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CLINICAL NEWS

CLINICAL STATUS

Bionor Pharma ASA (OSE:BIONOR), Oslo, Norway
Product: Vacc-4x
Business: Infectious
Molecular target: NA
Description: Therapeutic peptide composed of 4 modified synthetic peptides that correspond to a conserved domain of the p24 protein
Indication: Vaccinate against HIV/AIDS
Endpoint: NA
Status: Phase I/II start
Milestone: Start Phase I/II (4Q11); Phase I/II data (1H13)

By next quarter, Bionor will begin a German Phase I/II trial to compare its Vacc-4x in combination with Revlimid lenalidomide vs. Vacc-4x alone in HIV-infected patients on antiretroviral therapy (ART) with a CD4 T cell count of 250-400 cells/mL. The open-label, dose-escalation portion will evaluate 5, 10 and 20 mg doses of Revlimid to determine the maximum tolerated dose (MTD). In the double-blind, placebo-controlled portion, 24 patients will receive Vacc-4x plus the MTD of Revlimid or Vacc-4x alone for 26 weeks.

Revlimid, a thalidomide analog from Celgene Corp. (NASDAQ: CELG, Summit, N.J.), is marketed in the EU and U.S. in combination with dexamethasone to treat multiple myeloma (MM) and in the U.S. to treat patients with transfusion-dependent anemia due to low- or intermediate-1-risk myelodysplastic syndromes (MDS). Bionor and Celgene will jointly fund the trial.

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