Akums Drugs And Pharmaceuticals Gets CDSCO Panel Nod To Study Norethindrone, Estradiol, Relugolix FDC

New Delhi: The Subject Expert Committee (SEC) functional under the Central Drug Standard Control Organisation (CDSCO) has granted approval to the drug major Akums Drugs and Pharmaceuticals to conduct the Phase III clinical trial of Norethindrone Acetate USP 0.5 mg plus Estradiol (as Hemihydrate) USP eq. to Anhydrous Estradiol 1 mg plus Relugolix 40 mg film-coated tablet.

However, this approval came with conditions, which stated that a record of the training document should be maintained for each subject. In addition, the expert panel stated that a pictorial blood loss assessment chart (PBAC) should be available in a vernacular language with reference images to each subject.

The committee further stated that subjects need to be educated for the filing of the Blood Loss Assessment Chart.

This approval came after Akums Drugs and Pharmaceuticals presented the proposal along with a revised Phase III clinical trial protocol.

Norethindrone acetate is a synthetic form of the hormone progesterone. This medication is a hormone replacement to balance progesterone in the body. Norethindrone acetate treats endometriosis, uterine bleeding caused by abnormal hormone levels and secondary amenorrhea.

Estradiol is an estrogenic steroid used to treat vasomotor symptoms of vulvar and vaginal atrophy in menopause, hypoestrogenism, prevention of postmenopausal osteoporosis, treatment of breast cancer, and advanced androgen-dependent carcinoma of the prostate.

Relugolix is in a class of medications called gonadotropin-releasing hormone (GnRH) receptor antagonists. It works by decreasing the amount of testosterone (a male hormone) produced by the body. This may slow or stop the spread of prostate cancer cells that need testosterone to grow.

At the recent SEC meeting for reproductive held on July 4, 2024, the expert panel reviewed the revised Phase III clinical trial protocol of the fixed dose combination (FDC) Norethindrone Acetate plus Estradiol plus Relugolix film-coated tablet.

After detailed deliberation, the committee recommended the grant of permission to conduct the proposed Phase III clinical trial with the conditions mentioned below:

1. Subject to be educated for filing of Pictorial Blood Loss Assessment Chart.

2. A record of the training document should be maintained for each subject.

3. Pictorial Blood Loss Assessment Chart (PBAC) should be available in a vernacular language with reference images to each subject.

Accordingly, the expert panel suggested that the firm should submit a Phase III clinical trial report to CDSCO for further review by the committee.

News Source:

https://medicaldialogues.in/news/industry/pharma/akums-drugs-and-pharmaceuticals-gets-cdsco-panel-nod-to-study-norethindrone-estradiol-relugolix-fdc-132420