

## 7 of 17 DOCUMENTS

Copyright 1998 Business Wire, Inc. Business Wire

September 17, 1998, Thursday

**DISTRIBUTION:** Business Editors

LENGTH: 687 words

**HEADLINE:** ICOS Announces Clinical Results and Initiation of Trials

**DATELINE:** BOTHELL, Wash.

## **BODY:**

Sept. 17, 1998--ICOS Corporation (Nasdaq:ICOS) announced today that Thomas P. St. John, Ph.D., Vice President of Therapeutic Development will report results from several clinical trials at the Newsmakers in the Biotech Industry Conference in New York. As a part of ICOS' ongoing development plan, product candidates have been evaluated in multiple disease indications.

## LeukArrest(TM)

A 48 patient Phase 2 clinical trial with LeukArrest(TM) (previously referred to as Hu23F2G) to evaluate safety and efficacy following an ischemic stroke has been completed. The results indicated that LeukArrest(TM) was safe in this patient population and, while not powered to show statistical significance, the results suggest that the high dose group had improved neurological outcomes and had a higher positive response rate compared to placebo. Plans are underway to design a pivotal Phase 2/3 clinical trial.

The analysis of the Phase 2 single dose clinical trial with LeukArrest(TM) in 169 patients experiencing acute exacerbations of multiple sclerosis (MS) has been completed through the first ninety days of follow-up. The study, designed to evaluate the recovery of neurologic function following exacerbation of a patient's disease, demonstrated no clinical benefit for LeukArrest(TM. A second study, a Phase 2 multiple dose trial in approximately 50 MS patients suffering acute exacerbations, is continuing enrollment.

## Pafase(TM)

A Phase 2 trial with Pafase(TM) (the Company's recombinant human enzyme, formerly called rPAF-AH) in 18 patients at risk to develop acute respiratory distress syndrome demonstrated that Pafase(TM) is well tolerated and non-antigenic. While this study was designed to determine safety and pharmacology, it additionally suggested an improvement in blood oxygenation and severity of multiple organ dysfunction compared to patients treated with placebo. The improvements observed were not statistically significant. Based upon these results a double blind placebo controlled Phase 2 efficacy trial has been initiated and is expected to enroll approximately 240 patients.

The analysis of the Phase 2 clinical trial with a single dose of Pafase(TM)in an inhaled allergen-challenge model with 15 subjects has been completed. The primary endpoints in this trial were safety and efficacy as measured by lung function. In this placebo controlled, crossover study, there was no improvement in the early or late asthmatic responses following Pafase(TM) treatment. Additional trials utilizing a different dosing regimen are under consideration.

ICM3



The Phase 1 clinical trial with ICM3 was designed to evaluate safety and pharmacology in 25 patients with moderate to severe psoriasis. The single dose study has been completed and a multi-dose trial is planned. The Phase 1/2 multi-dose trial in Europe continues to enroll patients.

IC351

In a 44 patient overseas study assessing the safety and efficacy (erectile response) of IC351 (the Company's phosphodiesterase 5 inhibitor for the treatment of erectile dysfunction), IC351-treated patients showed significant improvement relative to placebo-treated patients in the primary endpoint (p<0.001) and all secondary endpoints. A second study evaluating safety and pharmacokinetics in healthy subjects was completed and shows that IC351 was well-tolerated. Additionally, patient enrollment in a study testing safety and efficacy has been initiated in the United States.

ICOS is discovering and developing new pharmaceuticals by seeking points of intervention in the inflammatory process that may lead to specific and efficacious drugs. ICOS' research and drug development programs involve several acute and chronic conditions.

**CONTACT: ICOS Corporation** 

Lacy Fitzpatrick, 425/485-1900 http://www.businesswire.com/cnn/icos.htm

Today's News On The Net - Business Wire's full file on the Internet with Hyperlinks to your home page.

URL: http://www.businesswire.com

LOAD-DATE: September 18, 1998

