Medarex and Bristol-Myers Squibb Joint Statement on Submission Status of Ipilimumab

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PRINCETON, N.J.--(BUSINESS WIRE)--Medarex, Inc. (NASDAQ: MEDX) and Bristol-Myers Squibb Company (NYSE: BMY) today announced that, after meeting with the U.S. Food and Drug Administration (FDA), the companies will delay the Biologics License Application (BLA) submission for ipilimumab, an investigational immunotherapy for patients with advanced metastatic melanoma. The FDA has requested additional overall survival (OS) data to further demonstrate the benefit of ipilimumab. Revised timelines are under development, but a BLA for ipilimumab will not be submitted to the FDA in 2008.

The randomized Phase 3 trial evaluating the efficacy of ipilimumab in combination with dacarbazine versus dacarbazine alone in patients with untreated unresectable Stage III or Stage IV melanoma is ongoing under Special Protocol Assessment (SPA). The companies are engaged in discussions with the FDA to change the primary endpoint in this trial from progression free survival (PFS) to OS. A potential submission for melanoma would include survival data from patients in the Phase 2 second-line studies and the randomized Phase 3 first-line trial currently ongoing.

Bristol-Myers Squibb and Medarex remain committed to the development of ipilimumab. The companies also have ongoing Phase 2 studies in hormone-refractory prostate cancer and lung cancer as well as a Phase 3 study, to be initiated shortly, in adjuvant melanoma.

Twelve abstracts evaluating ipilimumab in melanoma will be presented at the American Society of Clinical Oncology (ASCO) Annual Meeting this year. These include data from the three Phase 2 trials evaluating ipilimumab in patients with advanced Stage III or Stage IV metastatic melanoma (Abstract #9010, 9021 and 9025).

Ipilimumab is being developed through a joint partnership between Bristol-Myers Squibb and Medarex. Based on nonclinical and clinical studies showing that antibody blockade of CTLA-4 plays an important role in sustaining an active immune response to fight cancer, the companies are pursuing a broad clinical development program with ipilimumab. More than 2,000 patients have been treated in clinical trials with ipilimumab as a monotherapy or in combination with other agents.

For further information about ipilimumab clinical trials, please visit www.clinicaltrials.gov.

About Ipilimumab

Ipilimumab is a fully human antibody that binds to CTLA-4 (cytotoxic T lymphocyte-associated antigen 4), a molecule on T-cells that plays a critical role in regulating natural immune responses. The absence or presence of CTLA-4 can augment or suppress the immune system's T-cell response in fighting disease. Ipilimumab is designed to block the activity of CTLA-4, thereby sustaining an active immune response in its attack on cancer cells.

About Medarex

Medarex is a biopharmaceutical company focused on the discovery, development and potential commercialization of fully human antibody-based therapeutics to treat life-threatening and debilitating diseases, including cancer, inflammation, autoimmune disorders and infectious diseases. Medarex applies its UltiMAb® technology and product development and clinical manufacturing experience to generate, support and potentially commercialize a broad range of fully human antibody product candidates for itself and its partners. More than 40 of these therapeutic product candidates derived from Medarex technology are in human clinical testing or have had INDs submitted for such trials, with seven of the most advanced product candidates currently in Phase 3 clinical trials or the subject of regulatory applications for marketing authorization. Medarex is committed to building value by developing a diverse pipeline of antibody products to address the world's unmet healthcare needs. For more information about

Medarex Statement on Cautionary Factors

Except for the historical information presented herein, matters discussed herein may constitute forward-looking statements that are subject to certain risks and uncertainties that could cause actual results to differ materially from any future results, performance or achievements expressed or implied by such statements. Statements that are not historical facts, including statements preceded by, followed by, or that include the words "potential"; "believe"; "expect"; "could"; "may"; or similar statements are forward-looking statements. Medarex disclaims, however, any intent or obligation to update these forward-looking statements. These risks and uncertainties include whether the development of ipilimumab will be successful, whether the clinical studies described in this release will support the filing of a BLA with the FDA, or whether, if a BLA is filed with the FDA, it will be filed in the timeframe developed by the parties or will receive regulatory approval, as well as risks detailed from time to time in Medarex's public disclosure filings with the U.S. Securities and Exchange Commission (SEC), including its Annual Report on Form 10-K for the fiscal year ended December 31, 2007 and its quarterly reports on Form 10-Q. There can be no assurance that such development efforts will succeed or that other developed products will receive required regulatory clearance or that, even if such regulatory clearance were received, such products would ultimately achieve commercial success. Copies of Medarex's public disclosure filings are available from its investor relations department.

About Bristol-Myers Squibb

Bristol-Myers Squibb is a global biopharmaceutical and related health care products company whose mission is to extend and enhance human life.

Bristol-Myers Squibb Statement on Cautionary Factors

This press release contains "forward-looking statements" as that term is defined in the Private Securities Litigation Reform Act of 1995, regarding the development of biological products and the submission of applications to market such products. Such forward-looking statements are based on current expectations and involve inherent risks and uncertainties, including factors that could delay, divert or change any of them, and could cause actual outcomes and results to differ materially from current expectations. No forward-looking statement can be guaranteed. Among other risks, there can be no guarantee that the development of the product described in this release will be successful or that the clinical studies described in this release will support the filing of a Biological License Application (BLA) with the U.S. Food and Drug Administration (FDA). Furthermore, there can be no assurances that if a BLA is filed with the FDA, that it will be filed in the timeframe described in this release or that the BLA for the product described in this release will receive regulatory approval. There can be no assurances that if approved, the product described in this release will be commercially successful. Forward-looking statements in the press release should be evaluated together with the many uncertainties that affect Bristol-Myers Squibb's business, particularly those identified in the cautionary factors discussion in Bristol-Myers Squibb's Annual Report on Form 10-K for the year ended December 31, 2007, its Quarterly Reports on Form 10-Q, and Current Reports on Form 8-K. Bristol-Myers Squibb undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events, or otherwise.

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