KURZPROTOKOLL
ATLAS

Öffentlicher Titel	Phase III Studie zu Apalutamid bei fortgeschrittenem Hochrisiko-Prostatakrebs
Wissenschaftl. Titel	A Randomized, Double-blind, Placebo-controlled Phase 3 Study of JNJ-56021927 in Subjects with High-risk, Localized or Locally Advanced Prostate Cancer Receiving Treatment with Primary Radiation Therapy
Kurztitel	ATLAS
Studienart	multizentrisch, prospektiv, Therapiestudie, randomisiert, Pharma-Studie, doppelblind, zweiarmig
Studienphase	Phase III
Erkrankung	Geschlechtsorgane: Krebserkrankungen der männlichen Geschlechtsorgane: Prostatakrebs - Erstlinie

Einschlusskriterien

- Age >= 18 years
- Indicated and planned to receive primary radiation therapy for prostate cancer
- Histologically confirmed adenocarcinoma of an intact prostate, and 1 of the following at diagnosis: 1) Gleason score >=8 and >=cT2c, 2) Gleason score >=7, PSA >=20 nanogram per milliliters (ng/mL), and >=cT2c
- Charlson index (CCI) <=3
- An Eastern Cooperative Oncology Group (ECOG) Performance Status (PS) grade of 0 or 1
- Adequate organ function: (1) aspartate aminotransferase (AST), alanine aminotransferase (ALT), within normal limits (WNL), (2) serum creatinine less than (<) 1.5 milligram/deciliter (mg/dL) (<133 micromoles/Liter [mcmol/L]), (3) platelets greater than or equal to (>=)140,000/microLiter (mcL), independent of transfusion and/or growth factors within 3 months prior to randomization, (4) Hemoglobin >= 12.0 gram/deciliter (g/dL) (7.4 millimloes [mmol], independent of transfusion and/or growth factors within 3 months prior to randomization
- Participants who are sexually active (even men with vasectomies) and willing to use a condom and agree not to donate sperm during the trial
- Signed, written, informed consent
- Be able to swallow whole study drug tablets

Ausschlusskriterien

- Presence of distant metastasis, (clinical stage M1). Isolated pelvic nodal disease below the iliac bifurcation (clinical stage N1) is not an exclusion. Diagnosis of distant metastasis (clinical M stage; M0 versus M1a, M1b, M1c) and pelvic nodal disease (clinical N stage; N1 versus N0) will be assessed by central radiological review. Patients are considered eligible only if the central radiological review confirms clinical stage M0.
- Prior treatment with gonadotropin releasing hormone (GnRH) analogue or anti-androgen or both for >3 months prior to randomization
- Bilateral orchiectomy
- History of pelvic radiation
- Prior systemic (example [e.g.], chemotherapy) or local (e.g. radical prostatectomy, cryotherapy) treatment for prostate cancer
- History of seizure or any condition that may predispose to seizure (including, but not limited to prior stroke, transient ischemic attack or loss of consciousness <= 1 year prior to randomization; brain arteriovenous malformation; or intracranial masses such as schwannomas and meningiomas that are causing edema or mass effect)
- Prior treatment with enzalutamide, abiraterone acetate, orteronel, galeterone, ketoconazole, aminoglutethimide, estrogens, megestrol acetate, and progestational agents (including cyproterone acetate) for prostate cancer
- Prior treatment with radiopharmaceutical agents (e.g., strontium-89) or immunotherapy (e.g., sipuleucel-T) for prostate cancer

	- Prior treatment with systemic glucocorticoids <= 4 weeks prior to randomization or is expected to require long-term use of corticosteroids during the study - Use of 5-alpha reductase inhibitors (e.g., dutasteride, finasteride) <=4 weeks prior to randomization - Use of any investigational agent <=4 weeks prior to randomization - Current chronic use of opioid analgesics for >=3 weeks for oral or >7 days for non-oral formulations - Major surgery <=4 weeks prior to randomization - Current or prior treatment with anti-epileptic medications for the treatment of seizures - Gastrointestinal conditions affecting absorption - Known or suspected contraindications or hypersensitivity to apalutamide, bicalutamide or GnRH agonists or any of the components of the formulations - Any condition for which, in the opinion of the investigator, participation would not be in the best interest of the subject
Alter	18 Jahre und älter
Prüfzentren	**Universitätsklinikum Frankfurt** (Rekrutierung beendet) Zentrum für Chirurgie, Klinik für Urologie Theodor-Stern-Kai 7 60590 Frankfurt am Main Dr. med. Severine Banek Tel: 069 6301-80072 Fax: 069 6301-84029 severine.banek@kgu.de
Sponsor	Janssen Research & Development
Registrierung in anderen Studienregistern	ClinicalTrials.gov NCT02531516 EudraCT 2015-003007-38