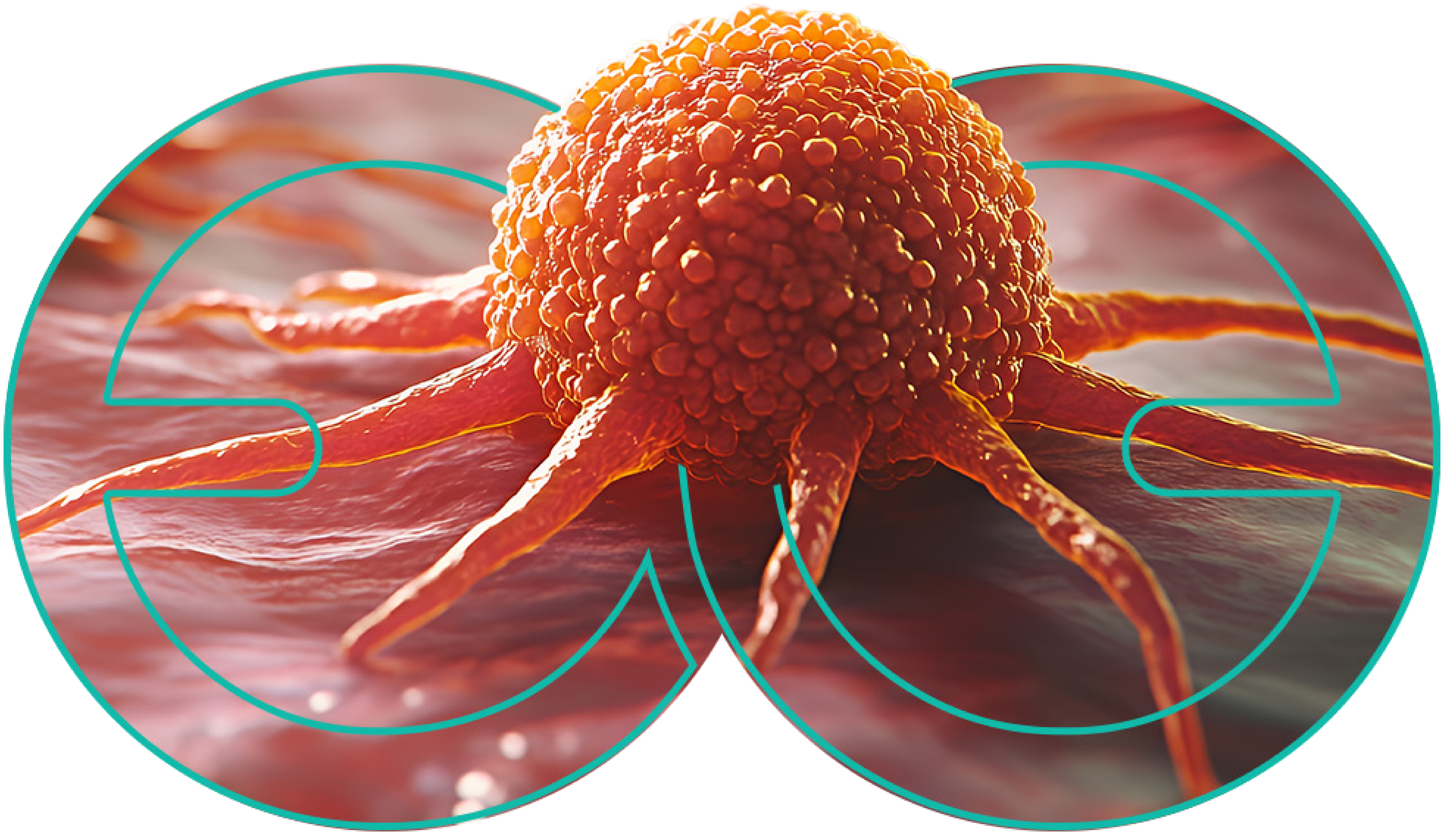
Veeda
Lifesciences



From Trial to Insight:

Leuprolide Acetate Pharmacokinetic Case Study in Prostate Cancer

Type of Study

An open label, multicenter, balanced, randomized, parallel, two-treatment, single-period, single dose Pharmacokinetic Study of Leuprolide acetate 30 mg in adult male subjects with advanced Prostatic Cancer undergoing initial therapy under fasting conditions.

Situational Analysis

A European research-centered pharmaceutical company was seeking marketing approval for its Leuprolide acetate 30 mg drug candidate.

Molecule Overview

Leuprolide acetate is a synthetic nonapeptide analog of naturally occurring gonadotropin releasing hormone (GnRH). It acts as an inhibitor of gonadotropin secretion. Administration of Leuprolide acetate has resulted in inhibition of the growth of certain hormone dependent tumors (prostatic tumors in Noble and Dunning male rats and DMBA-induced mammary tumors in female rats) as well as atrophy of the reproductive organs.

