BRISTOL-MYERS SQUIBB SUBMITS NDA FOR NEW FORMULATION OF ONCE DAILY VIDEX(R) (DIDANOSINE)

Princeton, New Jersey, February 1 /PRNEWSWIRE/ - Bristol-Myers Squibb (NYSE: BMY) announced today that it has submitted a New Drug Application (NDA) with the U.S. Food and Drug Administration (FDA) for a new formulation of VIDEX(R), also known as ddI. The new capsules contain enteric coated VIDEX beadlets designed to protect the essential medicine in VIDEX from degrading until it has passed through the stomach, thus eliminating the need for a buffer. If approved, VIDEX capsules will further reduce pill burden from two tablets to a single capsule dosed once a day.

"Guided by our mission to extend and enhance human life, Bristol-Myers Squibb has been a leader in the search to find effective therapies for HIV/AIDS for more than a decade," said Rick Winningham, President, Bristol-Myers Squibb Oncology/Immunology. "We are continuously conducting research to improve the tolerability, potency and convenience of our therapies. The submission of the new enteric coated formulation of VIDEX is an important milestone in our quest to ease the management of complex regimens for patients."

Today's antiretroviral drug regimens can be complicated and often result in unpleasant or serious side effects. As many as four drugs are often prescribed and patients are burdened with taking up to 20 pills, several times a day, making it especially difficult to remain on prescribed therapy. When patients do not adhere to prescribed treatment regimens, the efficacy of treatment is reduced.

VIDEX(R) (didanosine) received marketing clearance in the U.S. in 1991 for the treatment of HIV/AIDS and is marketed by Bristol-Myers Squibb in over 70 countries around the world. In October 1999, the FDA approved VIDEX tablets for once-a-day dosing; concurrently, BMS launched a 200 mg tablet which simplifies dosing to two tablets once a day. Patients must take at least two of the appropriate strength tablets to provide adequate buffer to prevent gastric acid degradation of VIDEX.

VIDEX tablets are the first and only once-daily nucleoside analogue reverse transcriptase inhibitor (NRTI), the class of drugs which form the foundation of anti-HIV therapy. VIDEX in combination with other antiretroviral agents is indicated for the treatment of HIV-1 infection.

Bristol-Myers Squibb is committed to research and development for therapies to fight infectious diseases. Together with the Bristol-Myers Squibb Foundation, the Company has pledged $100 million over the next five years to help South Africa, Botswana, Namibia, Lesotho and Swaziland. The program, SECURE THE FUTURE(TM), is committed to finding sustainable solutions for women, children and communities suffering from the HIV/AIDS epidemic in their countries.

Fatal and nonfatal pancreatitis has occurred during therapy with VIDEX used alone or in combination regimens in both treatment-naive and treatment-experienced patients, regardless of degree of immunosuppression. VIDEX should be suspended in patients with suspected pancreatitis and discontinued in patients with confirmed pancreatitis. Lactic acidosis and severe hepatomegaly with steatosis, including fatal cases, have been reported with the use of nucleoside analogues alone or in combination, including didanosine and other antiretrovirals.

Other important toxicities include retinal changes, optic neuritis and peripheral neuropathy. Patients treated with VIDEX in combination with stavudine, with or without hydroxyurea, may be at increased risk for adverse events such as pancreatitis, peripheral neuropathy and liver function abnormalities.

The most frequent side effects observed in adults taking the recommended dose of VIDEX in combination studies (AI454-148 and START 2) include diarrhea (69%, 45%), nausea (24%, 53%), neuropathy (22%, 21%), headache (20%, 46%), rash (11%, 30%), and vomiting (8%, 30%).

Bristol-Myers Squibb is a diversified worldwide health and personal care company whose principal businesses are pharmaceuticals, consumer products, nutritionals and medical devices. It is a leading maker of innovative therapies for cardiovascular, metabolic and infectious diseases, central nervous system and dermatological disorders, and cancer. The Company is a leader in consumer medicines, orthopaedic devices, ostomy care, wound management, nutritional supplements, infant formulas, and hair and skin products.

Note To Editors: The package insert for VIDEX tablets can be obtained by calling Mark Short at +1 609-897-2742. Full prescribing information for all Bristol-Myers Squibb drugs is also available via the BMSOI FAXback system at 800-426-7644 and on the World Wide Web at: http://www.bms.com/

Contact: Mark Short of Bristol-Myers Squibb, +1 415-537-6294, in San Francisco until February 2, or Pager, 1-800-341-7976, mark.short@bms.com

Web site: http://www.bms.com/
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