YS Biopharma Granted Phase I Clinical Trial License of Therapeutic Chronic Hepatitis B Virus Vaccine

April 18, 2024

GAITHERSBURG, Md., April 18, 2024 /PRNewswire/ -- YS Biopharma Co., Ltd. (Nasdaq: YS) ("YS Biopharma" or the "Company"), a global biopharmaceutical company dedicated to discovering, developing, manufacturing, and delivering new generations of vaccines and therapeutic biologics for infectious diseases and cancer, today announced that its YS-HBV-002 immunotherapeutic vaccine, designed to treat patients suffering from chronic hepatitis B virus ("HBV") infection, has been granted clinical trial approval by the Philippine Food and Drug Administration ("PFDA"). In light of the approval, the Company is preparing to initiate a Phase I clinical trial for YS-HBV-002 in the Philippines, which is expected to begin in June 2024.

Chronic HBV infection is a major global health concern, with an estimated 254 million people suffering from the condition, with 1.2 million new infections each year, according to the World Health Organization (WHO). Those infected are at higher risk for cirrhosis, liver failure, and liver cancer, with between 15%-40% of chronic HBV patients afflicted with one or more of these conditions. In 2022, HBV infection resulted in an estimated 1.1 million deaths, mostly from cirrhosis and hepatocellular carcinoma (primary liver cancer). Chronic HBV infections occur in both developing and developed countries, constituting a significant unaddressed public health threat. At present, the efficacy of existing anti-viral treatment paradigms is limited, and no cure for chronic HBV has yet been developed. Despite the availability of preventive vaccines for hepatitis B infection, there remains an urgent need for effective therapies for individuals who are already infected and have progressed to chronic stages of infection.

Dr. David Shao, Director, President, and CEO of YS Biopharma, commented, "The approval of YS-HBV-002 by the Philippines FDA and Ethics Committee represents a significant milestone in our efforts to develop innovative therapies for chronic hepatitis B infection. At present, there is no effective vaccine treatment option for patients suffering from chronic HBV, leaving them at higher risk for other conditions affecting the liver and significantly hampering their quality of life. With our recent approval and upcoming clinical study, we hope to provide these patients with a safe and effective solution to combat this significant unaddressed public health threat. As always, we plan to conduct the clinical trial to the highest safety and ethical standards, and we are eager to take the next step towards delivering these much-needed treatment options to chronic HBV patients."

The Phase I clinical trial for YS-HBV-002 will mark an important milestone in addressing this unmet medical need. This trial will employ a double-blind, randomized, placebo-controlled, dose-escalation approach, and aims to evaluate the safety, immunogenicity, and efficacy of YS-HBV-002 among adult patients diagnosed with chronic HBV infection. By targeting both humoral and cellular immune responses, YS-HBV-002 has the potential to disrupt immune tolerance mechanisms and facilitate the treatment of chronic HBV infection in patients.

About YS-HBV-002

YS-HBV-002 is a new generation of therapeutic HBV vaccine based on the proprietary technology and clinical results of YS-HBV-001, the first generation of HBV vaccine in the pipeline of YS Biopharma. YS-HBV-002 is formulated with several key components, including recombinant core and surface hepatitis B antigens, and YS Biopharma's proprietary PIKA adjuvant. This carefully designed set of components has the potential to activate both innate and adaptive immune responses in patients, thereby generating a more robust and targeted response to the virus. The re-establishment of a desirable and comprehensive immune response is the first step towards the eradication of chronic HBV infection from the body.

About YS Biopharma

YS Biopharma is a global biopharmaceutical company dedicated to discovering, developing, manufacturing, and commercializing new generations of vaccines and therapeutic biologics for infectious diseases and cancer. It has developed a proprietary PIKA® immunomodulating technology platform and a series of preventive and therapeutic biologics with a potential for improved Rabies, Coronavirus, Hepatitis B, Influenza, and Shingles vaccines. YS Biopharma operates in China, the United States, Singapore and the Philippines, and is led by a management team that combines rich local expertise and global experience in the bio-pharmaceutical industry. For more information, please visit www.ysbiopharma.com.

Cautionary Statement Regarding Forward-Looking Statements

This press release contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, Section 21E of the Securities Exchange Act of 1934, as amended, and the Private Securities Litigation Reform Act of 1995. All statements other than statements of historical or current fact included in this press release are forward-looking statements, including but not limited to statements regarding the expected growth of YS Biopharma, the development progress of all product candidates, the progress and results of all clinical trials, YS Biopharma's ability to source and retain talent, and the cash position of YS Biopharma. Forward-looking statements may be identified by the use of words such as "estimate," "plan," "project," "forecast," "intend," "will," "expect," "anticipate," "believe," "seek," "target" or other similar expressions that predict or indicate future events or trends or that are not statements of historical matters. These statements are based on various assumptions, whether identified in this press release, and on the current expectations of YS Biopharma's management and are not predictions of actual performance.

YS Biopharma cannot assure you that the forward-looking statements in this press release will prove to be accurate. These forward-looking

statements are subject to a number of risks and uncertainties, including those included under the heading "Risk Factors" in the Post-effective Amendment No. 2 to the Company's Registration Statement on Form F-1 filed with the SEC on January 23, 2024, and other filings with the SEC. There may be additional risks that YS Biopharma does not presently know or that YS Biopharma currently believes are immaterial that could also cause actual results to differ from those contained in the forward-looking statements. In light of the significant uncertainties in these forward-looking statements, nothing in this press release should be regarded as a representation by any person that the forward-looking statements set forth herein will be achieved or that any of the contemplated results of such forward-looking statements will be achieved. The forward-looking statements in this press release represent the views of YS Biopharma as of the date of this press release. Subsequent events and developments may cause those views to change. However, while YS Biopharma may update these forward-looking statements in the future, there is no current intention to do so, except to the extent required by applicable law. You should, therefore, not rely on these forward-looking statements as representing the views of YS Biopharma as of any date subsequent to the date of this press release. Except as may be required by law, YS Biopharma does not undertake any duty to update these forward-looking statements.

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