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Bristol-Myers Squibb Discontinues Development of BMS-986094, an Investigational NS5B Nucleotide for the Treatment of Hepatitis C

Company will share BMS-986094 data with other companies developing similar hepatitis C drugs to inform patient safety measures

CATEGORY: [CORPORATE/FINANCIAL NEWS](#), [R&D NEWS](#)

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PRINCETON, N.J. --(BUSINESS WIRE)-- [Bristol-Myers Squibb Company](#) (NYSE: BMY) announced today that the Company has discontinued development of BMS-986094 (formerly known as INX-189), a nucleotide polymerase (NS5B) inhibitor that was in Phase II development for the treatment of hepatitis C. This decision was made in the interest of patient safety, based on a rapid, thorough and ongoing assessment of patients in a Phase II study that the Company voluntarily suspended on August 1, 2012. The U.S. Food and Drug Administration (FDA) subsequently placed the compound on clinical hold.

The initial case of heart failure, which was the basis for halting the study, subsequently resulted in death. The Company is working in close collaboration with the FDA and clinical study investigators to conduct ongoing, comprehensive assessments and close follow-up of all BMS-986094 study patients. To date, nine patients have been hospitalized, including the initial patient; two patients remain hospitalized. While the cause of these unexpected events, which involve heart and kidney toxicity, has not been definitively established, the Company has determined that it is in the best interest of patients to halt development of BMS-986094.

“The decision to halt development of BMS-986094 has been guided by our overriding interest in protecting patients,” said [Elliott Sigal, M.D., Ph.D.](#), Executive Vice President and Chief Scientific Officer, Bristol-Myers Squibb. “In the interest of all patients participating in hepatitis C clinical studies, and in cooperation with the FDA, we will make relevant information on BMS-986094 available to inform the development of other investigational compounds to treat hepatitis C. We will also work expeditiously to share the results of our further investigations more broadly in the medical and scientific community.”

Bristol-Myers Squibb is committed to investigating this safety issue further, including studies to evaluate the potential mechanism of this toxicity. The Company will continue close monitoring and follow-up of patients who have received BMS-986094 across all studies.

About Bristol-Myers Squibb

Bristol-Myers Squibb is a global biopharmaceutical company whose mission is to discover, develop and deliver innovative medicines that help patients prevail over serious diseases. For more information about Bristol-Myers Squibb, visit www.bms.com or follow us on Twitter at <http://twitter.com/bmsnews>.

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