

# Pilot of the STAMP repurposing pathway

## Proposal of candidates by the Anticancer Fund

This document comprises details about potential candidates for the repurposing pilot, in accordance with the 'core components' of the repurposing framework as specified in the white paper. These proposed candidates have been suggested by the Anticancer Fund, because of the specific expertise of the Anticancer Fund, all proposed candidates are within the oncology field. The Anticancer Fund would be the champion in these proposed cases, possibly in collaboration with the principal investigator(s) of the clinical studies.

Since a single candidate cannot be representative of all repurposing scenarios, nine candidates with varying characteristics have been selected (e.g. late-stage vs. early-stage development, combination vs. monotherapy, nationally vs. centrally authorised). Information for each of the candidates was collected based on the template created in objective 2 of the STAMP working group (presented during the 10<sup>th</sup> STAMP meeting in 3 December 2018). The template used to present the candidates was considered relevant.

Candidates 1, 2, 3, 5, 6, 7 and 8 were discussed during a teleconference with EMA (January 2019) based on the background information provided by the Anticancer Fund. Candidates 4 and 9 (from objective 2 of the STAMP working group) were added after the teleconference with EMA.

### Overview

#### Late-stage (phase 3 or off-label use):

1. Zoledronic acid for the prevention of breast cancer spreading to the bone in post-menopausal women with primary breast cancer
2. Maintenance therapy with Letrozole in Epithelial Ovarian Cancer
3. Clarithromycin in multiple myeloma
  - a. In addition to lenalidomide and dexamethasone in multiple myeloma patients who are newly diagnosed and require treatment.
  - b. To overcome resistance to lenalidomide and dexamethasone in multiple myeloma patients who have an insufficient response or disease progression on lenalidomide and dexamethasone
4. Docetaxel in hormone sensitive metastatic prostate cancer

#### Early-stage (phase 1 - 2):

5. Propranolol for the treatment of angiosarcoma (neoadjuvant window of opportunity phase II study)
6. Metronomic cyclophosphamide and methotrexate combined with zoledronic acid and sirolimus in patients with solid tumours with bone metastasis and advanced pretreated osteosarcoma (phase Ib study)
7. Pancreatic Resection with perioperative use of a propranolol and etodolac (phase II randomised trial)
8. Acetylsalicylic acid and atorvastatin in patients with castrate-resistant prostate cancer (CRPC)
9. Combination of 9 repurposed drugs with low-dose chemotherapy (CUSP9v3)

## **Anticancer Fund ranking of candidates for repurposing pilot**

Based on the feedback from EMA, the Anticancer Fund has ranked the proposed candidates considering their pros and cons in the context of the pilot project.

- A. Clarithromycin in multiple myeloma
- B. Propranolol in angiosarcoma
- C. Zoledronic acid in primary breast cancer
- D. Docetaxel in hormone sensitive metastatic prostate cancer
- E. Combination of 9 repurposed drugs with low-dose chemotherapy
- F. Zoledronic acid and sirolimus in patients with solid tumours with bone metastasis and advanced pretreated osteosarcoma
- G. Perioperative use of a propranolol and etodolac in pancreatic cancer
- H. Letrozole in epithelial ovarian cancer
- I. Acetylsalicylic acid and atorvastatin in castrate-resistant prostate cancer