

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**

This document is a confidential communication of Bristol-Myers Squibb Company. Acceptance of this document constitutes an agreement by the recipient that no unpublished information contained herein will be published or disclosed without Bristol-Myers Squibb Company's prior written approval, except that this document may be disclosed to appropriate Institutional Review Committees so long as they are requested to keep it confidential. This study was conducted in accordance with Good Clinical Practice.

**Name and Affiliation of Principal Investigators:**

William Insull, M.D. (Houston), Carlos Dujovne, M.D.(Kansas), Howard Knapp, M.D.,  
Ph.D.(University of Iowa), Daniel Rader, M.D.(University of Pennsylvania), Evan Stein,  
M.D., Ph.D. (Cincinnati)

**Company Signatory**

Richard A. Reeves, M.D.  
Bristol-Myers Squibb  
Princeton, NJ 08543-4000  
Tel: 609-252-3452  
Fax: 609-252-6313

Department of Clinical Discovery  
Drug Discovery and Exploratory Development  
Bristol-Myers Squibb Pharmaceutical Research Institute  
Bristol-Myers Squibb Company  
Bristol-Myers Squibb  
Princeton, NJ 08543-4000

## 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

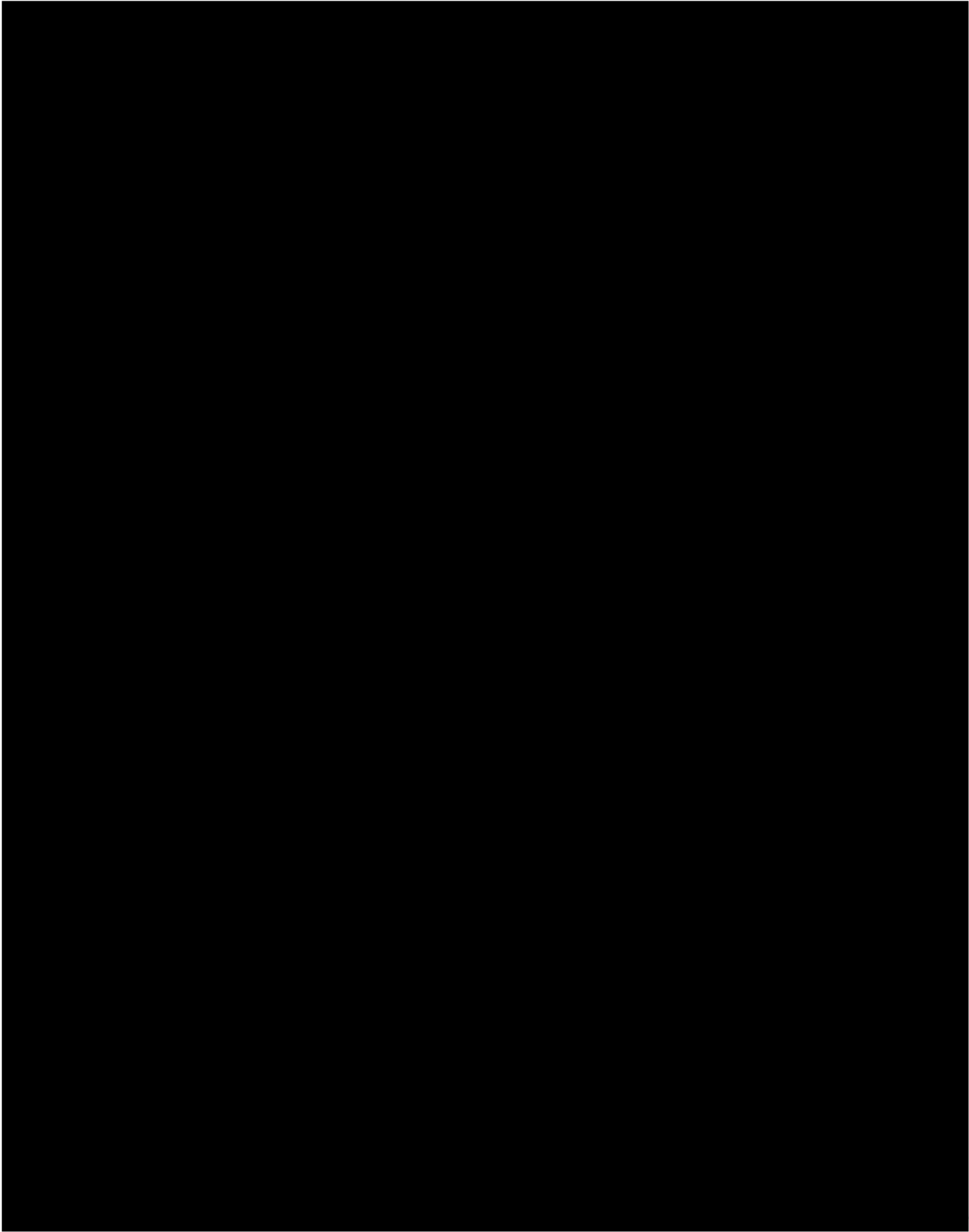
**STUDY PERIOD:** Date first subject enrolled: 19-Feb-1999  
Date last subject completed: 22-Dec-1999

