

## Clinical Study Experience

### Dr. Susan Feyerabend

#### Clinical AMG - Studies as LKP since 2009

2009

Extension study of Degarelix versus Goserelin in hormone-naive prostate cancer patients, phase III

2015

Randomized, double-blind study with enzalutamide in chemotherapy naive mCRPC patients treated with docetaxel who have progressed on enzalutamide alone, PRESIDE, phase IIIb, 9785-MA-1001, EudraCT No 2013-004711-50

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

Open Label, Randomized Study to Assess the Efficacy and Safety of Olaparib (Lynparza™) Versus Enzalutamide or Abiraterone Acetate in Men with Metastatic Castration-Resistant Prostate Cancer Who have Failed Prior Treatment with a New Hormonal Agent and Have Homologous Recombination Repair Gene Mutations, PROfound, phase III, D081DC00007, EudraCT No

2017-

Randomized, double-blind, placebo-controlled proof of concept study to investigate efficacy, safety, pharmacodynamics and pharmacokinetics 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

#### Clinical AMG - Studies as Principal Investigator since 2009

### Prostate Cancer

2009-2011

Treatment with Degarelix versus Goserelin in hormone-naive prostate cancer patients, phase III EudraCT No 2008-005276-27

2010-2013

Firstlinetherapy with Docetaxel / Prednisone +/- OGX-011 in metastatic hormone refractory prostate cancer patients, SYNERGY, phase III, EudraCT No 2010-021011-16

2011-2013

TAK-700 / Prednisone versus placebo in chemo-naive metastatic hormone refractory prostate cancer patients, C21004, phase III, EudraCT No 2010-018661-35

2011-2013

Randomized double-blind study with TAK-700 / Prednisone in metastatic hormone refractory prostate cancer patients who have progressed after docetaxel chemotherapy, C21005, phase III, EudraCT No 2010-018662-23

2011-2013

Randomized double-blind study with Integrinantibody EMD in bone metastasized, chemo-naive, hormone refractory prostate cancer patients, phase II, EMR 62242-006, EudraCT No 2010-021529-11

2011-2013

Randomized double-blind study with Tasquinimod in bone metastasized, chemo-naive, hormone refractory prostate cancer patients, 10TASQ10, phase III, EudraCT No 2010-021870-12

2012-

Secondlinechemotherapy Cabazitaxel 20 versus 25 mg/m<sup>2</sup> in patients having progressed after docetaxel treatment, PROSELICA, phase III, EudraCT No 2010-022163-35

2012-2017

Randomized double-blind study with RNaive versus placebo in metastasized, chemo-naive, hormone refractory prostate cancer patients, phase IIb, EudraCT No 2011-006314-14

2013-2014

Cabozantinib versus Prednisone in metastatic hormonrefractory prostate cancer, COMET-1, XL194-307, phase III, EudraCT No 2012-001834-33

2013-2014

Enzalutamid versus Bicalutamid in metastatic hormonrefractory prostate cancer, TERRAIN, 9785-CL-0222, phase II, EudraCT No 2010-021868-15

2014-2017

Randomized double-blind study with Abiraterone in combination with LH-RH therapy in newly diagnosed high risk, hormone-naive prostate cancer patients, LATITUDE, 212082PCR3011, phase II, EudraCT No 2012-002940-26

2014-2017

Abiraterone with different steroid regimens for preventing symptoms associated with mineralocorticoid excess in asymptomatic, chemotherapy-naive and metastatic CRPC, 212082PCR2023, phase II, EudraCT No 2012-004331-23

2014-2015

Randomized double-blind study with Tasquinimod as maintenance therapy in metastatic prostate cancer patients without progress after firstline docetaxel containing chemotherapy, p8-55-58102-002, hase II, EudraCT No 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, BNIT-PRV-301, phase III, EudraCT No 2010-021196-85

2014-

Randomized double-blind study with DCVAC/PCa in men with metastatic hormonrefractory prostate cancer eligible for 1<sup>st</sup> line chemotherapy, VIABLE, SP005, phase III, EudraCT No 2012-002814-38

2014-

Randomized double-blind study with ARN-509 in men with non-metastatic castration - resistant prostate cancer, SPARTAN, ARN-509-003, phase III, EudraCT No 2012-004322-24

2014-2017

Open label study with enzalutamide in patients with hormone-refractory prostate cancer having progressed on abiraterone therapy, 9785-CL-0410, phase IV, EudraCT No 2013-002271-17

2014-

Randomized double-blind study with MDV-3100 in patients with non-metastatic, castrate-resistant prostate cancer, PROSPER, MDV3100-14, phase III, EudraCT No 2012-005665-12

