

PROTOCOL SUMMARY

Name of Sponsor Company: Takeda Pharma GmbH Collaborators:	Drug Under Study: Leuprorelin
Brief Title of Protocol: 3 Months, Open-Label, Parallel-Group Study of the Pharmacodynamics, Pharmacokinetics and Safety of TAP-144SR 1-month Depot Gelatin-Free (GF) vs. Gelatin-Containing (GC) Formulation in Female Patients with Uterine Fibroids	
Protocol Number: ENG K001 GF / EC 406	Phase: II
Interventions: Study Drug Intervention Type: Drug Intervention Name: Leuprorelin	
Study Description: 80 female patients will be allocated to one of 2 groups of 40. 40 subjects will receive three subcutaneous (sc) doses of TAP-144SR (GF) and 40 subjects will receive three subcutaneous (sc) doses of TAP-144SR (GC). The injections will be given at days 0, 28 and 56. Total study duration for the patient is approx. 3 months.	
Study Type: open-label, randomised, parallel-group	
Study Status: ongoing	
Study Purpose: To compare TAP-144SR (GF) with the existing TAP-144SR formulation, with respect to safety, tolerability, pharmacokinetics and pharmacodynamics in women.	
Condition or Disease: uterine fibroids	
Key Criteria for Inclusion: Normotensive female patients with ultrasound confirmed uterine fibroids with body mass index (BMI) in the range 18 - 28; deemed otherwise healthy on the basis of a clinical history, physical examination, and laboratory tests of blood and urine; able to give fully informed written consent; mid-luteal phase E2, progesterone, FSH and LH results within the normal range; regular menstruation (except for symptoms of fibroids).	
Key Criteria for Exclusion: Pregnancy, nursing or lactating mothers; positive tests for hepatitis B & C, HIV 1 & 2; severe adverse reaction to any drug; sensitivity to study medication; drug or alcohol abuse; smoking of more than 10 cigarettes daily; participation in other clinical studies of unlicensed medicines, anaemia or loss of more than 400 mL blood within the previous 3 months; having received blood products in the previous 6 months; vital signs outside the acceptable range; clinically relevant abnormal findings at the screening assessment; acute or chronic illness; clinically relevant abnormal medical history or concurrent medical condition; possibility that patient will not co-operate; use of oral contraceptives and other drugs affecting production, activity or assay of sex steroids.	