**CLINICAL PHASE:** I

J-V1.0, C-V1.0

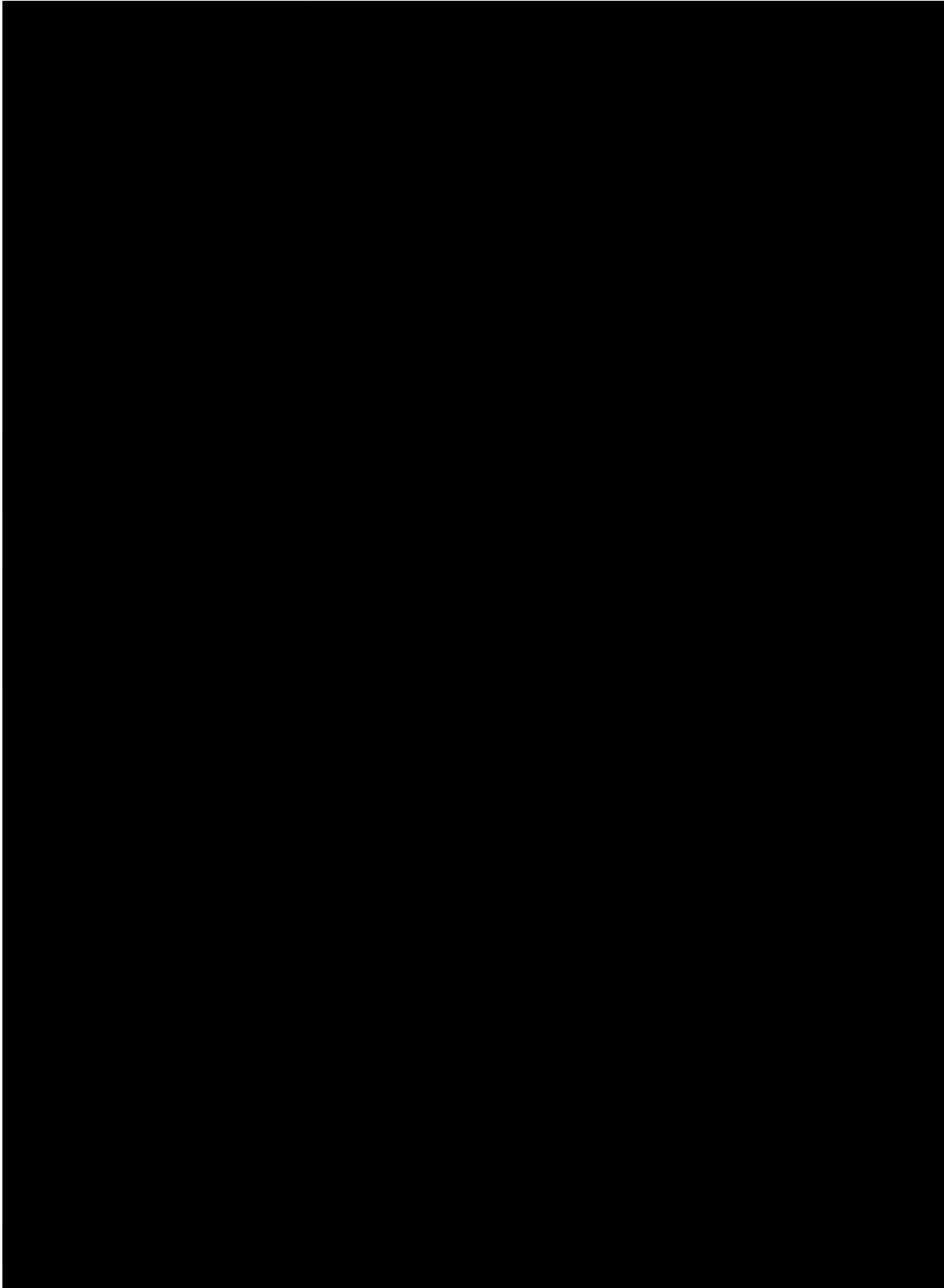
IDIS:93000110

IDIS:9300011C 3-v1.0, C-v1.0



IDIS:9300011r b-v1.0, C-v1.0

IDIS:9300011C 3-V1.0, C-V1.0



# Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

## Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

## Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

## Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

## API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

## LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

## FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

## E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.