Concord & Sage
T: +1-619 732 6858
F: +1-858 437 9891
E: info@concordsage.com
www.concordsage.com
Los Angeles
San Diego
New York
New Jersey

June 15, 2026

To: Legal Department of Shaanxi Micot Technology Co., Ltd

Re: U.S. Legal Opinion regarding Data Privacy and Protection Matters in Response to Inquiry No. 21 of the HKEX Hearing Bundle Letter dated May 15, 2026

Dear Legal Department:

This opinion letter addresses the views of U.S. legal advisers concerning data privacy in the United States during the Track Record Period and up to the Latest Practicable Date (the "**Relevant Period**") described in Inquiry No. 21 (see Annex A) of HKEX's Hearing Bundle Letter dated May 15, 2026.

I. SCOPE OF OPINION

Our role has been limited to advising on matters of United States federal law and the laws of the States (collectively, the "**Applicable Jurisdictions**"), including the California Consumer Privacy Act, as amended by the California Privacy Rights Act (collectively, "**CCPA/CPRA**"),in each case as they relate to data privacy, data security, and the protection of personal information in the context of Shaanxi Micot Technology Co. Ltd.'s (the **"Company"**) clinical development activities, collaboration arrangements, and operations within the United States.

We express no opinion with respect to:

(a) the laws of any jurisdiction other than the Applicable Jurisdictions;

(b) tax law, antitrust law, intellectual property law, employment law (except as expressly addressed herein), or environmental law of any jurisdiction;

(c) the laws of any state of the United States other than the Applicable Jurisdictions; and

(d) the enforcement of any law by any governmental authority or court.

II. DOCUMENTS REVIEWED

In connection with this opinion, we have reviewed the documents listed in Annex B hereto (collectively, the **"Reviewed Documents"**), including, without limitation:

1. the Data Compliance Due Diligence Questionnaire dated May 16,2026, executed by Song Lanlan, Clinical Project Director of the Company.

2. U.S. Clinical Trial IND Clearance Letters regarding the four clinical trial programs ("clinical trials"): MT1002, MT1013, MT200605 and MT2004;

3. the informed consent forms used in clinical trials during the Relevant Period for the MT1002, MT1013, MT200605, and MT2004 programs (collectively, the **"Subject ICFs"**);

4. the master services agreements and related amendments entered into between the Company, and the contract research organizations (the **CROs**) engaged in the United States (collectively, the **"CRO Agreements"**);

5. the Institutional Review Board ("IRB") approvals for each clinical trial site;

6. the Company's Standard Operating Procedures ("SOPs") for Clinical Trial Data Management, including Unblinded Data Control and Data

Management Workflows;

7. the CROs' relevant credentials;

8. the ClinicalTrials.gov Registration Records and Clinical Trial Protocol(s); and

9. such other documents, records, and certificates of officers of the Company and of public officials as we have deemed necessary or appropriate.

We have not undertaken any independent investigation to verify the factual statements made in the Data Compliance Due Diligence Questionnaire or any other Reviewed Documents. We did not identify any inconsistencies between the Data Compliance Due Diligence Questionnaire and other Reviewed Documents. Our opinion is based on, and expressly subject to, the accuracy and completeness of such factual statements. Data Compliance Due Diligence Questionnaire

III. ASSUMPTIONS

In rendering the opinions set forth herein, we have assumed, without independent verification, the following:

(a) the genuineness of all signatures on all documents we have reviewed, the authenticity of all documents submitted to us as originals, and the conformity to original documents of all documents submitted to us as copies;

(b) the legal capacity and authority of all natural persons executing documents;

(c) the due authorization, execution, and delivery of all documents by all

parties thereto, and that such documents constitute legal, valid, and binding obligations of such parties, enforceable in accordance with their respective terms;

(d) that the Company has complied, in all material respects, with the procedural and operational requirements set forth in its written policies and standard operating procedures;

(e) that all clinical trials have been conducted in accordance with the protocols approved by the applicable IRBs and the U.S. Food and Drug Administration ("FDA"); and

(f) that no facts or circumstances exist that have not been disclosed to us and that would alter the conclusions set forth herein.

(g) the truthfulness, accuracy, and completeness of all factual statements and representations made by the officer of the Company in the Data Compliance Due Diligence Questionnaire and any other written submissions provided to us in connection with this opinion.

Nothing has come to our attention that would cause us to believe that the Data Compliance Due Diligence Questionnaire and other Reviewed Documents are inaccurate or incomplete in any material respect.

