LakeShore Biopharma Initiates Biologics License Application of PIKA Rabies Vaccine to the Drug Regulatory Authority of Pakistan

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GAITHERSBURG, Md., Nov. 07, 2024 (GLOBE NEWSWIRE) -- LakeShore Biopharma Co., Ltd (Nasdaq: LSB) ("LakeShore Biopharma" or the "Company"), a global leader in the discovery, development, manufacturing, and delivery of next-generation vaccines and therapeutic biologics for infectious diseases and cancer, today announced the initiation of its Biologics License Application (BLA) submission to the Drug Regulatory Authority of Pakistan (DRAP) for the conditional approval of its PIKA rabies vaccine for post-exposure prophylaxis. This submission is based on the results that met the primary endpoints of the vaccine's global pivotal trial and demonstrated the vaccine's potential to achieve accelerated protection and meet the WHO's goal of a one-week rabies vaccine regimen to replace the conventional three- or four-week regimens.

Rabies has an almost 100% fatality rate once clinical symptoms appear, leading to approximately 59,000 deaths annually in over 150 countries. More than 95% of rabies fatalities result from bites by infected dogs, with 40% of victims being children under 15. While rabies is typically fatal without treatment, timely post-exposure prophylaxis can effectively prevent death.

Pakistan ranks among the top five countries in the world for human rabies prevalence, with over 1.5 million reported dog bites and an estimated 2,000–5,000 human deaths annually. The true impact is likely underestimated due to underreporting. Rabies vaccines remain costly and are often inaccessible in public health sectors. LakeShore Biopharma's PIKA rabies vaccine could play a pivotal role in addressing this urgently unmet medical need.

The PIKA Rabies Vaccine, which utilizes LakeShore Biopharma's proprietary PIKA adjuvant technology based on Toll-like receptor 3 immunological pathway, is designed to produce a more robust immune response in an accelerated timespan compared to existing rabies vaccines. It was granted orphan drug designation by the US FDA for prevention of rabies virus infection including post-exposure prophylaxis (PEP) for rabies.

The pivotal registration Phase 3 Trial was a randomized, comparator-controlled, double-blind, multicenter trial which includes 4,500 participants from the Philippines and Pakistan. It is designed to assess the immunogenicity, safety, and lot-to-lot consistency of three lots of the PIKA Rabies Vaccine in healthy adults using a 7-day vaccine schedule, versus a globally marketed comparator following the standard 28-day regimen. The primary immunogenicity endpoints of the study were geometric mean titers (GMTs) of rabies virus neutralizing antibodies (RVNA) and RVNA seroconversion rate at Day 14 in the first 900 participants. This accelerated and higher seroconversion rate came at no cost to safety, with the safety profile of the PIKA Rabies Vaccine remaining highly tolerable.

Dr. Zenaida Mojares, Chief Medical Officer of LakeShore Biopharma, commented, "Our existing rabies vaccine, YSJA, has protected tens of millions of patients in China from this deadly disease. We are committed to advancing next-generation PIKA adjuvanted rabies vaccines to enhance patient protection. The promising results from our pivotal trial validate the potential of PIKA technology to generate a stronger and faster immune response. We remain committed to working closely with drug regulatory agencies in various countries regarding the product registration and marketing application. We eagerly anticipate the early approval of this innovative therapy for the benefit of patients worldwide."

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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