SOUTHWESTERN NEWS

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NOTE: A NEWS RELEASE DISTRIBUTED DEC. 4 CONTAINED INCORRECT INFORMATION ON DERAMCICLANE'S AVAILABILITY IN EUROPE. THE DRUG IS IN LATE STAGE CLINICAL TRIALS IN EUROPE AND IS BEGINNING CLINICAL TRIALS IN THE U.S. A CORRECTED VERSION OF THE RELEASE FOLLOWS.

UT SOUTHWESTERN TO PARTICIPATE IN NATIONAL TRIAL OF EUROPEAN-TESTED DRUG FOR ANXIETY DISORDER

DALLAS – Dec. 12, 2002 – Heart pumping, adrenaline rushing, feeling out-of-control – people who suffer from generalized anxiety disorder experience these sensations chronically and unpredictably, leaving them helpless to carry on with their daily life.

UT Southwestern Medical Center at Dallas psychiatry researchers are hoping a new drug for generalized anxiety disorder (GAD) that is also being tested in Europe will prove to be equally effective in U.S. clinical trials, providing anxiety sufferers with an alternative to current treatments, which carry serious side effects and are sometimes addictive.

Dr. Harold Urschel III, clinical associate professor of psychiatry, is part of a 20-center national trial launched by the Pharmacia Corp. to evaluate whether deramciclane, an antidepressant, is a safe and effective option for patients with the disorder. The U.S. group will join Stage III trials in Europe, which have ongoing since 2000.

"We have treatments now for generalized anxiety disorder, but we need new ones for our patients – treatments that work better and with fewer side effects and aren't addictive like some of the older medications," Urschel said.

Anxiety can be so severe that 4 percent to 7 percent of the population of industrialized countries is crippled by GAD at any given time. Thinking, behavior and psychological responses are affected by the illness. Yet the medications approved to treat GAD in the United States are less than satisfactory, he said.

The study will compare the antidepressant deramciclane, a new type of serotonin re-uptake inhibitor, with venlafaxine hydrochloride (Effexor), a Food and Drug Administration-

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approved antidepressant that also works on serotonin brain receptors. GAD is not associated with accompanying psychiatric features such as panic disorder, major depression or psychotic episodes, Urschel said.

The 12-week, double-blind study will compare daily treatments of 30 milligrams of deramciclane, 60 mg of deramciclane, 30 mg of venlafaxine and a placebo. The 900 treatment volunteers will be divided into four groups, each receiving one of the treatments. The study will also look at the effects of drug withdrawal.

Trial participants must be at least 18 years old and diagnosed with generalized anxiety disorder. Volunteers may not have another psychiatric disorder or disease with features that might compromise the study findings. Women of childbearing age must be on contraception and must not be pregnant or breastfeeding. Participants will be given a year's supply of the new drug following completion of the study. For further information about participating, please call 214-879-6551.