

**Novacea Begins Phase 1 Dose Escalation Trial Of Anti-Cancer Agent AQ4N  
-- Study Will Determine Safety and Tolerability of Multiple Weekly Doses in Patients With Advanced Malignancies --**

SOUTH SAN FRANCISCO, CA - Sept. 23, 2004 – Novacea Inc., a privately held biopharmaceutical company, announced today that the first patient has been enrolled in the Company's multiple-dose, Phase 1 study of AQ4N, a novel proprietary anti-cancer agent that is activated by tumor cells with low oxygen levels (hypoxic tumor cells), present in solid tumors. Preclinical data also suggest that AQ4N may have anti-tumor activity in lymphoid malignancies. AQ4N is Novacea's second product candidate to enter clinical trials.

The primary objectives of this open-label study are to determine the safety and tolerance of multiple weekly intravenous doses of AQ4N given to patients with advanced malignancies (solid tumors or non-Hodgkin's lymphoma), as well as to obtain a maximum tolerated dose to guide subsequent studies.

"We are enthusiastic about the potential of AQ4N and are pleased to begin clinical trials in the United States following the submission and allowance of Novacea's investigational new drug application. With our European partner, KuDOS Pharmaceuticals, and Cancer Research UK conducting a Phase 1 study with AQ4N in the United Kingdom, the agent represents another product opportunity for Novacea that leverages our existing expertise in oncology and hematology," said John Curd, chief medical officer of Novacea. "The start of this trial marks another key milestone achievement for Novacea. We plan to move this promising program forward rapidly with its development in indications for which standard curative measures do not exist or are no longer effective."

In December 2003, Novacea licensed the North American rights to develop and commercialize AQ4N from UK-based KuDOS Pharmaceuticals. Interim data from the UK-based Phase 1 dose escalation study of AQ4N in combination with radiation in esophageal cancer was presented at the American Society for Clinical Oncology annual meeting in June 2004 and showed the agent to be well tolerated.

**About AQ4N**

As a first-in-class hypoxic cell-activated anti-tumor therapy, AQ4N represents a new approach to cancer treatment. The drug is designed to be inactive when administered and is selectively converted into its active cytotoxic form, known as AQ4, once it reaches hypoxic tumor cells (cells that are oxygen starved), reducing potential systemic toxicity. AQ4 is a potent topoisomerase II inhibitor and DNA intercalator. AQ4N also has activity on malignant lymphoid cell lines, suggesting another potential therapeutic opportunity for this compound.

More than two million patients each year are estimated to present with tumors in the U.S. and Europe. The large majority of these tumors have hypoxic components, which are relatively resistant to standard anti-cancer treatment, including radiotherapy and chemotherapy. As a result, a specific agent like AQ4N that can treat the hypoxic fractions should enhance the overall efficiency of cancer cell killing and reduce tumor recurrence.

AQ4N was originally discovered by Prof. Laurence Patterson of the School of Pharmacy, at University of London, working in collaboration with the intellectual property and technology commercialization company, BTG. KuDOS acquired a worldwide license for AQ4N from BTG in March 2001.

**About KuDOS**

KuDOS Pharmaceuticals, a privately held pharmaceutical company, holds a leading position in the discovery and development of small molecule drugs based upon the science of DNA damage sensing, signaling and repair to address unmet medical needs in cancer treatment. Potential applications for drugs that target DNA repair additionally extend to treatment of viral disease, ischemia and immunosuppression.

KuDOS currently has two drugs in clinical trials: Patrin™, which is being developed for the treatment of cancers resistant to alkylating agents, and AQ4N, which targets hypoxic regions of tumors. Research continues on DNA-PK, ATM, PARP and mTOR inhibitors, with a candidate compound for PARP currently in preclinical assessment. Further information on KuDOS can be found on the company's website: <http://www.kudospharma.co.uk>

**About Novacea**

Novacea is a privately held biopharmaceutical company committed to creating a world-class drug licensing, development and commercialization organization that addresses significant unmet medical needs in oncology. The Company's first product to enter the clinic is DN-101, a novel formulation of calcitriol. Also in

Novacea's pipeline is AQ4N, a novel proprietary hypoxic cell-activated agent with broad potential in a variety of cancers. Novacea holds North American development and commercialization rights for AQ4N in all indications. For more information about the Company and its programs, visit its World Wide Web site at [www.novacea.com](http://www.novacea.com)

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