Veeda™ Lifesciences

Accelerating Equitable Access for

Breast and Ovarian Cancer Therapies

Managing Complexities associated with BE (Bioequivalence) Study

Type of Study

A multicentre, open-label, balanced, randomized, two-treatment, two-period, two-sequence, single dose, cross-over bioequivalence study of Doxorubicin Hydrochloride (Pegylated liposomal) concentrate solution for infusion 20 mg/10mL (2 mg/ml) in advanced ovarian cancer and/or metastatic breast cancer patients under fed condition

Situational Analysis

A Global pharmaceutical company wanted submit the bioequivalence data generated from this study for EMEA approval. The approval of this application would permit the marketing of Doxorubicin Hydrochloride.

Veeda supported the client in the following services for the successful execution of the study

- Study Design and Execution
- Volunteer Recruitment & Retention
- Quality Assurance
- Site Feasibility & Investigator selection across India
- Investigational Medicinal Product Management
- Biostatistics
- Medical Writing
- PK Blood Sample Management
- Clinical Study Report
- Ethics Committee Dossiers Submission
- Phlebotomist Management across all sites
- Project Management
- Clinical Sites Monitoring

Highlights of Results Delivered

Recruitment was completed within **05 months**

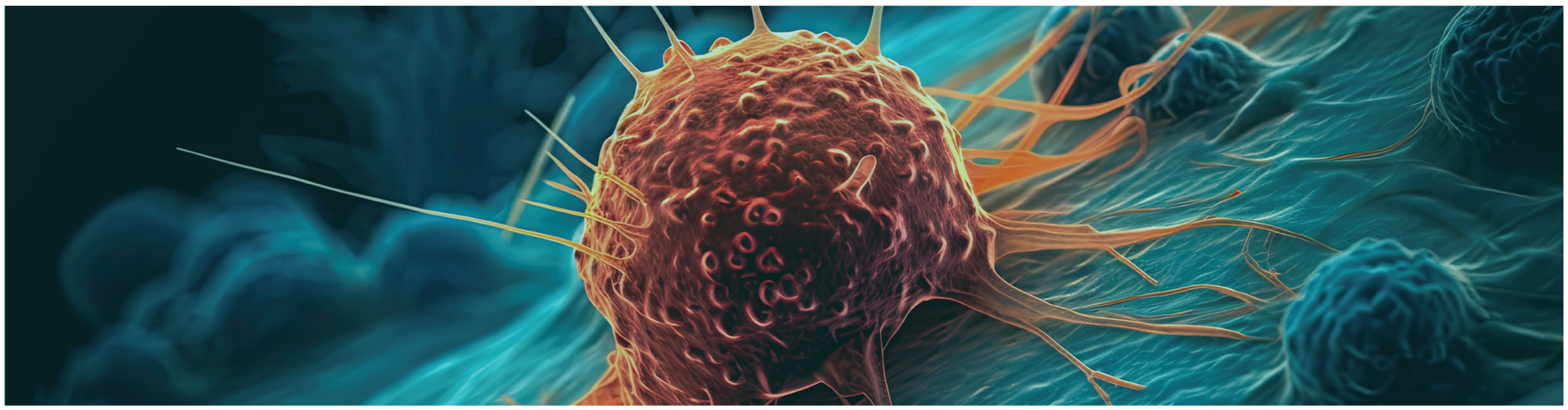
94 patients were enrolled

Major Study Challenges and Action Plan

Challenges	Action Plan
Pre-study Qualification Visit was a challenge for the sponsor during the COVID era due to travel	Veeda's Clinical Research Monitor team helped sponsor conducting a telephonic Pre-study Qualification Visit
PEGylated liposomal Doxorubicin is a sensitive molecule in terms of its formulation, hence, PK sample management, collection, and processing was a big challenge	A dedicated, trained team of phlebotomists was formed, which ensured sterile conditions during the whole sample collection and management process
As per protocol, Granisetron and Dexamethasone was to be given as pre-medication to all volunteers during the study dosing	Veeda's clinical dosing team maintained the administration of the same brand of Granisetron and Dexamethasone in volunteers across all sites

Results

- 74 patients completed the study as per protocol
- Primary and Secondary endpoints were successfully achieved in statistical analysis



India: +91 79677 73000
Europe: +30 210 699 7247

info@veedalifesciences.com

https://veedalifesciences.com

Excellence In Everything

Veeda™
Lifesciences