Clinical Study Experience

Dr. Michael Feyerabend

Subinvestigator Clinical Trials since 2009

Prostate Cancer

2009-2011
Treatment with Degarelix versus Goserelin in hormone-naive prostate cancer patients, phase III EudraCT Nr. 2008-005276-27

2010-2013
Firstlinetherapy with Docetaxel / Prednisone +/- OGX-011 in metastatic hormone refractory prostate cancer patients, phase III, EudraCT Nr. 2010-021011-16

2011-2013
TAK-700 / Prednisone versus placebo in chemonaive metastatic hormone refractory prostate cancer patients, phase III, EudraCT Nr. 2010-018661-35

2011-2013
TAK-700 / Prednisone versus placebo metastatic hormone refractory prostate cancer patients who have progressed after docetaxel chemotherapy, phase III, EudraCT Nr. 2010-018662-23

2011-2013
Integrinantibody EMD versus placebo in bone metastasized, chemonaive, hormone refractory prostate cancer patients, phase II, EudraCT Nr. 2010-021529-11

2011-2013
Tasquinimod versus placebo in bone metastasized, chemonaive, hormone refractory prostate cancer patients, phase III, EudraCT Nr. 2010-021870-12

2012-
Secondlinechemotherapy Cabazitaxel 20 versus 25 mg/m^2 in patients having progressed after docetaxel treatment, CAINTA, phase III, EudraCT Nr. 2010-022163-35

2012-2013
Treatment of painful pelvis syndrome / interstitial cystitis with ASP3652 in women, phase II, EudraCT Nr. 2011-004555-39

2012-2017
Treatment with RNActive versus placebo in metastasized, chemonaive, hormone refractory prostate cancer patients, phase IIb, EudraCT Nr. 2011-006314-14

2013-2014

Cabozantinib versus Prednison in metastatic hormonrefractory prostate cancer, COMET-1, phase III, EudraCT Nr. 2012-001834-33

2013-2014
Enzalutamid versus Bicalutamid in metastatic hormonrefractory prostate cancer, TERRAIN, phase II, EudraCT Nr. 2010-021868-15

2014-2017
Abiraterone versus placebo in combination with LH-RH therapy in newly diagnosed high risk, hormone-naive prostate cancer patients, LATITUDE, phase II, EudraCT Nr. 2012-002940-26

2014-2017
Abiraterone with different steroid regimens for preventing symptoms associated with mineralocorticoid excess in asymptomatic, chemotherapy-naive and metastatic CRPC, phase II, EudraCT Nr. 2012-004331-23

2014-2015
Tasquinimod versus placebo as maintenance therapy in metastatic prostate cancer patients without progress after firstline docetaxel containing chemotherapy, phase II, EudraCT Nr. 2012-001038-32

2014-
Randomized double-blind study with PROSTVAC-V/F +/- GM-CSF in men with asymptomatic or mildly symptomatic metastatic, castrate-resistant prostate cancer, phase III, EudraCT Nr. 2010-021196-85

2014-
Randomized double-blind study with ARN-509 in men with non-metastatic castration - resistant prostate cancer, SPARTAN, phase III, EudraCT Nr. 2012-004322-24

2014-2017
Open label study with enzalutamide in patients with hormone-refractory prostate cancer having progressed on abiraterone therapy, phase IV, EudraCT Nr. 2013-002271-17

2014-
Randomized double-blind study with DCVAC/PCa in men with metastatic hormonrefractory prostate cancer eligible for 1st line chemotherapy, phase III, EudraCT Nr. 2012-002814-38

2014-
Randomized double-blind study with MDV-3100 in patients with non-metastatic, castrate-resistent prostate cancer, PROSPER, phase III, EudraCT Nr. 2012-005665-12

2015-
Randomized cabazitaxel dose individualization and neutropenia prevention trial, CAINTA, phase II, EudraCT No 2013-005504-34

2015-2017
Radium-223 alpha emitter agent in non-intervention safety study in mCRPC population for long-term evaluation, phase IV

2015
Randomized, double-blind study with enzalutamide in chemotherapy naive mCRPC patients treated with docetaxel who have progressed on enzalutamide alone, PRESIDE, Study, Phase IIIb, EudraCT No 2013-004711-50

2015
Randomized double-blind study with ODM-201 in patients with non-metastatic, castrate-resistent prostate cancer, ARAMIS, phase III, EudraCT No 2013-003820-36

