1121B, across the spectrum of human cancer."

IMC-1121B is a fully human IgG1 monoclonal antibody designed to bind to the extracellular domain of VEGFR-2 found on tumor

vasculature, thereby inhibiting certain ligands known as vascular endothelial growth factors from binding to and activating the receptor. This action blocks a signaling pathway key to new blood vessel formation in growing tumors, which has been shown to starve tumors of their nutrient supply and result in significant tumor growth inhibition in pre-clinical models. In 2007, ImClone completed enrollment into two Phase 1 studies of IMC-1121B, which demonstrated favorable safety and pharmacokinetic profiles, as well as objective antitumor activity as a single agent in several patients with refractory solid cancers when administered either weekly or every two or three weeks. In addition to this Phase 3 study of IMC-1121B in women with breast cancer, disease-directed studies of IMC-1121B in patients with advanced melanoma, renal and liver cancers have begun to enroll patients, and additional Phase 2 and 3 evaluations are in various stages of development.

## About TRIO

TRIO, which was created as an international research network in oncology in 1997, is an academic global network of investigators capable of rapid accrual to clinical trials. TRIO arose out of the need to address the increasing number of new anticancer drugs and targeted therapies in development. TRIO has selected dedicated investigators from all around the world to participate in pivotal trials of new cancer agents in breast cancer and many other disease settings. TRIO has been highly successful in maintaining a strong and enthusiastic network by offering innovative and exciting science, and more recently, translational research. TRIO consists of an operations infrastructure that uses comprehensive pharmaceutical industry standards. By combining these two strategies, that of increasing

patient access through global investigator sites and that of applying efficient, well-established clinical trial operation systems, TRIO has since become recognized for its high quality data and rapid accrual rates. TRIO has also been highly successful at captivating the interests of patients and investigators throughout the world, in part, due to the incorporation of high quality and exciting science into its clinical evaluations. TRIO was incorporated as a Canadian not for profit entity in 1999.

### About ImClone Systems

ImClone Systems Incorporated is a fully integrated global biopharmaceutical company committed to advancing oncology care by developing and commercializing a portfolio of targeted biologic treatments designed to address the medical needs of patients with a variety of cancers. The Company's research and development programs include growth factor blockers and angiogenesis inhibitors. ImClone Systems' headquarters and research operations are located in New York City, with additional administration and manufacturing facilities in Branchburg, New Jersey. For more information about ImClone Systems, please visit the Company's web site at <http://www.imclone.com>.

Certain matters discussed in this news release may constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and the Federal securities laws. Although the company believes that the expectations reflected in such forward-looking statements are based upon reasonable assumptions it can give no assurance that its expectations will be achieved. Forward-looking information is subject to certain risks,

trends and uncertainties that could cause actual results to differ materially from those currently expected. Many of these factors are beyond the company's ability to control or predict. Important factors that may cause actual results to differ materially and could impact the company and the statements contained in this news release can be found in the company's filings with the Securities and Exchange Commission, particularly those factors identified as "risk factors" in the Company's most recent annual report of Form 10-K and in its quarterly reports on Form 10-Q and current reports on Form 8-K. For forward-looking statements in this news release, the company claims the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995. The company assumes no obligation to update or supplement any forward-looking statements whether as a result of new information, future events or otherwise.

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