| **Period** | | | **SCR** | **SCR** | **TRT** | | | | | | **EOT** | **FU** | | **Comments** | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Visit/Cycle** | | | **Tissue SCR** | **Cycle 1** | | **Cycle 2** | | **Cycle 3** | **Cycle 4** | **0** | **XD-FU** | **LTSFU** |
| **Day** | | | **-28 to -1** | **1** | **15** | **1** | **15** | **1** | **1** |
| **Window days** | | | **±2** | **±2** | **±2** | **±2** | **±7** | **±7** |
| **Eligibility Assessments** | | | | | | | | | | | | | | | | | |
| Main ICF | | |  |  |  |  |  |  |  |  |  |  |  | SCR\*True-Is Biosample screening informed Consent to be obtained?: True | | | |
| Eligibility Assessment | | | X | X |  |  |  |  |  |  |  |  |  |  | | | |
| Demographics | | |  |  |  |  |  |  |  |  |  |  |  |  | | | |
| Medical History | | | X | X |  |  |  |  |  |  |  |  |  |  | | | |
| **Safety Assessments** | | | | | | | | | | | | | | | | | |
| Height | | | X | X | X |  | X |  | X | X | X |  |  | A full physical examination including an examination of all major body systems and breasts, height (at screening  only), weight, blood pressure and pulse rate, which may be performed by a physician, registered nurse or other qualified health care provider. | | | |
| Weight | | |  |  | X |  | X |  | X | X | X |  |  | A full physical examination including an examination of all major body systems and breasts, height (at screening  only), weight, blood pressure and pulse rate, which may be performed by a physician, registered nurse or other qualified health care provider. | | | |
| Physical Exam | | |  |  | X |  | X |  | X | X | X |  |  | A full physical examination including an examination of all major body systems and breasts, height (at screening  only), weight, blood pressure and pulse rate, which may be performed by a physician, registered nurse or other qualified health care provider. | | | |
| Vital Signs | | | X | X | X |  | X |  | X | X | X |  |  | A full physical examination including an examination of all major body systems and breasts, height (at screening  only), weight, blood pressure and pulse rate, which may be performed by a physician, registered nurse or other qualified health care provider. | | | |
| 12-lead ECG | | | X | X |  |  |  |  |  |  |  |  |  | SCR\*True-Required ECGs are: : Local  SCR\*True-Required ECGs, are done in triplicate for all timepoints or only at screening(and if abnormality noted)?: Yes  SCR\*True-When is the 12-lead ECG done for screening?: [28, 'Randomization']  SCR\*True-SOC scans allowed?(if taken before ICF): No | | | |
| ECHO/MUGA | | |  |  |  |  |  |  |  |  |  |  |  |  | | | |
| ECOG PS | | |  |  | X |  | X |  | X | X | X |  |  |  | | | |
| Ophthalmologic Assessments | | | X | X |  |  |  |  |  | X | X |  |  | SCR\*True-Is Ophthalmologic Assessments done for screening?: Visual Acuity Testing | | | |
| **Adverse Events** | | | | | | | | | | | | | | | | | |
| AEs/SAEs | | | X | X | X | X | X | X | X | X | X | X | X | SCR\*True-Specify: Standard | | | |
| **Medications, Nondrug Therapies, and Radiotherapy** | | | | | | | | | | | | | | | | | |
| Prior/Concomitant therapies | | |  |  |  |  |  |  |  |  | X |  |  | SCR-Timing for screening?: [28, 'Randomization'] | | | |
| Subsequent Anti-Cancer Treatment | | |  |  |  |  |  |  |  |  |  |  |  |  | | | |
| **Laboratory Assessments** | | | | | | | | | | | | | | | | | |
| Hematology & Chemistry | | |  |  | X | X | X | X | X | X | X |  |  | SCR-Select an option: Local Testing  SCR-Select an option: False | | | |
| Coagulation | | |  |  |  |  |  |  |  |  |  |  |  | SCR-Select an option: False | | | |
| Troponin | | |  |  |  |  |  |  |  |  |  |  |  |  | | | |
| Urinalysis | | |  |  |  |  |  |  |  |  |  |  |  | SCR-Select an option: False | | | |
| Pregnancy Test | | | X | X |  |  |  |  |  |  |  |  |  | SCR\*True-Timing for screening?: [28, 'Randomization'] | | | |
| HBV and HCV Test | | |  |  |  |  |  |  |  |  |  |  |  |  | | | |
| HIV Test | | |  |  |  |  |  |  |  |  |  |  |  |  | | | |
| Additional Safety Tests | | |  |  |  |  |  |  |  |  |  |  |  |  | | | |
| **PK / ADA Assessments** | | | | | | | | | | | | | | | | | |
| Blood for PK | | | X | X |  |  |  |  |  |  |  |  |  | SCR\*True-Will multiple drugs be tested for PK?: No  SCR\*True-Sample type for PK: Plasma  SCR\*True-Collected from: : Other | | | |
| Blood for ADA | | |  |  |  |  |  |  |  |  |  | X | X |  | | | |
| **Biomarker Assessments** | | | | | | | | | | | | | | | | | |
| Archival Tumor | | |  |  |  |  |  |  |  |  |  |  |  |  | | | |
| Newly Obtained Tumor Biopsy | | |  |  |  |  |  |  |  |  |  |  |  |  | | | |
| Blood sample for ctDNA/cfDNA | | |  |  |  |  |  |  |  |  |  |  |  |  | | | |
| Blood sample for WES/WGS control | | |  |  |  |  |  |  |  |  |  |  |  |  | | | |
| Pharmacogenetics (Inherited Genetic Analysis) Sample | | |  |  |  |  |  |  |  |  |  |  |  |  | | | |
| Blood for biomarker analysis | | |  |  |  |  |  |  |  |  |  |  |  | TRT\_Cycle 1-Specify Window for collection: False | | | |
| Other biomarker analysis | | |  |  |  |  |  |  |  |  |  |  |  | SCR-Select an option: False | | | |
| **Efficacy Assessments** | | | | | | | | | | | | | | | | | |
| Radiographic Tumor Assessment | | | X | X |  |  |  |  |  |  |  |  |  | SCR\*True-Include bone scan if history or suspicion of bone metastasis?: True | | | |
| CT/MRI of Brain | | |  |  |  |  |  |  |  |  |  |  |  | SCR-Screening mandatory for: : All Subjects | | | |
| Survival FU | | |  |  |  |  |  |  |  |  |  |  |  | FU-Timing for Follow-Up: : At least every Months  FU-Timing for Follow-Up: : False | | | |
| **HEOR Assessments** | | | | | | | | | | | | | | | | | |
| EQ-5D-5L EORTC QLQ-C30 | | |  |  | X |  | X |  | X | X | X |  |  |  | | | |
| Healthcare Resource Utilization | | |  |  |  |  |  |  |  |  |  |  |  |  | | | |
| **Trial Interventions** | | | | | | | | | | | | | | | | | |
| Trial Intervention | | |  |  | X |  | X |  | X | X |  |  |  | Palbociclib  SCR-Enter investigational compound name: : Palbociclib | | | |
| Comparator/Combination Partner | | |  |  | X | X | X |  | X | X |  |  |  | SCR-Administered By: : Not Applicable | | | |