BMS-201038

Indication:	Hyperlipidemia
Protocol No.:	CV145-009
Phase:	I
Study Initiation Date:	19-Feb-1999
Study Completion Date:	22-Dec-1999
Report Date:	07-Jan-2002

THE EFFECTS OF CHRONIC DOSING OF BMS-201038 ON HEPATIC FAT ACCUMULATION AND REVERSIBILITY AS ASSESSED BY NUCLEAR MAGNETIC RESONANCE SPECTROSCOPY (NMRS)

AN ABBREVIATED CLINICAL STUDY REPORT

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FINAL REPORT SYNOPSIS

INTRODUCTION: BMS-201038 is an inhibitor of microsomal triglyceride transfer protein (MTP). In studies conducted in human volunteers BMS-201038 was shown to be a potent agent for lowering LDL-C and triglycerides. As an inhibitor of MTP it has the potential to increase hepatic fat content. To assess the possible accumulation of hepatic fat, a nuclear magnetic resonance spectroscopy (NMRS) technique was developed. This technique was originally described as a method to assess fat content in bone marrow, and subsequently developed as part of the MTP program to determine percent fat in the liver. In Protocol CV145-002, this technique demonstrated that at all doses of BMS-201038 from 10 mg QD to 100 mg QD, there appeared to be an increase in hepatic fat content. To further define the safety of this compound, a Reversibility Protocol, CV145-009, was developed to assess the extent of any hepatic fat accumulation and the degree of reversibility at 6 weeks post dosing of any accumulated hepatic fat. Based on the results of this trial, further clinical development on BMS-201038 was discontinued due to safety concerns. Therefore an Abbreviated Study Report is being issued.

TITLE OF STUDY: The Effects of Chronic Dosing of BMS-201038 on Hepatic Fat Accumulation and Reversibility as Assessed by Nuclear Magnetic Resonance Spectroscopy (NMRS)

INVESTIGATORS: Study conducted at 5 study centers in the U.S.A. The Principal investigators (site number) were William Insull, M.D. (001), Carlos Dujovne, M.D. (002), Howard Knapp, M.D., Ph.D. (003), Daniel Rader, M.D. (007), Evan Stein, M.D., Ph.D. (008)

STUDY CENTERS:
001: Lipid Research Clinic, Baylor College of Medicine, Houston, TX
002: Mid-Continent Clinical Trials, Overland, KS
003: Lipid Research Clinic, Iowa City, IA
004: Hospital of the University of Pennsylvania, Philadelphia, PA
008: Metabolic and Atherosclerosis Research Center, Cincinnati, OH

PUBLICATIONS: None

STUDY PERIOD: Date first subject enrolled: 19-Feb-1999
Date last subject completed: 22-Dec-1999

CLINICAL PHASE: I

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