2015-

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

2015-

Continued enzalutamide in chemotherapy naive mHRPC patients treated with docetaxel / prednisone having progressed on enzalutamide alone, PRESIDE, 9785-MA-1001, phase IIIb, EudraCT No 2013-004711-50

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 ODM-201 in patients with non-metastatic, castrate-resistant prostate cancer, ARAMIS, 17712, phase III, EudraCT No 2015-002590-38

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, UPWARD, 9785-CL-0403, phase IV, EudraCT No 2013-003022-92

2015-2016

Study to evaluate pharmacodynamic, pharmacokinetic and safety of Zoreline 10,8 mg subcutaneous Goserelin-implant 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, ACIS, 56021927PCR3001, phase III, 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, 56021927PCR3002, 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, 56021927PCR3003, 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, MK-3475-199, phase II, EudraCT: 2015-003644-40

2016-

European prospective non-interventional study to evaluate efficacy of enzalutamide in the treatment of patients with metastatic hormone-refractory prostate cancer, PREMISE, 9785-MA-1002, phase IV

2017-

Extension study for subjects with prostate cancer who previously participated in an Enzalutamide clinical study, 9785-CL-0123, 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

2017-

Randomized double-blind, placebo-controlled study of enzalutamide in men with metastatic hormone-sensitive prostate cancer plus androgen deprivation therapy, ARCHES, CL-9785-0335, Phase III, EudraCT Nr. 2015-003869-28

## **Painful Pelvis Syndrome**

2012-2013

Randomized double-blind study with ASP3652 in women with painful pelvis syndrome / interstitial cystitis, phase II, EudraCT No 2011-004555-39

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-

Randomized, double-blind, placebo-controlled proof of concept study to investigate efficacy, safety, pharmacodynamics and pharmacokinetics 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

## **Clinical AMG - Studies as Subinvestigator since 2003**

### **Prostate Cancer**

2004 - 2005

Safety in patients with bone metastases from prostate cancer treated with zoledronic acid, phase III

2004 - 2005

Randomized double-blind study with IgG - Antibody MT201 in biochemically relapsed patients after prostatectomy, phase II

2004 - 2013

Zometa versus active surveillance in high risk prostate cancer patients in prophylaxis for the development of bone metastases, phase III, EudraCT No

2004 - 2008

Peptide vaccination in patients with biochemical relapse after prostatectomy, phase I/II, EudraCT No

2005 -2008

Evaluation of bone markers as diagnostic tool in the screening for bone metastases in high-risk patients, phase IV

2005 - 2007

Tolerability and efficacy of a daily dose versus per need of Vardenafil versus placebo in men after verve-preserving radical prostatectomy, phase II, EurdraCT No 2006-002361-39

2006 - 2008

Randomized double-blind study with ZD6474 in combination with docetaxel / prednisone chemotherapy in hormone refractory, metastatic prostate cancer, phase III, EurdraCT No 2005-003593-16

2006 - 2008

Combination therapy of Glivec, Ovostat, Arcoxia, Actos and Fortecortin in metastasized hormone refractory prostate cancer, phase II, EurdraCT No 2006-00218-19

2007 - 2013

Randomized double-blind study with Denosumab prophylactic for prevention of development of bone metastases in hormone refractory prostate cancer, phase III

2007 - 2010

Denosumab versus Zometa in patients with bone metastases in hormone refractory prostate cancer, phase III, EurdraCT No 2006-000341-19

2007 - 2008

DN101 versus placebo in combination with docetaxel / prednisone (ASCENT), phase III, EurdraCT Nr.

2008 - 2009

Randomized double-blind study with integrinantibody in combination with docetaxel / prednisone in metastatic hormone refractory prostate cancer, phase II, EurdraCT No 2006-005766-39

2008 - 2010

Randomized double-blind study with docetaxel / prednisone in combination with Endothelin A receptor antagonist versus placebo in metastatic hormone refractory prostate cancer, phase II, EurdraCT No 2007-003228-39

2008 - 2009

Randomized double-blind study with endothelin A receptor antagonist in hormone refractory prostate cancer patients with bone metastases, phase III, EurdraCT No 2007-003224-38

2008 - 2009

Sagopilone +/- L-Carnithin in firstline treatment of metastatic hormone refractory prostate cancer, phase II, EurdraCT No 2008-000879-26

2009 - 2010

Randomized double-blind study with sutent in metastatic hormone refractory prostate cancer having progressed after docetaxel treatment, phase II, EurdraCT No 2008-002158-40

2009 - 2010

RNA vaccination therapy in metastatic hormone refractory prostate cancer, phase I, EudraCT No 2008-003967-37

2009 - 2010

Intermittent treatment with LH-RH antagonist Degarelix, phase III, EudraCT No 2008-005276-27

2010 - 2012

Randomized double-blind study with MDV3100 in metastatic hormone refractory prostate cancer having progressed after docetaxel treatment, phase III, EudraCT No 2009-013174-41

