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Bristol-Myers Squibb (BMS) has announced that the US Food and Drug Administration (US FDA) has granted Breakthrough Therapy Designation to the investigational compound BMS-663068, when used in combination with other antiretroviral (ARV) agents for the treatment of HIV-1 infection in heavily treatment-experienced adult patients. BMS-663068 is an oral prodrug of the molecule BMS-626529 and first-in-class HIV-1 attachment inhibitor.

The attachment inhibitor is designed to work differently than entry inhibitors, a current class of drugs that targets co-receptors' activity or fusion after HIV attaches to the CD4+ host cell. BMS-663068 is thought to work at an earlier point in the replication process to prevent the virus' initial interaction with immune cells entirely, and thus blocks its entry into the cell.

The designation is based on data from the Phase IIb clinical study comparing BMS-663068 to a boosted protease inhibitor (Reyataz (atazanavir sulfate) and ritonavir) in treatment-experienced patients, with a treatment backbone across all arms of raltegravir, in addition to tenofovir disoproxil fumarate. Week 48 results from the Phase IIb trial were presented earlier this year at the 22nd Conference on Retroviruses and Opportunistic Infections (CROI) and supported the continued clinical development of the attachment inhibitor.

A Phase III trial in heavily treatment-experienced patients (defined as individuals who can no longer formulate a viable three-drug treatment regimen due to accumulation of drug resistance, past intolerabilities or antiretroviral contraindications) began in February 2015 and is ongoing.

"We are now 30-plus years into the AIDS epidemic, and there is an ever-increasing number of long-term survivors of the condition, many of whom are facing issues of drug resistance and are in need of new treatment options," said Mr Douglas Manion, head of specialty development, Bristol-Myers Squibb. He added, "The Breakthrough Designation recognizes the unmet need for novel therapies for this growing group of heavily treatment-experienced patients, and is evidence of Bristol-Myers Squibb's continued focus on meeting that need."

Breakthrough Therapy Designation expedites the development and review of new therapies meant to treat serious or life-threatening conditions. The criteria for Breakthrough Therapy Designation require preliminary clinical evidence that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints. The Designation for BMS-663068 is a significant milestone and will help speed development of the investigational compound for heavily treatment-experienced patients.