IV. APPLICABLE U.S. LEGAL FRAMEWORK

Our opinion is based on our analysis of the following principal U.S. federal and relevant state laws, regulations, and regulatory guidance, as in effect on the date hereof:

A. Federal Law

1. the Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, and the implementing regulations promulgated thereunder, including the Privacy Rule (45 C.F.R. Part 160 and Subparts A and E of Part 164), the Security Rule (45 C.F.R. Part 160 and Subparts A and C of Part 164), and the Breach Notification Rule (45 C.F.R. Part 164, Subpart D) (collectively, **"HIPAA"**);

2. the Federal Policy for the Protection of Human Subjects, codified at 45 C.F.R. Part 46 (the **"Common Rule"**), and the FDA's parallel human subject protection regulations at 21 C.F.R. Parts 50 and 56;

3. the FDA's regulations governing investigational new drug applications at 21 C.F.R. Part 312, and electronic records and electronic signatures at 21 C.F.R. Part 11;

4. Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45, prohibiting unfair or deceptive acts or practices;

5. the Genetic Information Nondiscrimination Act of 2008, 42 U.S.C. § 2000ff et seq. (**"GINA"**);

6. Executive Order 14117 of February 28, 2024, "Preventing Access to Americans' Bulk Sensitive Personal Data and United States Government-Related Data by Countries of Concern," and the implementing regulations of the U.S. Department of Justice codified at 28 C.F.R. Part 202 (collectively, the **"Bulk Data Rule"**);

7. the Export Administration Regulations, 15 C.F.R. Parts 730–774

(**"EAR"**), to the extent applicable; and

8. such other federal laws and regulations as identified in our analysis below.

B. State Law

1. the California Consumer Privacy Act of 2018, as amended by the California Privacy Rights Act of 2020 (collectively, **"CCPA/CPRA"**), and the California Confidentiality of Medical Information Act (**"CMIA"**); and

2. such other applicable state privacy laws.

V. FACTUAL BACKGROUND

Based upon the Data Compliance Due Diligence Questionnaire and the other Reviewed Documents, we understand the following facts to be true and correct in all material respects:

A. Clinical Development Activities

During the Relevant Period, the Company has engaged contract research organizations (the **"CROs"**) to conduct clinical trials in the United States for the following product candidates: MT1002, MT1013, MT200605, and MT2004. Such trials were conducted at the clinical investigation sites identified in IRB approvals, in collaboration with the CROs, and under investigational new drug applications cleared by the FDA.

The U.S. clinical trials for the MT1002, MT1013, MT200605, and MT2004 programs were conducted between 2019 and December 2022. No new clinical trials have been initiated in the United States by or on behalf of the Company since 2023, and no additional personal data has been collected from clinical trial subjects in the

United States since such time.

B. Categories of Personal Data Processed

In connection with such clinical trials, the CROs, on behalf of the Company, collected, used, stored, and transmitted the following categories of personal data via their Electronic Data Capture (EDC) System:

(a) Personally Identifiable Information ("PII"), including names, addresses, social security numbers, medical record numbers, and other identifiers

(b) Personal Clinical Trial Data, including demographic characteristics, medical history, physical examination, vital signs, electrocardiogram (ECG), serology and clinical laboratory tests (including blood, urine, and stool), SARS-CoV-2 PCR testing, infectious disease markers, reproductive status (including FSH and pregnancy testing), drug abuse/alcohol/cotinine screening, pharmacokinetic and pharmacodynamic (PK/PD) samples (blood and urine), infusion site evaluation, as well as adverse events and concomitant medication records, all of which fall within the scope of subject data commonly collected in clinical trials.

C. De-identification Practices

Prior to the transfer of clinical data outside the United States, the CROs caused such data to be de-identified through the removal of direct identifiers, including names, addresses, social security numbers, medical record numbers, and other identifiers in accordance with the Safe Harbor method specified in 45 C.F.R. § 164.514(b)(2).

D. Outbound Data Transfers

Following de-identification, certain clinical data were transferred through

emails from the CROs to the Company for purposes of statistical analysis, safety and efficacy evaluation, and regulatory submissions. Such data were encrypted prior to transmission via email and were sent exclusively to the head of the Clinical Development Department of the Company. The decryption keys were transmitted to such recipient through a separate email communication.

VI. ANALYSIS

A. HIPAA Compliance

1. **Authorization and Waiver.** The Subject ICFs included the language addressing the use and disclosure of subjects' personal data for purposes of the clinical investigation and integrated within the consent document, satisfying the requirements of 45 C.F.R. § 164.508.

