

## **KURZPROTOKOLL ARAMIS**

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| <b>Öffentlicher Titel</b>   | Phase-III-Studie zur Wirksamkeit und Sicherheit von ODM-201 bei männlichen Hochrisikopatienten mit nicht metastasiertem, kastrationresistentem Prostatakrebs                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| <b>Wissenschaftl. Titel</b> | Multizentrische, randomisierte, doppelblinde, placebokontrollierte Phase-III-Studie zur Wirksamkeit und Sicherheit von ODM-201 bei männlichen Hochrisikopatienten mit nicht metastasiertem, kastrationresistentem Prostatakrebs                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <b>Kurztitel</b>            | ARAMIS                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <b>Studienart</b>           | multizentrisch, randomisiert, Pharma-Studie, doppelblind, zweiarmig                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| <b>Studienphase</b>         | Phase III                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| <b>Erkrankung</b>           | Geschlechtsorgane: Krebserkrankungen der männlichen Geschlechtsorgane: Prostatakrebs - Erstlinie                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <b>Einschlusskriterien</b>  | <ul style="list-style-type: none"><li>- Castration-resistant prostate cancer (CRPC) with castrate level of serum testosterone.</li><li>- Prostate-specific antigen doubling time of 10 months and PSA &gt; 2ng/ml.</li><li>- Eastern Cooperative Oncology Group (ECOG) performance status of 0-1.</li><li>- Blood counts at screening: haemoglobin 9.0 g/dl, absolute neutrophil count 1500/μl, platelet count 100,000/μl.</li><li>- Screening values of serum alanine aminotransferase (ALT) and/or aspartate transaminase (AST) 2.5 x upper limit of normal (ULN), total bilirubin 1.5 x ULN, creatinine 2.0 x ULN.</li><li>- Sexually active patients, unless surgically sterile, must agree to use condoms as an effective barrier method and refrain from sperm donation during the study treatment and for 3 months after the end of the study treatment.</li></ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| <b>Ausschlusskriterien</b>  | <ul style="list-style-type: none"><li>- History of metastatic disease or presence of detectable metastases.</li><li>- Acute toxicities of prior treatments and procedures not resolved to grade 1 or baseline before randomisation.</li><li>- Prior treatment with: second generation androgen receptor (AR) inhibitors, other investigational AR inhibitors, or CYP17 enzyme inhibitor.</li><li>- Use of estrogens, 5- reductase inhibitors or AR inhibitors.</li><li>- Prior chemotherapy or immunotherapy for prostate cancer.</li><li>- Use of systemic corticosteroid.</li><li>- Radiation therapy within 12 weeks before randomisation.</li><li>- Severe or uncontrolled concurrent disease, infection or co-morbidity.</li><li>- Treatment with bisphosphonate or denosumab within 12 weeks before randomisation.</li><li>- Known hypersensitivity to the study treatment or any of its ingredients.</li><li>- Major surgery within 28 days before randomisation.</li><li>- Any of the following within 6 months before randomisation: stroke, myocardial infarction, severe/unstable angina pectoris, coronary/peripheral artery bypass graft; congestive heart failure New York Heart Association (NYHA) Class III or IV.</li><li>- Uncontrolled hypertension.</li><li>- Prior malignancy.</li><li>- Gastrointestinal disorder or procedure which expects to interfere significantly with absorption of study treatment.</li><li>- Active viral hepatitis, active human immunodeficiency virus (HIV) or chronic liver disease.</li><li>- Any condition that in the opinion of the investigator would impair the patients' ability to comply with the study procedures.</li></ul> |
| <b>Alter</b>                | 18 Jahre und älter                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |

**KURZPROTOKOLL**  
**ARAMIS**

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| <b>Fallzahl</b>                                  | 1500                                                     |
| <b>Sponsor</b>                                   | Bayer Healthcare                                         |
| <b>Registrierung in anderen Studienregistern</b> | ClinicalTrials.gov NCT02200614<br>EudraCT 2013-003820-36 |