廣州白雲山醫藥集團股份有限公司

GUANGZHOU BAIYUNSHAN PHARMACEUTICAL HOLDINGS CO., LTD.

(a joint stock company with limited liability established in the People's Republic of China)

(H Share Stock Code: 0874)

Inside Information

IMPORTANT NOTICE

1. This announcement is made by Guangzhou Baiyunshan Pharmaceutical Holdings Company Limited (the "Company") pursuant to Rule 13.09 of the Rules Governing the Listing of Securities (the "Listing Rules") on The Stock Exchange of Hong Kong Limited (the "Stock Exchange") and the Inside Information Provisions (as defined under the Listing Rules) of Part XIVA of the Securities and Futures Ordinance (Chapter 571 of Laws of Hong Kong).

2. On 9 March 2014, the therapeutic dual-plasmid HBV DNA vaccine project (the "Research") held a meeting at Beijing Oriental Garden Hotel to review the IIb clinic test (the "Review Meeting") and published the test result. This announcement is prepared pursuant to the summary of the Review Meeting.

3. The Company will communicate with the relevant parties and experts as soon as possible, and the Company and the relevant parties will, base on the report of the Research, report to the China Food and Drug Administration (國家食品藥品監督管理局) and will, base on the response of the relevant governmental department(s), consider whether to enter into III clinical research continue the II clinical research or terminate the Research.
4. Research on new medicine involves high-risk, high-investment and long time. The Research in particular IIb clinic test is an exploratory clinical experiment, investors are reminded of the risk of investment and to exercise caution in dealing in the securities of the Company.

5. This announcement is prepared in both English and Chinese. In the event of discrepancy, the Chinese version shall prevail.

On 13 December 2013, and the Company had published an announcement on inside information disclosing the preliminary result and detailed statistical data of the IIb clinic research.

On 9 March 2014, the Review Meeting was held at Beijing Oriental Garden Hotel to review the IIb clinic test. The Review Meeting was presided over by the team leader of the clinic research for the phase, and totally 44 people attended the meeting, including representatives of 14 clinical research units such as Peking University First Hospital (北京大學第一醫院), representatives of clinic statistics units, representatives of project research and development units, representatives of drug delivery instrument units, representatives of clinic supervision units and representatives of bidders. Experts attended the Review Meeting had careful discussion of the clinical data and issues based on the conditions of the clinic test, and the main contents of the discussion are as follows:

1. this phase of clinic test is a standardised research conducted according to the GCP principles under a multiple centers, random, double-blind and controlled clinical program. The entire clinic test was monitored by a professional CRO company, being a third party, and the statistical analysis of the clinical data was made by professional clinical statistics institution. Therefore, the clinical data are true and reliable and the statistical analysis is objective and detailed.

2. Based on the process and result of the whole clinical process, the therapeutic dual – plasmid HBV DNA vaccine (治療性雙質粒HBV DNA疫苗) is safe and showed good tolerance while the compliance of the subjects is good with low explusion rate.

3. Immune therapy is the future development trend for viral diseases. Therapy of CHB is currently at the stage of migrating from non-specific treatment to specific treatment, whereas tumor treatment has also undergone such course of research development. In this phase of clinic test, effective result is seen in the enhanced CHB immune response and virology response of the vaccine.

   At the same time, through this phase of clinic test, it is also observed that the vaccine has little impact on the mutation of the HBV virus. Therefore, it is still debatable whether it is reasonable to take YMDD as the major observation indicator for immune therapy. In the course of treatment, the impact of HBsAg on the detection result as indicated by the vaccine should also be considered. As the vaccine is for specific immune therapy, relevant immune indicator detection should be added in the process of the clinical test. Since molecular biological detection technology is quite matured now, it is suggested that observation of changes in immune indicators after injection of the vaccine should be made on the subjects through PCR and rapid gene sequencing.

