FDA APPROVES NEW INDICATIONS FOR ZERIT(R) (STAVUDINE) AND VIDEX(R) (DIDANOSINE)

- Each Drug Approved for Use as a First-Line Component of Combination Antiretroviral Therapy for Patients with HIV -

- Bristol-Myers Squibb Also Files Supplemental New Drug Application for Additional VIDEX Improvements -

Princeton, N.J., September 9 (PRN) - Bristol-Myers Squibb (NYSE: BMY) announced yesterday that the U.S. Food and Drug Administration (FDA) has approved new indications for its currently marketed nucleoside analogues ZERIT (also known as d4T) and VIDEX (also known as ddI). Each of these products may be used as a first-line component of a combination antiretroviral therapy regimen for HIV-I infected patients. The approval reflects current HIV treatment guidelines, which recommend initiating therapy with two nucleoside analogues plus a protease inhibitor or the non-nucleoside analogue efavirenz.

"We are pleased that the availability of ZERIT(R) (stavudine) and VIDEX(R) (didanosine) for use in first-line and subsequent antiretroviral combination regimens will provide the healthcare practitioner with additional options for the effective treatment of HIV," said Rick Winningham, president, Bristol-Myers Squibb, Oncology/Immunology. "This is a reflection of Bristol-Myers Squibb's commitment to meeting the needs of people living with HIV disease. We are also extremely pleased to file a Supplemental NDA for additional VIDEX improvements and remain very committed to improving our current products and researching new and novel HIV drug therapies."

The approvals of ZERIT and VIDEX each as a component of combination antiretroviral regimens for first-line and subsequent treatment of HIV infected patients are based on these agents' proven efficacy and durability. Furthermore, the approvals of ZERIT and VIDEX suggest that these two agents can be used as a dual-nucleoside foundation of first-line combination therapy.

Bristol-Myers Squibb is seeking to expand the role of ZERIT in the U.S., which is already one of the most prescribed nucleoside reverse transcriptase inhibitors. The Company is investigating the use of ZERIT in multiple combination regimens with other nucleosides analogues, non-nucleoside analogues and protease inhibitors. BMS is also evaluating other formulations and improvements to VIDEX that should eliminate the need for buffers and antacids, and improve upon current VIDEX dosing.

The major toxicity of VIDEX is pancreatitis, which has been fatal in some

cases. Other toxicities include retinal changes and optic neuritis. Patients treated with VIDEX in combination with stavudine may be at increased risk for adverse events such as pancreatitis, peripheral neuropathy, and liver function abnormalities. Lactic acidosis and severe hepatomegaly with steatotis, including fatal cases, have been reported with the use of nucleoside analogues alone or in combination, including didanosine and other antiretrovirals.

The major clinical toxicity of ZERIT(R) (stavudine) is peripheral neuropathy which may resolve if stavudine is withdrawn promptly. Patients treated with ZERIT in combination with didanosine may be at increased risk for adverse events such as pancreatitis, peripheral neuropathy, and liver function abnormalities. Lactic acidosis and severe hepatomegaly with steatotis, including fatal cases, have been reported with the use of nucleoside analogues alone or in combination, including stavudine and other antiretrovirals.

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, orthopedic devices, ostomy care, wound management, nutritional supplements, infant formulas and hair and skin care products.

NOTE TO EDITORS: Package inserts for all products mentioned in this news release can be obtained by calling Patti Doykos Duquette at +1 609-897-3077. Full prescribing information for all Bristol-Myers Squibb drugs is also available via the BMSOI FAXback system at +1 800-426-7644 and on the World Wide Web at: http://www.bms.com.

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