# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

## FORM 6-K

REPORT OF FOREIGN PRIVATE ISSUER PURSUANT TO RULE 13a-16 OR 15d-16 UNDER THE SECURITIES EXCHANGE ACT OF 1934

For the month of March 2023

Commission File Number: 001-41598 YS BIOPHARMA CO., LTD.

(Exact name of registrant as specified in its charter)

Building No. 2, 38 Yongda Road Daxing Biomedical Industry Park Daxing District, Beijing, PRC Tel: 010-89202086

(Address of principal executive offices)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F.
Form 20-F ⊠ Form 40-F □
Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1): $\Box$
Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7): $\Box$

#### **SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

#### YS Biopharma Co., Ltd.

Date: March 27, 2023 By: /s/ Yi Zhang

Name: Yi Zhang

Title: Chairman and Director

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## EXHIBIT INDEX

Exhibit No.	Description
Exhibit 99.1	YS Biopharma's PIKA Recombinant COVID-19 Vaccine Demonstrates Antibody Neutralization Responses Compared to Inactivated
	COVID-19 Vaccine in Phase II Head-to-Head Clinical Study



# YS Biopharma's PIKA Recombinant COVID-19 Vaccine Demonstrates Superior Antibody Neutralization Responses Compared to Inactivated COVID-19 Vaccine in Phase II Head-to-Head Clinical Study

- The trial met its primary endpoint of superior immunogenicity of PIKA COVID-19 Vaccine vs inactivated COVID-19 vaccine, measured by GMT of neutralizing antibody against Omicron virus on Day 14, with statistical significance (95%CI: 2.1, 3.4, P<0.0001) based on interim data analysis
- The trial also met its key secondary endpoint of superior immunogenicity of PIKA COVID-19 Vaccine vs inactivated COVID-19 vaccine, measured by the seroconversion rate of neutralizing antibody against Omicron virus from Day 0 to Day 14, with statistical significance (95%CI: 2.1, 8.1, P<0.0001) based on interim data analysis.
- Compared to inactivated COVID-19 vaccine, PIKA COVID-19 vaccine also demonstrated that it is able to elicit an early immune response with significantly higher GMT of neutralizing antibody against Omicron virus as early as Day 7 after the booster dose, with statistical significance (95%CI: 1.5, 2.7, P<0.0001).
- The PIKA adjuvant has been proven for its capability of accelerating immune responses, as consistently observed in other PIKA adjuvanted vaccines such as HBV and rabies vaccines.
- PIKA COVID-19 vaccine presented a safety and reactogenicity profile with no significant safety issues identified at the time of database lock.

Gaithersburg, Maryland, March 27, 2023 /PRNewswire/ -- YS Biopharma (Nasdaq: YS), a global biopharmaceutical company dedicated to discovering, developing, manufacturing and commercializing new generations of vaccines and therapeutic biologics for infectious diseases and cancer, announced its positive interim Phase 2 safety and immunogenicity data for its PIKA recombinant COVID-19 Vaccine. The interim data was from Phase II part of the Phase II/III head-to-head clinical study to evaluate PIKA recombinant COVID-19 vaccine vs. inactivated COVID-19 vaccine. The interim data analysis of Phase II study presented that the trial met both primary and secondary endpoints, measured by geometric mean titers (GMTs) of neutralizing antibody against Omicron virus and by seroconversion rates on Day 7 and Day 14 post a booster dose administration.

PIKA recombinant COVID-19 vaccine is an innovative prophylactic and therapeutics vaccine candidate against multiple SARS-CoV-2 variants. PIKA recombinant COVID-19 vaccine is composed of YS Group's proprietary PIKA adjuvant and recombinant trimeric SARS-CoV-2 spike (S) protein subunit antigen (CHO cells).

The on-going Phase II/III study was designed as a multiple country, multi-center trial and conducted in the Philippines and United Arab Emirates, which finished the enrollment of 300 and 5656 subjects for the Phase II and III trials, respectively. It is a randomized, double-blinded study to evaluate the efficacy, safety and immunogenicity of a booster dose of PIKA recombinant protein COVID-19 vaccine (CHO cell, S protein) in adults  $\geq$  18 years old who had received two or more doses of inactivated COVID-19 vaccine as primary series. The aforementioned interim data analysis were from the first 300 enrolled subjects, with 150 subjects in each group.