2010 - 2013

Docetaxel / Prednisone +/- OGX-011 in firstline chemotherapy in metastatic hormone refractory prostate cancer, phase III, EudraCT No 2010-021011-16

2011-2013

Randomized double-blind study with TAK-700 / Prednisone in chemo-naive metastatic hormone refractory prostate cancer patients, phase III, EudraCT No 2010-018661-35

2011-2013

Randomized double-blind study with TAK-700 / Prednisone metastatic hormone refractory prostate cancer patients who have progressed after docetaxel chemotherapy, phase III, EudraCT No 2010-018662-23

2011-2013

Randomized double-blind study with integrinantibody EMD in bone metastasized, chemo-naive, hormone refractory prostate cancer patients, phase II, EudraCT No 2010-021529-11

2011-2013

Randomized double-blind study with Tasquinimod in bone metastasized, chemo-naive, hormone refractory prostate cancer patients, phase III, EudraCT No 2010-021870-12

2011 - 2012

Docetaxel / Prednisone in combination with Lenalidomide versus placebo in firstline chemotherapy in hormone refractory prostate cancer, phase III, EudraCT No 2008-007969-23

2011 - 2013

MDV3100 in hormone refractory prostate cancer in chemo-naive hormone refractory prostate cancer, phase III, EudraCT No 2010-020821-41

2012-2013

Secondline chemotherapy Cabazitaxel 20 versus 25 mg/m<sup>2</sup> in patients having progressed after docetaxel treatment, phase III, EudraCT No 2010-022163-35

2012 - 2013

Randomized double-blind study with RNAActive versus placebo in chemo-naive hormone refractory prostate cancer, phase IIb, EudraCT No 2011-006314-14

2012 - 2013

Dose titrating study of Pasireotide in chemo-naive, metastasized hormone refractory prostate cancer, phase I, EudraCT No 2010-024399-25

2013-2014

Cabozantinib versus prednisone in metastatic hormonrefractory prostate cancer, phase III, EudraCT No 2012-001834-33

2013-2014

Abiraterone with different steroid regimens for preventing symptoms associated with mineralocorticoid excess in asymptomatic, chemotherapy-naive and metastatic CRPC, phase II, EudraCT No 2012-004331-23

2014

Randomized double-blind study with Tasquinimod as maintenance therapy in metastatic prostate cancer patients without progress after firstline docetaxel containing chemotherapy, phase II, EudraCT No 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 No 2010-021196-85

2014

Randomized double-blind study with DCVAC/PCa in men with metastatic hormonrefractory prostate cancer eligible for 1<sup>st</sup> line chemotherapy, phase III, EudraCT No 2012-002814-38

2014

Randomized double-blind study with ARN-509 in men with non-metastatic castration - resistant prostate cancer, phase III, EudraCT No 2012-004322-24

2014

Open label study with enzalutamide in patients with hormone-refractory prostate cancer having progressed on abiraterone therapy, phase IV, EudraCT No 2013-002271-17

## **Benigne Hyperplasia of the Prostate**

2007 - 2008

Safety and efficacy of Lonidamine in patients with benigne prostate hyperplasia, phase II, EudraCT No 2005-001073-94

## **Urothelial Carcinoma**

2004 - 2013

Gemcitabine plus Cisplatin in combination with or without Gefitinib sequentiell or concomitant in metastatic urothelial cancer, phase II, EudraCT No



2004 - 2006

Secondline Chemotherapie in Cisplatin pretreated patients with Gemcitabine / Paclitaxel, phase II

2004 - 2005

MVAC in organe restricted urothelial cancer in patients who are p53 positive, phase II, EudraCT No

2005 - 2007

Comparison between Hexvix - fluorescence and whitelight cystoscopy in prospect to detection and recurrence rates in papillary urothelial tumors, phase III, EudraCT No 2011-004269-34

2007 - 2008

Gemcitabine plus Cisplatin in with or without Sorafenib sequentially versus concomitant in advanced or metastasized urothelial cancer, phase II, EudraCT No

2007 - 2009

Extended versus restricted pelvine lymphadenectomy along with cystectomy in urothelial cancer, LEA, phase III

2010 - 2011

Secondlinetherapy with TKI258 in patients with urothelial chemotherapy having progressed after firstline chemotherapy, phase II, EudraCT No 2008-005870-11

2011 - 2012

Hexvix controlled cystoscopy in the follow up of superficial urothelial cancer in intermediate risk patients versus intravesical maintenance therapy with Mitomycin, phase II

2012 - 2013

Adjuvant treatment with rec-MGAE - A3 + ASCI versus placebo in patients with advanced, non-metastatic urothelial cancer, phase II, EudraCT No 2010-024355-85