4. It is suggested that more detailed analysis at different levels should be made on the clinic test data such as for different age groups, pathological inflammation grades, genders and serological indicators, so as to identify the best target group of the vaccine.

5. The associated drug used in this phase of clinical test is lamivudine, which is not deemed as the preferred drug for treating CHB patients by nearly all clinicians. It is expected that there will be great difficulty for group admission if the associated drug is not changed in the next phase of clinical studies.

6. The medication history of patients enrolled in this phase of clinicl test should be considered. It cannot be ruled out that some subjects may hold back their records of long-term anti-virus treatment in order to join the test, which will affect the effect of their treatment.

7. In the program design and clinical approach of the next stage of clinicl test, the influence of factors such as age, pathological condition, serological indicators and medication history of the patients enrolled should be considered to optimise the enrollment criteria and detection indicators, and adjust the associated drug used and dosing program (dosage, timing and duration).

8. The results achieved in this clinic test should be put into a paper and published in prime journals. This is recognition of the achievement of the research team and will benefit the certificate application of the new drug later on.

9. The clinical units showed great interest in the clinical studies of this vaccine and indicated that they will continue to support and participate in the subsequent stage of the vaccine's clinical studies and product promotion.

The results of this test as concluded at the Review Meeting are (summary):

1. Data rated as effective by the therapeutic effect indexes

During the observation of the following clinic indexes, the test group is better than the control group with significance statistical differences ($P<0.05$).

(1) The result that HBV DNA dropped by 2 logarithmic degrees

(a) For the test group and the control group in the 48th week versus the 12th week, proportion of subjects with HBV DNA titers down by 2 logarithmic degrees:

Results of FAS set analysis: the test group (11 cases/107 cases=10.28%), better than the control group (4 cases/115 cases=3.48%), upon chi-square test, the inter-group difference is of statistical significance ($P = 0.044$);

Results of PPS set analysis: the test group (11 cases/96 cases=11.46%), better than control group (4 cases/106 cases=3.77%), upon chi-square test, the inter-group difference is of statistical significance ($P = 0.037$).

(b) For the test group and the control group in 64 weeks versus 12 weeks, proportion of subjects with HBV DNA titers down by 2 logarithmic degrees:

Results of PPS set analysis: the test group (13 cases/70 cases=18.57%), better than control group (6 cases/84 cases=7.14%), upon chi-square test, the inter-group difference is of statistical significance ($P = 0.032$).

(2) The result of negative conversion of HBV DNA

Percentage of HBV DNA negative conversion rate of the test group versus control group in the 64th week that cannot be detected by quantitative testing:

Results of PPS set analysis: the test group (29 cases/70 cases=41.43%), better than the control group (20 cases/84 cases=23.81%), upon chi-square test, the inter-group difference is of statistical significance (P = 0.019).

(3) The result that HBeAg fell to 300COI

Proportion of HbeAg in the the test group and the control group in the 24th week that fell down to 300COI:

Results of FAS set analysis: the test group (83 cases/107 cases=77.57%), better than the control group (75 cases/115 cases=65.22%), upon chi-square test, the inter-group difference is of statistical significance (P = 0.042).

(4) The result of test of immunological responses

The test results of the memory function of the immune cells of 45 subjects 50 to 70 weeks after the final injection of vaccine:

(a) According to ELISA test, HBsAg stimulates subjects for 9 days externally that the response of IFN-γ secretion from PBMC is positive. Results of FAS set analysis: the test group (19 cases/22 cases=86.36%), better than the control group (13 cases/23 cases=56.52%), the inter-group difference is of statistical significance (P = 0.047); results of PPS set analysis: the test group (16 cases/17 cases=94.12%), better than the control group (10 cases/19 cases=52.63%), the inter-group difference is of statistical significance (P = 0.008).

