YS Biopharma Announces Positive Interim Results of Pivotal Phase 3 Clinical Study of PIKA Rabies Vaccine

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GAITHERSBURG, Md., April 9, 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 positive interim results from the ongoing Phase 3 clinical trial (the "Phase 3 Trial" or the "Trial") of its next-generation PIKA Rabies Vaccine. The interim results indicate that the PIKA Rabies Vaccine has successfully met the primary endpoints of the Trial and has the potential to achieve best-in-class accelerated protection and meet the WHO's goal of a one-week rabies vaccine regimen to replace the conventional three- or four-week regimens.

The PIKA Rabies Vaccine, which utilizes YS Biopharma's proprietary PIKA adjuvant technology, 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 is 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. The secondary immunogenicity endpoints were RVNA seroconversion rate and GMTs of RVNA at Day 28, Day 42, Day 90, and Day 180 in the first 900 participants, and RVNA seroconversion rate at Day 7 and Day 365 in all participants.

Based on the interim data analysis, the PIKA Rabies Vaccine demonstrates non-inferior immunogenicity to a globally marketed comparator, while also helping patients achieve immunity in a shorter timeframe of 7 days. The data, which comes from the first 900 participants enrolled in the Trial, revealed that the RVNA seroconversion rate of the PIKA Rabies Vaccine was twice that of the comparator by Day 7, showing the superiority of PIKA rabies vaccine to offer quick onset of protection against virus infection. 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 YS Biopharma, commented, "The interim results of the pivotal Phase 3 Trial provide compelling evidence of the robust immunogenicity and favorable safety profile of the PIKA Rabies Vaccine. By providing a shortened treatment regimen without sacrificing safety or quality, the PIKA Rabies Vaccine has the potential to improve rabies treatment and compliance. At present, the long and inconvenient regimen length for existing rabies vaccines represents a major barrier to treatment completion, and we are eager to see how the enhanced speed of the PIKA Rabies Vaccine might have a positive impact on patients. We are proud of our team for the hard work and dedication which got us to this point, and we are excited to see how our advances will contribute to the ongoing global fight against rabies."

Dr. David Shao, Director, President, and CEO of YS Biopharma, added, "We would like to extend our sincere gratitude to all the investigators and participants who participated in the clinical trial. Thanks to their dedication and efforts, animal bite patients are expected to have access to a new rabies vaccine, thereby reducing the rate of immune failure. We remain committed to working closely with drug regulatory agencies in various countries including the Philippines, Pakistan, Singapore, China, and other jurisdictions regarding the product registration and marketing application. We eagerly anticipate the early approval of this innovative therapy for the benefit of patients worldwide."

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 the Company, the development progress of all product candidates, the progress and results of all clinical trials, the Company's ability to source and retain talent, and the cash position of the Company. 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 Company's most recent annual report on Form 20-F, as well as discussions of potential risks, uncertainties and other important factors in the Company's subsequent 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.

Investor Relations Contact

Alyssa Li
Director of Investor Relations
Email: ir@yishengbio.com

Robin Yang
Partner, ICR, LLC
Tel: +1 (212) 537-4035
Email: YSBiopharma.IR@icrinc.com

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