



Expanding **TREATMENT OPTIONS**  
for **CANCER PATIENTS**

## ANNUAL IMPACT SHEET 2016

### VISION & MISSION

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#### MAIN ACTIVITIES

Research projects  
Status 2016 - Applications - Drug repurposing  
Patient support  
Partnerships

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### FINANCE

#### Our vision

- The Anticancer Fund is dedicated to expanding the range of treatment options available to patients, regardless of their commercial value.

#### Our dual mission

- Developing promising cancer treatments that are currently neglected and bringing the most valuable treatments to the patient as quickly as possible.
- Providing free comprehensive, evidence-based information about cancer treatments.

# MAIN ACTIVITIES

## Research projects – status 2016

| Cancer type | Nr. of patients     | Project info  | Country  | Status  |
|-------------|---------------------|---|--|---|
| Brain       | 35                  | <b>Fluvabrex:</b> A phase I study assessing the safety of the association of fluvastatin in addition to celecoxib in children with refractory optic-pathway glioma  | France   | Ongoing study – including patients              |
| Bone        | 26                  | <b>Metzolimos:</b> A phase Ib study assessing a combination of 4 repurposed drugs in patients with advanced solid tumour with bone metastasis and advanced pre-treated osteosarcoma   | France   | Ongoing study – including patients              |
| Breast      | 134                 | <b>B-AHEAD-3:</b> A randomised phase II trial to determine the effect of a 2-day calorie/energy restricted diet in overweight women with advanced breast cancer   | UK   | Ongoing study – including patients              |
| Lung        | 86                  | <b>Modulung:</b> A prospective phase II, randomised multi-centre trial of a biomodulatory treatment with 3 oral drugs in patients with non-small cell lung cancer after platin failure  | Germany  | Ongoing study – including patients              |
| Brain       | 10                  | <b>CUSP9v3:</b> A combination of 9 repurposed drugs for the treatment of recurrent glioblastoma   | Germany  | Ongoing study – including patients              |
| Breast      | 149                 | <b>Pioneer:</b> A randomised phase II trial in early stage operable ER+ breast cancer patients who will receive 2 weeks of drug treatment prior to surgery  | UK   | In preparation                                  |
| Colon       | 400                 | <b>Aspirin trial:</b> A phase III double-blind placebo-controlled randomised trial of adjuvant low-dose acetylsalicylic acid in curatively operated, stage II and III colon cancer patients   | Belgium (& the Netherlands including 1,188 patients) | In preparation                                  |
| Uterus      | 43                  | <b>PRIMMO:</b> A phase II investigation of pembrolizumab (Keytruda®) in combination with radiation and an immune modulatory cocktail in patients with advanced and/or refractory cervical cancer, endometrial carcinoma or uterine sarcoma  | Belgium  | In preparation                                  |
| Leukaemia   | 76                  | <b>AML-VIVA:</b> A randomised phase II trial with safety run-in phase evaluating low-dose azacitidine, all-trans retinoic acid and pioglitazone versus standard dose azacitidine in patients with acute myeloid leukaemia (AML) who are refractory to standard induction chemotherapy | Germany  | In preparation                                  |
| Breast      | 200                 | <b>Perioperative ketorolac</b> during breast cancer surgery in high-risk patients with and without inflammation. A prospective, randomised, placebo-controlled clinical trial   | Belgium  | Completed – awaiting results (inclusion closed) |
| Lung        | 60                  | <b>Nitroglycerin</b> as a radio-sensitizer in the treatment of non-small cell lung cancer: a phase II trial   | The Netherlands                                      | Completed – awaiting results (inclusion closed) |
| Melanoma    | 12                  | Treatment of patients with metastatic melanoma with <b>ultra-low dose paclitaxel</b> (Taxol®): a pilot trial for “proof of principle”   | Germany  | Completed with results <sup>(1)</sup>           |
| All comers  | 16                  | <b>Boost your Mind:</b> Mindfulness for young adults after cancer treatment   | Belgium  | Completed with results <sup>(2)</sup>           |
| Uterus      | n.a.                | <b>EFFECT:</b> Effectiveness of Endometrial Cancer Treatments   | Belgium  | Completed with results <sup>(3)</sup>           |
| Ovarian     | 6                   | Phase I <b>adoptive T-Cell therapy</b> based on tumour infiltrating lymphocytes in women with stage IV ovarian cancer with recurrent or progressive disease   | Denmark  | Completed with results <sup>(4)</sup>           |
| Pancreatic  | n.a.                | Testing promising drug combinations in experimental mouse models of pancreatic cancer   | USA  | Ongoing study                                   |
| Colon       | 10<br>(3 completed) | <b>Vagus Nerve Stimulation:</b> pilot trial: matched randomised-controlled trial in patients with advanced colon cancer (stage IV) aimed to extend the investigation of the role of vagal activity in cancer prognosis  | Belgium  | No further investment                           |
| All comers  | 9<br>(4 completed)  | Non-randomized, single arm phase I/II study evaluated the safety and efficacy of adjuvant therapy with <b>sodium bicarbonate</b> for tumour-related pain  | USA  | No further investment                           |
| Liver       | 15<br>(0 completed) | A phase I dose-escalation study evaluated the safety and pharmacokinetics of oral <b>artesanate</b> in hepatocellular carcinoma   | Belgium  | No further investment                           |
| Uterus      | n.a.                | <b>Verlest Uterine Cancer Fund</b> at KULeuven (University of Leuven)   | Belgium  | Ongoing – explorative                           |