(b) After the antigen externally stimulated for 6 to 8 hours, the result of response of CD3+CD8+IFN-γ+T); results of FAS set analysis: the test group (17 cases/22 cases=77.27%), better than the control group (10 cases/23 cases =43.48%), the inter-group difference is of statistical significance (P = 0.021).

2. Data rated as having effective trend by the therapeutic indexes

In the therapeutic indexes under observation, the treatment group is better than the control team with the difference of statistical significance is in between the thresholds ($0.05<P<0.1$).

(1) The result that HBV DNA carrying capacity shrunk

(a) For the test group and the control group in the 40th week versus the 12th week, proportion of subjects with HBV DNA titers down by 2 logarithmic degrees:

Results of FAS set analysis: the test group (11 cases/107 cases=10.28%), better than the control group (5 cases/115 cases=4.35%), upon chi-square test, P=0.088.

(b) For the test group and the control group in the 56th week versus the 12th week, proportion of subjects with HBV DNA titers down by 2 logarithmic degrees:

Results of PPS set analysis: the test group (12 cases/87 cases=13.79%), better than the control group (6 cases/97 cases=6.19%), upon chi-square test, P=0.083.

(c) The group carrying capacity of HBV DNA of the test group and the control group between the 64th and 12th week:

Results of PPS set analysis: the test group (down by 0.49±1.89), better than the control group (up by 0.05±1.79), upon Wilcoxon's Sign Rank Test, P=0.072.

(d) Rate of change in group carrying capacity of HBV DNA of the test group and the control group between the 64th and 12th week:

Results of PPS set analysis: the test group (down by 0.14±0.54), better than the control group (up by 0.05±0.75), upon Wilcoxon's Sign Rank Test, P=0.089.

(e) Percentage of HBV DNA negative conversion rate of the test group versus the control group in the 64th week that cannot be detected by quantitative testing:

Results of FAS set analysis: the test group (30 cases/107 cases=28.04%), better than the control group (20 cases/115 cases=17.39%), upon chi-square test, P=0.058.

(2) Comparative results of analysis of drug resistance mutation

Results of FAS set analysis: adefovir dipivoxil 181 sites, drug resistance mutation occur respectively in the test group and the control group: 9 cases/109 cases=8.26% and 19 cases/116 cases =16.38%, upon Cox regression tests, P=0.105.

Results of PPS set analysis: adefovir dipivoxil 181 sites, drug resistance mutation occur respectively in the test group and the control group: 8 cases/102 cases=7.84% and 9 cases/113 cases =16.81%, upon Cox regression tests, P=0.080.

Results of FAS set analysis: adefovir dipivoxil 181*236 sites, drug resistance mutation occur respectively in the test group and the control group: 9 cases/109 cases=8.26% and 19 cases/116 cases =16.38%, upon Cox regression tests, P=0.105.

Results of PPS set analysis: lamivudine 173 sites, drug resistance mutation occur respectively in the test group and the control group: 4 cases/102 cases=3.92% and 12 cases/113 cases =10.62%, upon Cox regression tests, P=0.095.

(3) Comparative results of occurrence rates of drug resistance mutation

(a) Accumulative occurrence rates of drug resistance mutation in the test group and the control group for adevovir dipivoxil 181 sites in the 48th week:

Results of PPS set analysis (7 cases/96 cases=7.29%), better than the control group (16 cases/107 cases =14.95%), upon chi-square test, P=0.086.

(b) Accumulative occurrence rates of drug resistance mutation in the test group and the control group for adevovir dipivoxil 181*236 sites in the 48th week:

Results of PPS set analysis (7 cases/96 cases=7.29%), better than the control group (16 cases/107 cases =14.95%), upon chi-square test, P=0.086.

(c) Accumulative occurrence rates of drug resistance mutation in the test group and the control group for lamivudine 173 sites after the end of the interview video for the 72th week, upon the end of interview;

Results of PPS set analysis: the test group (1 case/61 cases=1.64%), better than the control group (8 cases/79 cases =10.13%), upon chi-square test, P=0.077.