"In this head-to-head study, we are very pleased to observe the multiple folds higher immune responses demonstrated by PIKA COVID-19 vaccine against Omicron virus as measured by GMT levels of neutralizing antibody in subjects boosted with PIKA recombinant COVID-19 vaccine as compared to inactivated COVID-19 vaccine based on interim data analysis," said by Dr Zenaida Mojares, the Chief Medical Officer of YS Biopharma. "These results provide more evidence in supporting the high potential of PIKA recombinant COVID-19 vaccine as an effective booster vaccine to address the continuous burden of COVID-19 in many countries and regions where inactivated Covid-19 vaccines were widely administered. We will communicate and publish the Phase II/III final results in peer-reviewed journals in due course."

A booster dose of PIKA recombinant COVID-19 vaccine in participants who had previously received two or more doses of the inactivated COVID-19 vaccine elicited superior neutralizing immune responses against Omicron virus as compared to the responses in participants receiving a booster dose of the inactivated COVID-19 vaccine. The differences of multiple folds of GMTs were observed with 95%CI of neutralizing antibody against Omicron virus. A statistical difference of the GMTs of neutralizing antibody against Omicron virus was observed on Day 7 and Day 14 post-vaccination between PIKA COVID-19 vaccine and inactivated COVID-19 vaccine. The interim data results indicated that PIKA COVID-19 vaccine generated a significantly higher GMTs of neutralizing antibody against Omicron virus on both Day 7 and Day 14 after the booster dose compared with inactivated COVID-19 vaccine. In addition, similar immunogenicity superiority and statistical significance were also achieved by the measurements of GMTs of neutralizing antibody against wild type SARS-CoV-2 virus on both Day 7 and D14 after the booster dose compared with inactivated COVID-19 vaccine. These results further confirmed PIKA adjuvant's capability of accelerating human immune responses, a similar trend observed in other clinical studies of PIKA adjuvanted rabies vaccine and HBV vaccine.

#### 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 targeting Rabies, Coronavirus, Hepatitis B, Influenza and Shingles. YS Biopharma operates in China, the United States, Singapore, the United Arab Emirates, and the Philippines with over 800 employees and is led by a management team that combines rich local expertise and global vision in the vaccine and pharmaceutical industry.



#### **Cautionary Statement Regarding Forward-Looking Statements**

This press release includes "forward-looking statements" within the meaning of the "safe harbor" provisions of the United States Private Securities Litigation Reform Act of 1995. 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 forward-looking statements also include, but are not limited to, statements regarding the expected growth of YS Biopharma, YS Biopharma's ability to source and retain talent, and the cash position of YS Biopharma following closing of the Business Combination. These statements are based on various assumptions, whether or not identified in this press release, and on the current expectations of YS Biopharma's management and are not predictions of actual performance.

These statements involve risks, uncertainties and other factors that may cause actual results, levels of activity, performance or achievements to be materially different from those expressed or implied by these forward-looking statements. Although YS Biopharma believes that it has a reasonable basis for each forward-looking statement contained in this press release, YS Biopharma caution you that these statements are based on a combination of facts and factors currently known and projections of the future, which are inherently uncertain. In addition, there are risks and uncertainties described in the final prospectus relating to the proposed Business Combination, and other documents filed by YS Biopharma from time to time with the SEC. These filings may identify and address other important risks and uncertainties that could cause actual events and results to differ materially from those contained in the forward-looking statements.

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, among others, the ability to recognize the anticipated benefits of the Business Combination, costs related to the transaction, the impact of the global COVID-19 pandemic, the risk that the transaction disrupts current plans and operations as a result of the consummation of the transaction, the outcome of any potential litigation, government or regulatory proceedings, the sales performance of the marketed vaccine product and the clinical trial development results of the product candidates of YS Biopharma, and other risks and uncertainties, including those included under the heading "Risk Factors" in the final prospectus filed with the SEC on February 8, 2023, as supplemented on February 21, 2023, and other filings with the SEC. There may be potential risks that the final clinical results may deviate from the interim analysis as reported. 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 st