# **EXHIBIT C**

In consideration for the Stipulation and Agreement of Settlement, BMS agrees to publicly disclose the results of all BMS-Sponsored Clinical Studies, regardless of outcome, for all BMS medicines that are approved for marketing. BMS also agrees that, upon commencement of each clinical trial, it will register the study on an appropriate publicly-accessible database.

Described below is the manner in which BMS agrees to implement this commitment. It is understood, however, that the particular manner in which the commitment is implemented may evolve over time as a result of changes in law, advances in technology, practical logistics considerations and any BMS decision to expand its disclosure commitments. BMS nevertheless agrees that any changes in the manner of its disclosures will result in disclosure of clinical trial data on terms equivalent to or greater than those described below.

# 1.0 Definitions

- (a) "Clinical Study" means a research investigation on human subjects to answer specific questions about a BMS drug. The term Clinical Study is not limited to a research study that is randomized, controlled or blinded. The term "Clinical Study" does not include non-interventional studies, i.e., outcomes research studies.
- (b) "Clinical Study Report" means a report containing the results of a

  Clinical Study that is consistent in content and format with applicable law, regulation and
  regulatory guidance, for example, as currently required by the guidelines of the International
  Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals
  for Human Use (ICH) on Structure and Content of Clinical Study Reports (E3). Such report
  includes, among other information, a description of the protocol, and evaluations of the safety

and efficacy of the drug.

- (c) "BMS-Sponsored Clinical Study" means a Clinical Study of a BMS

  Drug for which BMS holds the IND or NDA, as applicable, or the non-US equivalent and is
  ultimately responsible for regulatory approvals, site selection, protocol development, initiation,
  monitoring, safety reporting, and analysis of the results of the Clinical Study, even if some or
  all of these activities are transferred to another party or contract research organization. "BMSsponsored Clinical Study" excludes Clinical Studies for which BMS provides support and may
  assume certain responsibilities associated with the sponsor role, but for which BMS does not
  hold the IND or NDA of the product under investigation in the Clinical Study.
- (d) "BMS Drug" means a compound that is developed to be or is a prescription pharmaceutical product sold for human consumption in the United States by BMS, for which BMS holds the IND or NDA, as applicable.
- (e) "BMS Web Site" refers to BMS's main corporate Internet site, currently www.bms.com.
- (f) "Post[ed][ing]" means to provide access to information on an Internet site that provides unrestricted access to both the site and the information BMS has provided through the site.
- (g) "Study Completion Date" is the date on which the last observation is made either of the last patient who remains enrolled in the Clinical Study or following a decision to terminate the Clinical Study early, whichever happens first.

### 2.0 Registration of Clinical Studies

- BMS will provide information regarding BMS Drugs designed to treat (a) serious or life-threatening diseases and conditions and developed under the FDA's investigational new drug (IND) regulations to the Clinical Trials Data Bank (CTDB) in accordance with the FDA Modernization Act of November 1997, Section 113.
- BMS will register all BMS-Sponsored Phase II, III, and IV Clinical (b) Studies. BMS will also register BMS-Sponsored Phase I in-patient Clinical Studies, except for single dose Clinical Studies ("Phase I 'in-patient' Clinical Studies" does not include Phase I Clinical Studies conducted with healthy volunteers). Where BMS transfers Clinical Study responsibilities to a third party or contract research organization, the registration responsibilities will be clarified in the contract.
- Where BMS does not hold the IND or NDA, but is a co-development (c) partner, BMS will endeavor in good faith to explicitly define in the contract agreements/charters the registration/disclosure scope and responsibilities between BMS and the partner.
- (d) The registration referred to in 2(b) above will occur on the www.clinicaltrials.gov Web site, and the BMS Web Site, once formatted to allow such registration, within 21 days of the initiation of patient enrollment, unless applicable legal requirements specify an alternative timeframe. BMS-Sponsored non-U.S. Clinical Studies will also be registered at appropriate international or local country registries in compliance with local law. For each Clinical Study registered, BMS will provide the information required by applicable law, regulation and regulatory guidance, for example, as currently required by the HHS Clinical Trial Registry at www.clinicaltrials.gov, and will also provide a complete

description of the Clinical Study in accordance with applicable law, regulation and regulatory guidance, for example, in accordance with the "minimum data set" currently identified in the report from the World Health Organization (WHO) Technical Consultation on Clinical Trial Registration Standards Meeting (25-27 April 2005). The fields in the WHO minimum data set will be completed and disclosed when the Clinical Studies are first registered.

As part of the registration, BMS will provide each Clinical Study with a (e) unique identifier number.