(d) Accumulative occurrence rates of drug resistance mutation in the test group and the control group for lamivudine 173*180 sites after the end of the interview video for the 72th week, upon the end of interview.

Results of PPS set analysis: the test group (10 cases/61 cases=16.39%), better than the control group (23 cases/79 cases =29.11%), upon chi-square test, P=0.079.

(4) HbeAg level dropped one logarithmic degree

(a) Proportion of subjects in the test group and the control group in the 72nd week, HbeAg of which dropped one logarithmic degree compared with week zero:

Results of PPS set analysis: the test group (47 cases/61 cases=77.05%) better than the control group (49 cases/78 cases=62.82%), upon chi-square test, P=0.072.

(b) Proportion of subjects in the test group and the control group in the 24nd week, HbeAg of which dropped one logarithmic degree compared with the 12th week:

Results of FAS set analysis: the test group (11 cases/107 cases=10.28%) better than the control group (5 cases/115 cases=4.35%), upon chi-square test, P=0.088.

(c) The proportion of subjects in the test group and the control group in the 72nd week d HbeAg of which dropped one logarithmic degree compared with the 12th week:

Results of FAS set analysis: the test group (37 cases/107 cases=34.58%) better than the control group (27 cases/115 cases=23.48%), upon chi-square test, P=0.068.

Results of PPS set analysis: the test group (29 cases/61 cases=47.54%) better than the control group (25 cases/78 cases=32.05%), upon chi-square test, P=0.063.

3. Date rated as be negative or invalid by therapeutic indexes

For the survival analysis of virology prepared by the research and development of this phase, the test group is better than the control group, however, upon cox regression test, the intergroup difference is of no statistical influence.

For the survival analysis of virus resistance variation prepared by the research and development of this phase, such as Lamivudine 80 sites, Lamivudine 173 points, Lamivudine 180 points, Lamivudine 204 fixed points, the test group is better than the the control group; however upon Cox regression test, the intergroup difference and variation are of no statistical meaning; lamivudine 80 sites, lamivudine 173 sites, lamivudine 180 sites and lamivudine 204 sites after the inspection visit of the 72nd week, the test group is better than the control group, upon Cox's regression test, the intergroup difference has no statistical meaning.

The exploration and research value of the therapeutic vaccine for phase IIb

According to 2010 Guidance for Prevention and Curing of Chronic HBV, immunologeneration is expected to be an important mean to cure chronic HBV. However, the China has no specificity immunity with explicit therapeutic effects. Exploring and enhancing research and development of therapeutic vaccine that to enhance immunologenerationof CHB patients is a hot issue and difficult point in the field.

Although the drug resistance mutation and virology breakthrough intended by the research and studies show no obvious statistic meaning, there are virology responses in the 12^{th} and 28^{th} week after the end of immune therapy. The test group is better than the control group and has certain importance of obvious statistical significance, and the indicative theatrical double plasmids HBV DNA vaccine together improving virology responses to CHB patients, and has provided basis for further clinic exploration and research.

Special risk warning: As the Research is an IIb exploratory clinical experiment, factors such as the responses of relevant governmental in respect of the Research and changes of industry policy may influence the future of the clinical research, investors of the Company are reminded to pay attention to the risk of investment.

The Board of
Guangzhou Baiyunshan Pharmaceutical Holdings Company Limited

Guangzhou, the PRC, 13 March 2014

As at the date of this announcement, the Board comprises Mr. Li Chuyuan, Mr. Chen Mao, Ms. Liu Juyan, Ms. Cheng Ning, Mr. Ni Yidong, Mr. Wu Changhai and Mr. Wang Wenchu as executive directors, and Mr. Wong Lung Tak Patrick, Mr. Qiu Hongzhong, Mr. Fang Shuting and Mr. Chu Xiaoping as independent non-executive directors.