



## TerSera Therapeutics LLC Comprehensive Compliance Program

### I. Introduction

TerSera Therapeutics LLC (“TerSera” or “Company”) is committed to implementing and maintaining an effective Compliance Program in accordance with all applicable laws, policies, and standards in the healthcare industry. TerSera’s Compliance Program is also consistent with the Compliance Program Guidance for Pharmaceutical Manufacturers, published in 2003 by the Office of Inspector General, U.S. Department of Health and Human Services (the “HHS-OIG Guidance”) and the provisions of the Code on Interactions with Healthcare Professionals created by the Pharmaceutical Research and Manufacturers of America (“PhRMA Code”).

#### Declaration of Compliance

Based upon a good faith understanding of the applicable statutory requirements, TerSera Therapeutics LLC believes that its Compliance Program meets the requirements of California Health & Safety Code §§119400- 119402. TerSera also believes that it complies with its Compliance Program in all material respects.

Copies of this document can be obtained by calling **855-710-0090**.

TerSera’s Compliance Program and corporate culture are designed to promote proper legal and ethical conduct by all employees. In the event of noncompliance with applicable laws, industry standards, and/or company policy, TerSera will investigate in a timely manner and, where appropriate, enforce disciplinary action and establish corrective measures to prevent future violations. The fundamental elements of TerSera’s Compliance Program are described below. TerSera’s Compliance Program is regularly reviewed to meet the Company’s needs and to reflect changes in relevant laws and regulations.

### II. Overview of Compliance Program

#### 1. Leadership and Structure

- **Compliance Officer:** The Compliance Officer is responsible for overseeing the development and implementation of policies, procedures, and practices designed to ensure compliance with regulations affecting federal healthcare programs. Additionally, he has responsibility for the monitoring of the Company’s day to day compliance activities as well as internal and external compliance audits and investigations. The Compliance Officer has direct access to TerSera senior management and is the chair of the Compliance Committee.
- **Compliance Committee:** The Compliance Committee is made up of individuals representing multiple business units and disciplines across the Company and who are

of sufficient seniority to represent their respective departments' views and effectuate change within each department with respect to compliance related matters. The Compliance Committee supports the Compliance Officer in fulfilling his responsibilities as well as oversees and formulates compliance policy at TerSera.

## **2. Written Standards**

TerSera has implemented written policies and procedures that provide employees with the knowledge and training to act ethically and with proper judgment in various activities related to sales, marketing, and reporting prices for government reimbursed products, as well as interactions between TerSera employees and Healthcare Professionals.

As required by California Health & Safety Code §§119400-119402, TerSera has established an annual dollar limit of \$2,500 on items, promotional materials, or items or activities for an individual California medical or health care professional in any fiscal year. The following items are excluded from the scope of this policy: (1) drug samples for patients; (2) CME financial support; (3) health education scholarships that conform to the HHS-OIG Guidance and PhRMA Code; and (4) fair market value professional service and consulting fees that conform to the HHS-OIG Guidance and PhRMA Code.

## **3. Education and Training**

TerSera is committed to effective education and training for all employees on their legal and ethical obligations under all applicable laws, regulations, and industry standards. All employees complete training on the Company's written policies and procedures, which includes testing and follow-up education as necessary. Additionally, more specific training is provided to employees regarding the policies and procedures of their respective departments. The content for all training is reviewed annually at a minimum and updated in accordance with changes in applicable legal and ethical guidelines, or for other purposes.

## **4. Internal Lines of Communication**

As a matter of policy, each employee at TerSera is responsible for reporting any circumstances that the employee believes in good faith may constitute a violation of the Company's written policies and procedures, as well as other laws and policies. To foster this open line of dialogue, TerSera has developed a corporate culture that emphasizes open-door communication with employees of all levels. Suspected violations must be reported to the employee's supervisor and to the Compliance Officer, or anonymously via TerSera's Compliance Hotline. No retribution is permitted against employees who, in good faith, report suspected violations.

## **5. Auditing and Monitoring**

TerSera's Compliance Program includes regular auditing and monitoring regarding compliance with the Company's policies and procedures. In accordance with the HHS-OIG Guidance, the nature, extent and frequency of compliance monitoring and auditing varies according to a number of factors, including new regulatory requirements, changes

in business practices, and other considerations. The Compliance Officer is responsible for internal and external audits and investigations.

## **6. Response to Potential Violations**

As the HHS-OIG Guidance recognizes, the implementation of a compliance program cannot guarantee that improper conduct will be entirely eliminated. TerSera's policies provide that any individual who receives a report of a known or suspected compliance violation must promptly forward the information to the Compliance Officer. The Compliance Officer will determine, depending on the nature of the report, the appropriate individual or department to handle the investigation. All TerSera personnel must cooperate with any investigation of a known or suspected violation and answer all inquiries truthfully. Any TerSera employee who withholds information or attempts to mislead or misdirect an investigation is subject to disciplinary action, up to and including termination. The Compliance Committee or other appropriate investigative body, in consultation with the General Counsel and Compliance Officer or authorized legal representative, shall determine whether and when TerSera must submit reports of violations to regulators or other federal or state government authorities. TerSera will also assess whether violations are in part due to gaps in the Company's policies and procedures, and if so, take appropriate action to prevent future violations.