

## **DUSKA THERAPEUTICS AND CATO RESEARCH PLAN 505(b)(2) NDA FILING ROUTE FOR ATPace™**

LA JOLLA, Calif., April 25 /PRNewswire-FirstCall/ -- **Duska Therapeutics, Inc.** (OTC Bulletin Board: [DSKA](#) - [News](#); "Duska" or the "Company"), a biotechnology company developing medical products based on adenosine 5'-triphosphate (ATP) and P2 receptor-related technologies, announced today that the Company's management and clinical and regulatory consultants met on April 16 with members of the United States Food and Drug Administration (FDA) Division of Cardiovascular and Renal Products. The purpose of the meeting was to discuss the appropriate regulatory pathway for filing a marketing application of ATPace(TM) as an antiarrhythmic drug for the acute termination of paroxysmal supraventricular tachycardia (PSVT). Based on discussions held during the meeting and prior written communications between Duska and the FDA, the Company believes that the FDA would consider a New Drug Application (NDA) under section 505(b)(2) for ATPace(TM) subject to additional clinical data to be furnished by the Company. The 505(b)(2) NDA relies in part upon relevant published data obtained by entities other than the Company.

Dr. James Kuo, Duska's Chairman and CEO, said, "I am pleased to report that this meeting with the FDA was both positive and constructive. Together with our CRO, **Cato Research, Ltd.**, we have already commenced activities aimed at the generation of the supplemental data requested by the FDA. The 505(b)(2) NDA filing provides an expedited route for potential approval of ATPace(TM)," he added.

Dr. Amir Pelleg, Duska's President and Chief Scientific Officer, stated, "It has been our goal to commercialize the first ATP-based drug in the United States and I believe we are now much closer to attaining that goal as a result of this meeting. Formulations of ATP, which is the active ingredient in ATPace(TM), have been used for over 50 years in Europe in the treatment of PSVT. I am confident that our drug would manifest a safety and efficacy profile similar to that of the European formulations."

### **About ATPace(TM)**

ATPace(TM) is Duska's investigational intravenous pharmaceutical formulation of ATP for the acute treatment of paroxysmal supraventricular tachycardia (PSVT). The bradycardic (heart rate slowing) effect of ATP, in particular its transient blockade of atrio-ventricular nodal conduction, has been shown in multiple published clinical studies to terminate re-entrant PSVT involving the atrio-ventricular node.

### **About PSVT**

PSVT (paroxysmal supraventricular tachycardia) is a rapid regular heart rate originating in the atria. It has been estimated that there are 89,000 new cases per year in the United States alone. PSVT is one of the most common cardiac arrhythmias.

**About Cato Research**

Founded in 1988 by Allen Cato, M.D., Ph.D., and Lynda Sutton and headquartered near Research Triangle Park, Cato Research is a global, full-service contract research and development organization providing strategic and tactical support for clients in the pharmaceutical, biotechnology, medical device, and medical diagnostic industries. With a staff of more than 300 employees located in the United States, Europe, Canada, Israel, and South Africa, Cato Research's services range from design and management of preclinical and clinical studies to submission of regulatory documents required for marketing approval. For more information, visit Cato's website at <http://www.cato.com>.

**About Duska Therapeutics, Inc.**

Duska Therapeutics, Inc., based in La Jolla, California, is an emerging biotechnology company that is focused on the development of therapeutic, medical device and diagnostic products related to adenosine 5'-triphosphate (ATP) and cell-surface P2 receptors (P2R). Duska owns or has exclusive license rights to a number of proprietary products, four of which are currently in various stages of development for the treatment and diagnosis of certain cardiac arrhythmias, enhancement of sperm motility, treatment of chronic obstructive pulmonary disorder, and mitigation of the toxic effects of radiation exposure. For more information, visit Duska's website at <http://www.duskatherapeutics.com>.