2. **De-identification.** Based upon the Data Compliance Due Diligence Questionnaire, the method employed by the CROs, i.e. Safe Harbor method to de-identify protected health information prior to outbound transfer satisfies the standards set forth in 45 C.F.R. § 164.514(b).

3. **Safeguards.** To the Company's knowledge, the CROs have implemented administrative, physical, and technical safeguards reasonably designed to comply with the HIPAA Security Rule (45 C.F.R. Part 164, Subpart C).

4. **Breach History.** Based on the Data Compliance Due Diligence Questionnaire, during the Relevant Period, the CROs have not experienced any "Breach" of Unsecured Protected Health Information (as such terms are defined in 45 C.F.R. § 164.402) requiring notification under the HIPAA Breach Notification Rule.

B. Human Subject Protection and Clinical Trial Compliance

1. **Informed Consent.** The Subject ICFs were prepared and administered in accordance, in all material respects, with the requirements of 21 C.F.R. Part 50 and the Common Rule (to the extent applicable). The Subject ICFs include, among other disclosures, statements regarding (i) the purposes of the research, (ii) the categories of data collected, (iii) the potential use of such data for future research, and (iv) how the data are protected.

2. **IRB Oversight.** Each clinical investigation conducted in the United States during the Relevant Period was reviewed and approved by an IRB constituted in accordance with 21 C.F.R. Part 56 and, where applicable, 45 C.F.R. Part 46, Subpart A.

3. **Electronic Records.** The electronic data capture system used by the CROs operated in compliance, in all material respects, with the requirements of 21 C.F.R. Part 11, including validation, audit trails, access controls, and electronic signature controls.

C. Outbound Data Transfer Compliance

1. **Authorization for Transfer.** The Subject ICFs expressly disclose to subjects that their data will be transferred to and processed by the Company (MT1002, MT1013 and MT200605) and its Wholly Owned Subsidiary Xi'an Biocare Pharma Ltd. (MT 2004) for the purposes specified therein. Accordingly, the outbound transfer is supported by the informed consent of subjects.

2. **Executive Order 14117 / Bulk Data Rule.** The U.S. clinical trials for the four programs were conducted from 2019 through December 2022,

and all related outbound data transfers from the United States to the Company were completed prior to April 8, 2025, the effective date of the implementing regulations of the U.S. Department of Justice codified at 28 C.F.R. Part 202. The Bulk Data Rule, by its express terms, applies only to covered data transactions occurring on or after April 8, 2025. Based on the Data Compliance Due Diligence Questionnaire, no covered data transactions involving the relevant clinical data have occurred, or are scheduled to occur, on or after such effective date. Accordingly, the Bulk Data Rule does not apply to the outbound transfers conducted during the Relevant Period.

3. **Export Control.** The clinical data transferred do not constitute "technology" subject to the EAR in a manner that would require a license for export that has not been obtained.

D. State Privacy Law Compliance

1. **California.** To the extent one of the contract research organizations processed personal information of California residents (MT1013), it has implemented measures reasonably designed to comply with the CCPA/CPRA and, with respect to medical information, the CMIA. The Subject ICFs include the notices at collection required by Cal. Civ. Code § 1798.100(b).

2. **Other States.** Based upon the Data Compliance Due Diligence Questionnaire, the CROs' data processing activities are conducted in material compliance with applicable state privacy laws of the Applicable Jurisdictions.

E. Regulatory and Enforcement History

Based upon the Data Compliance Due Diligence Questionnaire, during the Relevant Period, neither the contract research organizations nor, to our knowledge, the Company has:

(a) received any subpoena, civil investigative demand, warning letter, or similar communication from the U.S. Department of Health and Human Services Office for Civil Rights, the Federal Trade Commission, the FDA, any State Attorney General, or any other U.S. governmental authority alleging non-compliance with data privacy or data security laws;

(b) been a party to any litigation, arbitration, or administrative proceeding alleging violation of U.S. data privacy or data security laws; or

(c) entered into any consent decree, settlement agreement, corporate integrity agreement, or resolution agreement relating to U.S. data privacy or data security.

VII. OPINIONS

Based upon and subject to the foregoing, and the qualifications and limitations set forth below, we are of the opinion that, as of the date hereof:

1. The collection, use, storage, processing, and outbound transfer by the CROs on behalf of the Company of personal data in connection with the Company's clinical development activities, collaboration arrangements, and operations during the Relevant Period have been conducted, in all material respects, in compliance with the applicable laws of the United States, including HIPAA, the FDA's human subject protection regulations, and the applicable laws of the Applicable

Jurisdictions.