2015

Adjuvant PD-L1-selected high-risk muscle invasive bladder cancer after cystectomy, phase II, WO29636

2015

Nivolumab in 2nd line metastatic urothelial cancer patients having progressed after use of platinum agent, CA209-275, phase II

## **Renal Cell Carcinoma**

2005 - 2013

Adjuvant vaccination therapy in M0 patients with advanced renal cell carcinoma, phase I - II

2005 - 2007

Safety of Zometa in patients with renal cell carcinoma and bone metastases, phase II

2006 - 2007

PEG-PGA and DON in advanced renal cell carcinoma, phase I

2007 - 2008

Safety and efficacy of vaccination therapy with IMA901 in patients with advanced renal cell carcinoma, phase I, EudraCT No 2005-001778-28

2008 - 2009

Safety and efficacy of vaccination therapy with IMA901 in patients with metastasized renal cell carcinoma, phase II, EudraCT No 2006-006370-25

2008 - 2009

Extended access program RAD001,

2009 - 2012

Adjuvant treatment with Sutent versus placebo in advanced renal cell carcinoma, phase II

2009 - 2010

Treatment with Axitinib and dose escalation in metastatic renal cell carcinoma, phase II

2009 - 2011

Treatment with BEV + RAD versus BEV + IFN in metastatic renal cell carcinoma, phase II, EudraCT No 2007-005460-28

2010 - 2013

Adjuvant treatment with Pazopanib versus placebo in advanced renal cell carcinoma, phase II, EudraCT No 2010-020965-26

2011 - 2012

Treatment with Sutent in combination with IMA902 in HLA-A2 positive patients in metastatic renal cell carcinoma, phase III, EudraCT No 2010-022459-45

2012 - 2014

Open-label study evaluating the sequential therapy with sorafenib followed by Pazopanib versus Pazopanib followed by Sorafenib, phase III. EudraCT No 2011-004396-36

2012 – 2014

Open randomized trial evaluating the sequential therapy with Bevacizumab, RAD001 and a tyrosine kinase inhibitor in first line clear cell metastatic renal cell carcinoma, phase II, EudraCT No 2011-005939-78

2012 – 2014

Second to fourth line therapy in metastatic renal cell carcinoma with PD-1 antibody versus Everolimus at progression after first line tyrosine kinase inhibitor therapy, phase II, EudraCT No 2011-005132-26

## Testes Cancer

2007 - 2009

Darbepoietin alfa as supportive therapy in the treatment of "good / intermediate prognosis" germ cell tumors, phase II

2007 - 2012

Comparison between 1 versus 2 cycles of PEB in high-risk non seminoma germ cell tumors, phase II

## **Erectile Dysfunction**

2007 - 2008

Vardenafil per need or daily versus placebo in patients with milde erectile dysfunction, phase II, EudraCT No 2005-001678-28

## **Incontinence**

2005 - 2006

Safety and efficacy of Duloxetine in patients with stress incontinence, phase II

2005 - 2006

Safety and efficacy of Trosipiumchlorid in patients with urge incontinence, phase II

2007 - 2009

Safety and efficacy of Botox in patients with idiopathic urge incontinence, phase II, EudraCT No 2005-001936-59

2007 - 2009

Safety and efficacy of Botox in patients with neurogenic urge incontinence, phase II, EudraCT No 2006-002143-83

2010 - 2013

Safety and efficacy of Botox in patients with idiopathic urge incontinence, phase III

2010 - 2013

Urethral sphincter system in patients with grade III stress incontinence after radical prostatectomy or TUR-P, phase II

2011

Treatment with autologue satellite cells derived from skeletal muscle in female patients with moderate urinary stress incontinence, phase II, EudraCT No 2009-011797-15

## **Urinary markers**

2006 - 2007

Evaluation of PCA3 in exprimate urine prior to rebiopsy of the prostate

2007 - 2008

Evaluation of Annexin A3 in exprimate urine prior to rebiopsy of the prostate

## **Solid Tumors**

2007

Treatment with Gimatecan after firstline chemotherapy in solide tumors, phase I, EudraCT No 2005-004923-20

## **Clinical MPG - Studies as Subinvestigator since 2003**

2010 - 2011

Clinical Feasibility Investigation of the Safety and PeRformancEof GT UroLogical, LLC's Tape Mechanical OcclusivE Device (TMOD) ArtiFicial Urinary Sphincter

2012 - 2013

Hybrid Knife in Bladder Cancer Resection Initially Detected by Hexvix based BLUe-Light Enhancement (HYBRID-BLUE )

2012 - 2013

BPH-6: A UroLift® System Post Market Multi-Center Randomized Study

2012 - 2013

Hydrojet versus common TUR-B resection of superficial urothelial cancer