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(54) Title: METHODS FOR THE TREATMENT OF SUBJECTS HAVING A HEPATITIS B VIRUS (HBV) INFECTION

(57) Abstract: The present invention provides methods for the treatment of a subject having a Hepatitis B virus (HBV) infection, e.g., a chronic HBV infection, using a combination of an RNAi agent that targets HBV and an HBV vaccine. It is disclosed a RNAi agent and an HBV vaccine for use in treatment of HBV infection, comprising sequentially administering to the subject having an HBV infection: a) an RNAi agent that inhibits expression of at least three HBV transcripts, wherein the RNAi agent forms a double stranded region; b) a protein-based vaccine comprising a first HBV core antigen (HBcAg) polypeptide, and a first HBV surface antigen (HBsAg) polypeptide; and c) a nucleic acid-based vaccine comprising an expression vector construct encoding a second HBcAg polypeptide, and/or a second HBsAg polypeptide, wherein the second HBcAg polypeptide, and/or the second HBsAg polypeptide, shares at least one epitope with at least one of the first HBcAg polypeptide, and/or the first HBsAg polypeptide.

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