DBCG 2020 – MASTER STUDY **INCLUSION FORM**

DANISH BREAT CANCER COOPERATIVE GROUP **(IN- AND EXCLUSION CRITERIA)**

Name: CPR nr:	Hospital, department

This form and CCI sheet must be filled in before inclusion in the MASTER STUDY protocol.
Patients are only eligible for randomization if all boxes are checked in the marked column.

Inclusion Criteria (must be answered "Yes")		
Women with primary, estrogen receptor positive breast cancer who are candidates for (neo)adjuvant systemic therapy OR have received ≤3 years of adjuvant endocrine therapy.	☐ Yes	☐ No
Age > 18 years.	☐ Yes	☐ No
Performance status of ECOG ≤ 2.	☐ Yes	☐ No
Prior to patient registration, written informed consent must be given according to ICH/GCP, and national/local regulations.	☐ Yes	☐ No
Exclusion Criteria (must be answered "No")		
History of any prior (ipsi- and/or contralateral) invasive breast carcinoma	☐ No	☐ Yes
Prevalent cholesterol lowering therapy (statins, fibrates, ezetimibe, PCSK9 inhibitors). These patients can be enrolled in the observational cohort given fulfillment of other in- and exclusion criteria.	☐ No	☐ Yes
Evidence of hepatic dysfunction (alanine aminotransferase level more than three times the upper limit of the normal range) or renal dysfunction (creatinine level more than three times the upper limit of the normal range).	☐ No	☐ Yes
Predisposing factors for rhabdomyolysis, including hypothyroidism, reduced renal function, any muscle – or liver disease, or excessive alcohol consumption above 14 drinks/week AND creatine kinase (CK) measured to more than five times the upper limit (CK only measured in case of predisposing factors).	☐ No	☐ Yes
Current medication with potent CYP3A4-inhibitors (e.g. ketokonazole, erythromycin) or gemfibrozile, ciclosporin or danazol.	☐ No	☐ Yes
Pregnancy or breast-feeding (contraception according to clinical routines for premenopausal, fertile breast cancer patients, that includes non-hormonal contraception such as condom, vaginal diaphragm, or intrauterine device).	☐ No	☐ Yes
Psychological, familial, sociological or geographical condition potentially hampering compliance with the study protocol and follow-up schedule; these conditions will be discussed with the patient before registration in the trial.	☐ No	☐ Yes
History of allergic reactions attributed to compounds of similar chemical or biological composition to atorvastatin.	☐ No	☐ Yes

Strata[1]: Neoadjuvant entry ☐ Adjuvant early entry ☐ Adjuvant late entry ☐

[1] **Early stratum:** Randomisation before start of (neo)adjuvent therapy.
Late stratum: Randomisation after start of adjuvant therapy, but within three years of initiation af endocrine therapy

Observational cohort – non randomized patients:		
Observational cohort: non-randomized cohort of patients already on cholesterol-lowering medication at time of diagnosis. Patients that are not able to participate in the randomized placebo-controlled part of the trial due to prevalent cholesterol lowering therapy (statins, fibrates, ezetimibe, PCSK9 inhibitors), but otherwise fulfill in-and exclusion criteria can be included in the observational cohort.	☐ Yes	☐ No

Date of informed consent:	**Filled in by:**
Patient:_____ MD:_____ Randomized: ☐ Date: |___|___|___|___|___|___|___|___| dd mm yyyy Randomization no.:_____	Name:_____ (CAPITAL LETTERS) Sign:_____ Date: |___|___|___|___|___|___|___|___| dd mm yyyy