LakeShore Biopharma Granted Phase III Clinical Trial Approval to Explore Simplified Regimens for YSJA Rabies Vaccine

October 25, 2024

GAITHERSBURG, Md., Oct. 25, 2024 /PRNewswire/ -- LakeShore Biopharma Co., Ltd (Nasdaq: LSB) ("LakeShore 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 it has been granted approval for a Phase III clinical trial (the "Trial") by the National Medical Products Administration (NMPA) in China to explore the immunogenicity and safety of a simplified four-dose regimen for its YSJA rabies vaccine which is the first generation of the Company's rabies vaccine and has sold more than 100M doses since its market approval. This simplified immunization schedule has the potential to provide patients with more immunization options, reduce physician workload, minimize hospital visits, improve patient adherence to vaccination and also reduce the financial burden on patients under comparable immunogenicity, boosting the vaccine's utility and aiding in the prevention of rabies deaths.

The Trial, which is expected to begin in December 2024, will evaluate the immunogenicity and safety of the YSJA rabies vaccine across two distinct four-dose immunization schedules to determine their immunogenicity and safety compared to the existing Essen regimen (1-1-1-1-1). It will be a single center, randomized, double-blind, controlled study. The two four-dose immunization regimens which will be explored are the Zagreb Regimen (2-1-1), which involves two shots in the first session and one shot each across two subsequent sessions; and the Modified Essen Regimen (1-1-1-1), which involves four sessions of a single shot each. Compared to the conventional five-dose, Essen regimen (1-1-1-1-1), both options offer greater flexibility for medical professionals and patients and stand to improve the existing standard of rabies care.

Mr. Xu Wang, Chief Executive Officer of LakeShore Biopharma, commented, "The approval of this Phase III clinical trial for our YSJA rabies vaccine marks a significant milestone in our efforts to expand the regimen profile of our product. By evaluating simplified immunization schedules, we aim to make our vaccine more competitive in the rapidly expanding rabies vaccine market. We believe that this trial will validate the clinical superiority of the YSJA rabies vaccine, and will help attract increased recognition and support from researchers, academics, and industry players around the world."

"The YSJA rabies vaccine is our flagship product and has already proven to be a game-changer in preventing deaths and disabilities related to rabies," Mr. Wang continued. "The potential impact of this clinical trial, combined with our efforts to become a leading rabies vaccine supplier, strengthens our confidence in continuing expanding our market share in China. We are proud to be making another critical contribution to the global fight against this disease, and are eager to forge ahead as a leading innovator in rabies vaccine development."

Rabies has an almost 100% fatality rate upon emergence of clinical symptoms. Each year, it claims the lives of approximately 59,000 individuals in more than 150 countries. Transmission through bites from infected dogs accounts for over 95% of rabies-related fatalities, and 40% of these deaths occur in children under the age of 15. Although rabies is typically lethal without treatment, the administration of post-exposure prophylaxis can effectively prevent fatalities when initiated following possible exposure.

About LakeShore Biopharma
LakeShore Biopharma, previously known as YS Biopharma, is a global biopharmaceutical company dedicated to discovering, developing, manufacturing, and delivering new generations of vaccines and therapeutic biologics for infectious diseases and cancer. It has developed a proprietary PIKA® immunomodulating technology platform and a new generation of preventive and therapeutic biologics targeting Rabies, Coronavirus, Hepatitis B, Influenza, Shingles, and other virus infections. The Company 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 biopharmaceutical industry. For more information, please visit investor.lakeshorebio.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 LakeShore Biopharma, the development progress of all product candidates, the progress and results of all clinical trials, LakeShore Biopharma's ability to source and retain talent, and the cash position of LakeShore Biopharma. Forward-looking statements may be identified by the use of words such as "estimate," "plan," "project," "potential," "forecast," "intend," "will," "expect," "anticipate," "believe," "goal," "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 LakeShore Biopharma's management and are not predictions of actual performance.

LakeShore Biopharma cannot assure you the forward-looking statements in this press release will 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 Company's Annual Report on Form 20-F filed with the Securities and Exchange Commission (the "SEC"), and other risks described in documents subsequently filed or furnished by the Company from time to time with the SEC. There may be additional risks that LakeShore Biopharma does not presently know or that LakeShore 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 LakeShore Biopharma as of the date of this press release. Subsequent events and developments may cause those views to change. However, while LakeShore 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 LakeShore Biopharma as of any date subsequent to the date of this press release. Except as may be required by law, LakeShore Biopharma does not undertake any duty to update these forward-looking statements.

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