2015-2017
Single-arm, open-label, post marketing safety study to evaluate the risk of seizure among subjects with metastatic castration-resistant prostate cancer treated with enzalutamide who are at potential increased risk for seizure, phase IV, UPWARD, EudraCT No 2013-003022-92

2015-2016
Study to evaluate pharmakodynamic, pharmacokinetic and safety of Zoreline 10,8 mg subcutaneous Goserelin-implant (Novalon) in subjects with prostate cancer, phase III, EudraCT No 2013-000799-14

2015-
Randomized double-blind study with JNJ-56021927 versus placebo in combination with Abiraterone in metastatic HPRC in chemotherapy-naive men, phase III, ACIS, EudraCT No 2014-001718-25

2016-
Randomized double-blind study with JNJ-56021927 plus androgen deprivation therapy (ADT) versus ADT in subjects with low volume metastatic, hormone sensitive prostate cancer, TITAN, phase III, EudraCT No 2015-000735-32

2016-
Randomized double-blind study with JNJ-56021927 plus androgen deprivation therapy (ADT) versus ADT in subjects with high risk or locally advanced prostate cancer receiving primary radiation therapy, ATLAS, phase III, EudraCT No 2015-003007-38

2016-
Clinical efficacy of abiraterone acetate while sparing LHRH-therapy in patients with castration-resistant prostate cancer progressing after chemotherapy, SPARE, AP 67/11, phase II, EudraCT No 2012-005717-39

2016
Comparator study in men expressing androgen receptor splice variant-7 mRNA (AR-V7) and metastatic castrate resistant prostate cancer, ARMOR3-SV, phase III, EudraCT 2014-005079-10

2016-
Pembrolizumab (MK-3475) in subjects with mCRPC previously treated with chemotherapy, KEYNOTE-199, phase II, EudraCT: 2015-003644-40

2017-
Randomized study of 2 doses of AQX-1125 targeting the SHIP1 pathway in subjects with Interstitial Cystitis / Bladder Pain syndrome followed by a 40-week extension period

Phase III, EudraCT No 2016-000906-12

2017-
Extension study for subjects with prostate cancer who previously participated in an Enzalutamide clinical study, Phase II, EudraCT No 2016-001694-32

2017-
Efficacy and safety study of Niraparib in men with metastatic castration resistant prostate cancer and DNA-repair anomalies, PROFOUND, Phase II, EudraCT No

2017-
Randomized study of ODM-201 in additon to standard androgen deprivation therapy and docetaxel in patients with metastatic hormone-sensitive prostate cancer, ARASENS, Phase III, EudraCT No 2015–002590–38

2017-
Randomized, open-label study of Cabazitaxel versus an androgen receptor (AR)-targeted agent (abiraterone or enzalutamide) in mCRPC patients previously treated with Docetaxel and who rapidly failed a prior AR-targeted agent, CARD, Phase IV, EudraCT No 2014-004676-29

2017-
Randomized double-blind, placebo-controlled study of enzalutamide in men with metastatic hormone-sensitive prostate cancer plus androgen deprivation therapy, ARCHES, Phase III, EudraCT Nr. 2015-003869-28

2017
Extension study for subjects with prostate cancer who previously participated in an Enzalutamide clincal study, phase II, EudraCT No 2016-001694-32

2017-
Randomized study of ODM-201 in addition to standard androgen deprivation therapy and docetaxel in patients with metastatic hormone-sensitive prostate cancer, ARASENS, 17777, Phase III, EudraCT No 2015–002590–38

2017-
Randomized, open-label study of Cabazitaxel versus an androgen receptor (AR)-targeted agent (abiraterone or enzalutamide) in mCRPC patients previously treated with Docetaxel and who rapidly failed a prior AR-targeted agent, CARD, LPS14201, Phase IV, EudraCT No 2014-004676-29

Painful Pelvis Syndrome

2012-2013
Randomized double-blind study with ASP3652 in women with painful pelvis syndrome / interstitial cystitis, phase II, EudraCT Nr. 2011-004555-39
2017-

Randomized, double-blind, placebo-controlled proof of concept study to investigate efficacy, safety, pharmacodynamics and pharmakokinetics of ASP6294 in the treatment of female subjects with bladder pain syndrome / interstitial cystitis, SERENITY, 6294-CL-0101, phase IIa, EudraCT No 2016-004138-12

Superficial Urothelial Cancer

2015
Randomized, intravesical Mistletoe Extract in Superficial Bladder Cancer: A Phase III Efficacy Study, TIM, EudraCT No 2013-003446-16