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

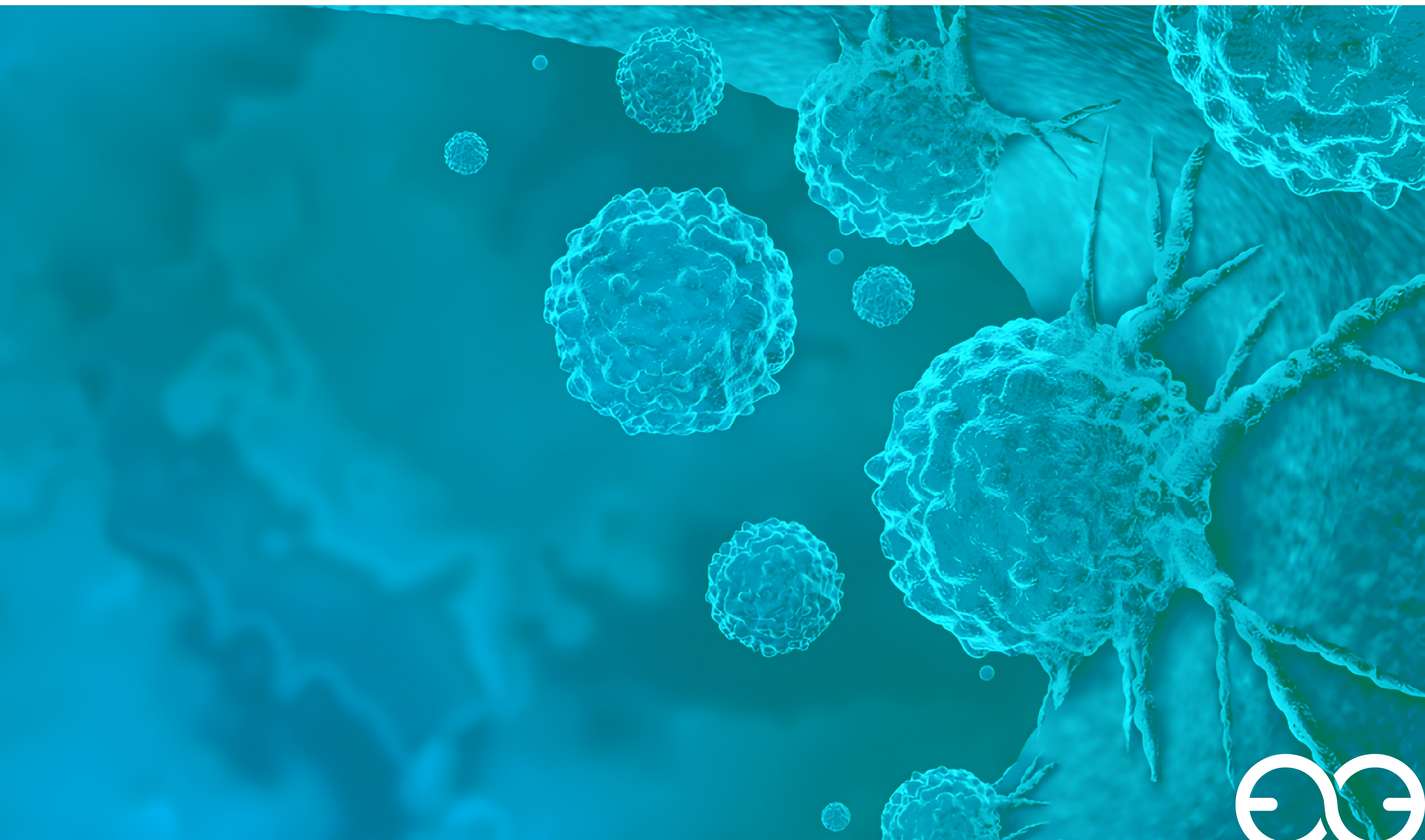
- Study Design & Execution
- Medical & Protocol writing
- Local Regulatory Applications
- Ethics Committee Dossiers Submissions
- Recruitment and Retention
- Investigational Product Management (IMP)
- Investigational Product Administration
- PK Blood Samples Management
- Bioanalytical Method Validation & Analysis
- Biostatistics & Data Management

Highlights of Results Delivered

- Total **32 patients** were enrolled, **29 patients** completed the study with Retention Rate as : **91%**
- PK profile of both test and reference were evaluated successfully

Safety Assessment parameters assessed throughout the study as below

- Subjects throughout the study were monitored, and safety and preventive measures were ensured to minimise the risk of AEs.
- Safety parameter assessments such as Medical History, Vital Signs, Clinical Examinations, Clinical Laboratory Tests (Hematology, Biochemistry, Urinalysis, Hb1Ac, HIV, Hepatitis, Fasting Blood Sugar-FBS, random blood sugar, Prostate Specific Antigen (PSA), Serum testosterone, X-Ray, ECHO and ECG were conducted
- The Test and reference product were well tolerated by the patients



Major Study Challenges	Action Plan
Recruitment Challenges: Requirement of specific population for the study included the need for patients who were new to a specific surgical procedure as required in study protocols.	Additional referrals were made through physician referrals, facilitated by principal investigators, to locate patients recently diagnosed with Prostate Cancer
Timeliness & Efficiency: The extended duration of the study, which involved multiple ambulatory visits spanning approximately four months.	Additional sites were incorporated into the study for matching the timelines and study schedule. A thorough follow-up regimen was implemented with the sites to mitigate the occurrence of dropouts during these four months
Adverse Events-Monitoring & Management: Given the complexity of the study, it was necessary to monitor and manage adverse events effectively	Continuous monitoring of adverse events associated with Leuprolide treatment was conducted throughout the study, prioritizing patient safety and retention

Results

Within the designated timeline, the study was successfully completed. Pharmacokinetic assessment was concluded as per protocol standards

| +91 79677 73000
| info@veedalifesciences.com
| www.veedalifesciences.com

Excellence in Everything