CLAIMS

What is claimed is:

1. Use of a compound in the manufacture of a medicament for treating or preventing hepatocellular carcinoma (HCC) characterized by hepatitis B virus (HBV) infection in a patient, wherein the compound is 7-(6-(2-hydroxypropan-2-yl)pyridin-3-yl)-l-((*trans*)-4-methoxycyclohexyl)-3,4- dihydropyrazino[2,3-*b*]pyrazin-2(l*H*)-one or a pharmaceutically acceptable salt or tautomer thereof and wherein an effective amount of the compound is to be administered to the patient.

2. The use of claim 1, wherein the patient's HCC is first screened for HBV infection prior to the administration of the compound; or

wherein the patient's response to the treatment with the compound is first predicted by analysing a biological test sample from the patient for HBV infection and predicting an increased likelihood of response to treatment with 7-(6-(2-hydroxypropan-2-yl)pyridin-3-yl)-l-((*trans*)-4-methoxycyclohexyl)-3,4- dihydropyrazino[2,3-*b*]pyrazin-2(l*H*)-one or a pharmaceutically acceptable salt or tautomer thereof in the patient having HCC if HBV infection is determined in the sample prior to the administration of the compound; or

wherein therapeutic efficacy of the compound in the patient having HCC is first predicted by analyzing a biological test sample from the patient for HBV infection and predicting an increased likelihood of the therapeutic efficacy of the compound in the patient having HCC if HBV infection is determined in the sample.

3. The use of any one of claim 1 or 2, wherein HBV infection is determined by at least one of the variables selected from the group consisting of: patient history of HBV, prior or current treatment for HBV, cirrhosis attributed to HBV, the presence of HBV proteins or antigens, the presence of antibodies to HBV proteins or antigens, the use of HBV medications, the HBV viral load, the presence of HBV DNA and the presence of HBV mRNA.

4. The use of claim 3, wherein HBV infection is determined by patient history of HBV; or

wherein HBV infection is determined by prior treatment for HBV; or

wherein HBV infection is determined by current treatment for HBV; or

wherein HBV infection is determined by cirrhosis attributed to HBV; or

wherein HBV infection is determined by the presence of HBV proteins or antigens; or

wherein HBV infection is determined by the presence of antibodies to HBV proteins or antigens; or

wherein the HBV infection is determined by the use of HBV medications; or

wherein HBV infection is determined by HBV viral load; or

wherein HBV infection is determined by the presence of HBV DNA; or

wherein HBV infection is determined by the presence of HBV mRNA.

5. The use of claim 1 or 2, wherein HBV infection is determined by at least one of the variables selected from the group consisting of: the presence of HBV surface antigen (HBsAG), the presence of HBV core antigen (HBcAG), the presence of HBV envelope antigen (HBeAg), the presence of HBV x antigen (HBxAg), the presence of HBV core-related antigen (HBcrAg), the presence of antibody to HBV surface antigen (anti-HBsAg), the presence of antibody to HBV core antigen (anti-HBcAg), the presence of antibody to HBV envelope antigen (anti-HBeAg), the presence of antibody to HBV x antigen (anti-HBxAg), and the presence of antibody to HBV core-related antigen (anti-HBcrAg).

6. The use of claim 5, wherein HBV infection is determined by the presence of HBsAg; or

wherein HBV infection is determined by the presence of HBcAg; or

wherein HBV infection is determined by the presence of HBeAg; or

wherein HBV infection is determined by the presence of HBxAg; or

wherein HBV infection is determined by the presence of HBcrAg; or

wherein HBV infection is determined by the presence of anti-HBsAg; or

wherein HBV infection is determined by the presence of anti-HBcAg; or

wherein HBV infection is determined by the presence of anti-HBeAg; or

wherein HBV infection is determined by the presence of anti-HBxAg; or

wherein HBV infection is determined by the presence of anti-HBcrAg.

7. The use of any one of claims 1 to 6, wherein the medicament is to be administered in combination with a second therapeutic agent.

8. The use of claim 7, wherein the second therapeutic agent is sorafenib; or

wherein the second therapeutic agent is 3-(5-amino-2-methyl-4-oxo-4H-quinazolin-3-yl)-piperidine-2,6-dione (Compound 2); or

wherein the second therapeutic agent is an immune check point inhibitor.

9. The use of any one of claims 1 to 6, wherein the medicament is to be administered in combination with a second and a third therapeutic agent.

10. The use of claim 9, wherein the second and the third therapeutic agent are selected from the group consisting of sorafenib, 3-(5-amino-2-methyl-4-oxo-4H-quinazolin-3-yl)-piperidine-2,6-dione (Compound 2), and an immune check point inhibitor.

11. The use of claim 10, wherein the immune check point inhibitor is nivolumab.

12. The use of any one of claims 1 to 11, wherein the HCC is unresectable HCC; or

wherein the HCC is previously untreated HCC; or

wherein the HCC is previously treated HCC, wherein the previous treatment comprises sorafenib; or

wherein the HCC is previously treated HCC, wherein the previous treatment comprises chemotherapy.