2. The informed consent process employed by the CROs for clinical trials conducted in the United States during the Relevant Period satisfies, in all material respects, the requirements of 21 C.F.R. Part 50, the Common Rule (to the extent applicable), and HIPAA (with respect to authorization for the use and disclosure of protected health information).

3. The agreements between the Company and its CROs and other third-party service providers in the United States include provisions reasonably designed to comply with applicable U.S. data privacy and security laws.

4. The de-identification methodology employed by the CROs prior to the outbound transfer of clinical data satisfies the requirements of 45 C.F.R. § 164.514(b).

5. Based on the Data Compliance Due Diligence Questionnaire, during the Relevant Period, the CROs have not been subject to any material administrative penalty, enforcement action, litigation, or governmental investigation by any U.S. authority relating to data privacy or data security.

6. Based upon the foregoing, we are not aware of any matter concerning the CROs' data privacy and protection practices under U.S. law that would be reasonably likely to have a material adverse effect on the Company's U.S. clinical development activities or its ability to conduct future operations in compliance with applicable U.S. data privacy and protection laws.

VIII. QUALIFICATIONS AND LIMITATIONS

The opinions set forth above are subject to the following qualifications and limitations:

(a) The opinions expressed herein are limited to the federal laws of the United States and the laws of the Applicable Jurisdictions, in each case as in effect on the date hereof. We express no opinion as to the laws of any other jurisdiction or as to any law of the United States or any state thereof not specifically referenced herein.

(b) We express no opinion with respect to the application of any law to facts or circumstances that we have not been informed of, or as to the application of any law other than as in effect on the date hereof.

(c) The phrase "**in all material respects**," as used herein, means that any non-compliance, individually or in the aggregate, would not reasonably be expected to result in a material adverse effect on the business, financial condition, or results of operations of the Company.

(d) The phrase "**to our knowledge**" and similar phrases, as used herein, mean the actual conscious awareness of facts or matters by the partners and associates of this firm who have devoted substantive attention to this engagement, after such inquiry as such persons have deemed appropriate, but without any independent investigation.

(e) Our opinion is based on the Reviewed Documents and the factual representations made to us. We assume no obligation to update or supplement this opinion to reflect any facts or circumstances that may hereafter come to our attention or any changes in law that may

hereafter occur.

(f) The U.S. data privacy and protection legal landscape is rapidly evolving. New federal and state laws, regulations, and regulatory guidance, as well as enforcement actions and judicial decisions, may materially alter the conclusions expressed herein. We express no opinion as to the future application of existing laws or the enactment of new laws.

(g) We express no opinion as to (i) the enforceability of any contractual provision in any jurisdiction other than the Applicable Jurisdictions; (ii) the application of equitable principles or principles of public policy; or (iii) the discretion of any court, regulator, or other governmental authority.

(h) We express no opinion regarding the receipt, storage, use, processing, or further transfer of any data after such data has been transferred outside the United States, including any obligations or liabilities of the recipient under the laws of any non-U.S. jurisdiction.

(i) We express no opinion as to whether any disclosure made or to be made in any offering document, listing document, or any related document is accurate, complete, or in compliance with any applicable disclosure requirements.

(j) No opinion is expressed as to the law of any state or jurisdiction in which any clinical trial site is located if such state or jurisdiction is not an Applicable Jurisdiction.

(k) This opinion is not a guarantee that any particular governmental

authority will not take a contrary position to that expressed herein, and we express no opinion as to how any governmental authority would exercise its enforcement discretion.

IX. RELIANCE AND USE

This opinion is furnished to you solely in connection with Inquiry No. 21 of the Hearing Bundle Letter and may not be relied upon by, quoted to, or distributed to any other person, or used for any other purpose, without our prior written consent; provided that this opinion may be (i) furnished to and relied upon by the Stock Exchange of Hong Kong Limited in connection with its review of the Listing application, and (ii) furnished to and relied upon by the Sponsors of the Company, in its capacity as the sponsors of the Listing.

This opinion is rendered as of the date hereof. We undertake no obligation to advise you of any changes in law or fact occurring after the date hereof that might affect the opinions set forth herein, except as we may agree in a separate written engagement.

Very truly yours,

For Concord & Sage PC

Concord & Sage PC
美国和睿律师事务所
State Bar Reg. No.28430
州律师协会注册号:28430
www.concordsage.com

Qin Li Esq.
Partner
SBN: 349218

Xuan, Xian Esq.
Counsel
SBN: 344335

ANNEXES

Annex A: Excerpt of Inquiry No. 21 from the HKEX Hearing Bundle Letter dated May 15, 2026

Annex B: List of Reviewed Documents