Product	Nubeqa ™ (Darolutamide, ODM 201, BAY1841788)
Swissmedic approval date:	June 19, 2020
Swissmedic approval ID	67521

Bayer study ID	Study title	WS direct link
17719	An open label Phase I study to evaluate the safety, tolerability and pharmacokinetics of BAY 1841788 in Japanese subjects with metastatic castration-resistant prostate cancer	https://s3.amazonaws.com/ctr-bsp-7261/17719/49839d94-96cd-42c6-af31-e9a345c09882/8bf3515b-d325-41d0-a703-a3eff39a49ed/17719_Study_Synopsis_CTP-v6.pdf
17721	A Phase I, non-randomized, open-label, single-dose study to investigate the pharmacokinetics, safety and tolerability of darolutamide (ODM-201/BAY1841788) in male subjects with hepatic impairment, renal impairment and normal hepatic and renal function	https://s3.amazonaws.com/ctr-bsp-7261/17721/c2fe8da2-21c0-4f70-b4da-80ee83528274/1bca1961-2499-4b67-bbed-d56b586ba157/17721_Study_Synopsis_CTP-v8.pdf
17723	A Phase 1, open label, fixed-sequence study to evaluate the effect of BAY1841788 (ODM-201) on drug transporters using rosuvastatin as probe substrate and to assess pharmacokinetics and safety of BAY1841788 in female and male volunteers	https://s3.amazonaws.com/ctr-bsp-7261/17723/c6048ec4-a726-4e9c-ba0b-e064e1c72b62/f6f29a0d-0eff-4a27-b8ba-3a10e399eb79/17723_Study_synopsis_CTP-v11.pdf
17726	A Phase I, non-randomized, open-label, fixed-sequence study to investigate the effect of a probe CYP3A4 inhibitor and inducer on the pharmacokinetics of BAY1841788 (ODM 201) in healthy male volunteers	https://s3.amazonaws.com/ctr-bsp-7261/17726/ebe7f539-ab37-4808-b71d-8488eb1a5565/27c52e21-8a8e-4ab6-9746-e866f86cdc28/17726_Study_synopsis_CTP-v6.pdf
17829	Safety and pharmacokinetics of ODM-201 in patients with castrate resistant prostate cancer: open, non-randomised, uncontrolled, multicentre, multiple dose escalation study with a randomised Phase II expansion component (ARADES)	https://s3.amazonaws.com/ctr-bsp-7261/17829/836957e4-a906-4d8b-8be1-e61e6c409aba/1535d938-6eff-40cd-bcf6-db0f70280d66/17829_Study_synopsis_CTP-v3.pdf
17830	A bioavailability study of ODM-201 formulations with a safety and tolerability extension component in subjects with metastatic chemotherapy-naïve castration-resistant prostate cancer (ARAFOR)	https://s3.amazonaws.com/ctr-bsp-7261/17830/4961d939-33f1-41f4-9e01-3c3409c35171/9c0a5d72-d14f-4d1f-86c5-d80902b4ab45/17830_Study_synopsis_CTP-v3.pdf
17831	A Two-Part Open-Label, Single-Centre Mass Balance, Pharmacokinetics, Biotransformation and Absolute Bioavailability Study of ODM 201 in Healthy Male Subjects	https://s3.amazonaws.com/ctr-bsp-7261/17831/79bef31d-6289-44fa-9e9c-fb0dfe88f412/c5b24c84-2825-410c-8196-3d776bbf6b96/17831_Study_synopsis_CTP-v3.pdf
18035	Safety and tolerability of ODM-201 in patients with castrate-resistant prostate cancer: Open, non-randomised, uncontrolled, multicenter, extension study to Study 3104001 (ARADES-EXT)	https://s3.amazonaws.com/ctr-bsp-7261/18035/4941a13d-0e25-45ee-b1cf-edece0ed57f6/731effc9-e294-40c9-bc82-a8da10a9035e/18035_Study_synopsis_CTP-v3.pdf
18860	A Phase I, non-randomized, open-label, fixed-sequence study to investigate the effect of darolutamide (ODM-201) on the pharmacokinetics of a probe substrate of CYP3A4 and P-gp in healthy male volunteers	https://s3.amazonaws.com/ctr-bsp-7261/18860/e236dd9c-edb6-44b8-8bd5-cd9056c10616/ad5ed4c9-2f41-4771-a94b-9a4a635f1d56/18860_Study_synopsis_CTP-v6.pdf