#### 3.0 Disclosure of Clinical Study Results

- (a) BMS will Post the results of any BMS-Sponsored in-patient Clinical Studies regardless of development phase or outcome, for BMS Drugs that have at least one indication approved for marketing in at least one country. Clinical Study results will be Posted for Clinical Studies conducted for indications not yet approved, as long as the medicine has one approved indication. Clinical Study results will not be Posted for new formulations of marketed products until the new formulation is approved, unless the results of the Clinical Study are clinically relevant to the use of the marketed product. BMS will also Post the results of long-term extensions of any Clinical Studies.
- (b) The results referred to in 3(a) above will be Posted on the PhRMAsponsored clinical trials Web site: www.clinicalstudyresults.org and to the BMS Web Site, once formatted to allow such Posting. Clinical Study results meeting the disclosure criteria will be Posted regardless of the country or region in which they were conducted.
- (c) Results of BMS-Sponsored Clinical Studies for BMS Drugs developed and marketed exclusively by BMS will be Posted on the PhRMA-sponsored clinical trials Web site: www.clinicalstudyresults.org and to the BMS Web Site, once formatted to allow such

Posting. Decisions on disclosing results of BMS-Sponsored Clinical Studies for BMS Drugs that are not exclusively marketed by BMS will be made on a case-by-case basis by BMS and its respective development/marketing partners, with the intent to publish all results which meet the criteria for a given product in one location on the PhRMA-sponsored Web site.

- (d) The Posting will be in the form of a synopsis of a BMS Clinical Study Report for a completed Clinical Study. The synopsis will be presented in accordance with applicable law, regulation and regulatory guidance, for example, as currently set forth in the standard, non-promotional ICH E3 format. For Clinical Study Reports that were completed before the adoption of the ICH E3 format, the Clinical Study executive summary will be Posted on the PhRMA-sponsored clinical trials Web site: www.clinicalstudyresults.org and to the BMS Web Site, once formatted to allow such Posting. The synopsis will include a description of the study design and methodology, results of the primary and secondary outcome measures described in the protocol, and safety results. If results of the Clinical Study are published in a peer-reviewed medical journal, the Posting will include a citation to and, when available, a link to the abstract of the journal article. Any changes or proposed additions to the synopsis of a BMS Clinical Study Report already submitted to regulatory authorities prior to Posting will require the approval of the BMS Medical Review Group or its equivalent.
- (e) The Clinical Study results will be described objectively. There will be no promotional messaging and no marketing input into the summaries. The Posting will include reference to the Clinical Study unique identifier number in the clinical trial registry, www.clinicaltrials.gov.
- (f) The Posting of results will occur within one year of the Study Completion Date, unless there is a plan for publication or a manuscript submitted for review by

Page 14 of 15

a recognized journal at that time. In the case where there is a planned publication but no manuscript yet submitted, BMS will indicate on the PhRMA-sponsored Web site, "planned for publication." In the case where the manuscript has been submitted, BMS will indicate "submitted for publication" and then Post the reference to the article, once published. For Clinical Studies where BMS seeks publication, BMS will Post references to the publication no later than two years after completion of the Clinical Study. If the manuscript has not been published in that time frame, BMS will Post the Clinical Study Report synopsis. At the time of launch for a new medicine or indication, BMS will Post the results or reference the publication status for any Clinical Studies with the completed Clinical Study Report synopsis for the new medicine or indication, and will continue to meet the PhRMA guidelines on disclosure of clinical trial results while also disclosing results for any other BMS-Sponsored Clinical Studies in patients that complete post-launch.

- (g) Posting may be delayed or withheld if necessary for BMS to obtain intellectual property protection, or if required for BMS to comply with confidentiality obligations to a third party.
- (h) Clinical Study results for BMS Drugs that fit the disclosure criteria, which are marketed in the United States and were completed from October 2002 onward, will be Posted. For those BMS Drugs not marketed in the United States but marketed in at least one other country, Clinical Studies completed by January 2005 and onward will be Posted.

### 4.0 Term of Agreement

BMS shall endeavor in good faith to follow this disclosure protocol for a (a) period of ten years after the Effective Date of the Stipulation and Agreement of Settlement, subject to subparagraph 4.0(b) below.

- BMS may modify its obligations under this Exhibit C by providing the (b) Court with notice of the modification and by simultaneously providing counsel for Lead Plaintiff with notice of the modification by certified mail. If Lead Plaintiff does not object to the modification within 10 days of receiving notice, BMS may make the modification without further action by the Court. BMS need not provide notice to the Court or Lead Plaintiff of any modification to its disclosures under this Exhibit C that is required by federal or state law or for any modification that would provide additional disclosures or for any modifications resulting from any changing circumstances referred to in 4.0(c) below.
- As noted above, the manner in which BMS implements its obligations (c) under this agreement is subject to changing circumstances, including changes in law, advances in technology, practical logistics considerations and any BMS decision to expand its disclosure commitments. BMS agrees that any changes in the manner of disclosure as described above will result in disclosure on terms equivalent to or greater than those described above.
- BMS's obligations under this agreement are subject to applicable law, (d) regulation and regulatory guidance.
- Neither Lead Plaintiff nor any member of the Class may enforce the (e) terms of this Exhibit C by power of contempt.