### Legend:

- Cancer Drug repurposing
- Non-cancer Drug repurposing
- Immunotherapy and non-cancer Drug repurposing
- Immunotherapy
- Complementary treatment
- Perioperative intervention
- Observational study
- Preclinical study

- (1) Manuscript in preparation. Follow-up study under discussion.
- (2) Publication available: Van der Gucht, K.; et al. A Mindfulness-Based Intervention for Adolescents and Young Adults After Cancer Treatment: Effects on Quality of Life, Emotional Distress, and Cognitive Vulnerability. *Journal of Adolescent and Young Adult Oncology*. 2016 Dec 21.
- (3) Report available: [www.kankerregister.org/media/docs/Projecten/Effect/NL/EFFECT\\_FB2015\\_General.pdf](http://www.kankerregister.org/media/docs/Projecten/Effect/NL/EFFECT_FB2015_General.pdf)
- (4) Safety and feasibility demonstrated. Follow-up study under discussion

## The Anticancer Fund received 21 project applications in 2016

The Anticancer Fund is the preferred scientific partner for many international institutions and researchers. In 2016, 21 international project applications were registered at the Anticancer Fund. 1 project request on refractory paediatric solid tumours will be partially supported by the Anticancer Fund and is planned to be launched in 2017. 4 project applications are still under evaluation.

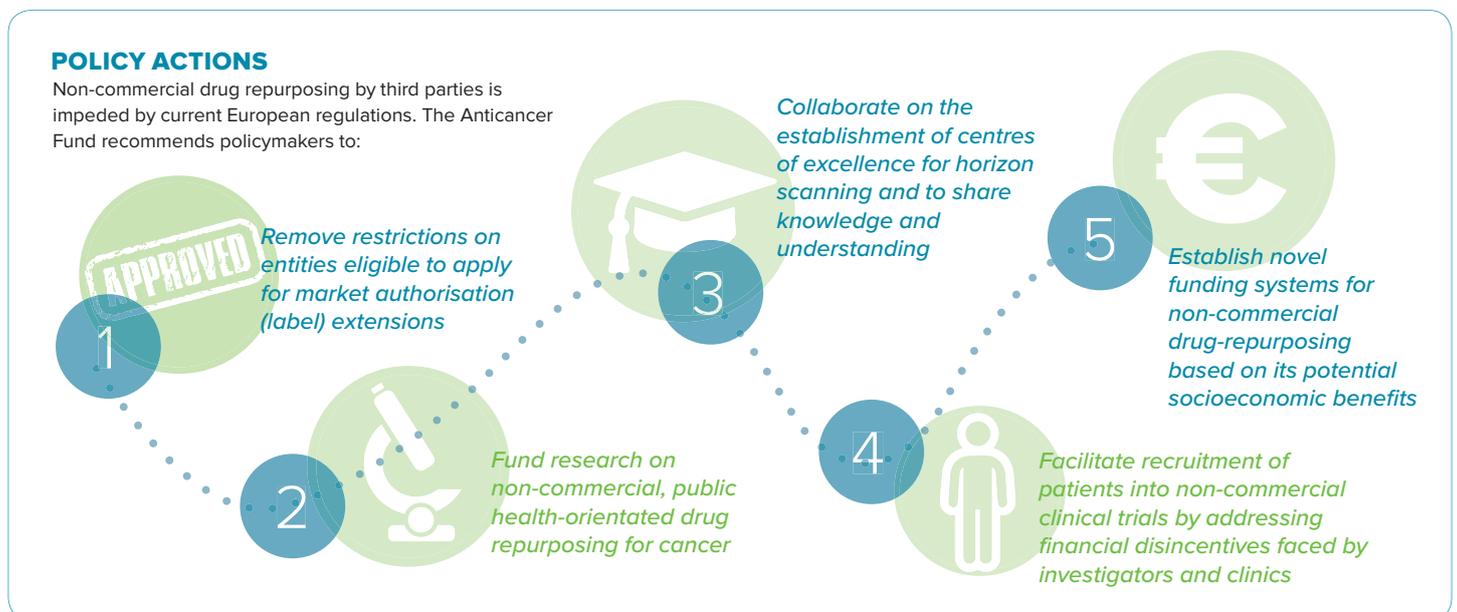
## Repurposing Drugs in Oncology

The Repurposing Drugs in Oncology (ReDO) project is a collaboration with the US not-for-profit organisation Global Cures. The aim of the project is to identify a range of existing non-cancer drugs which show strong evidence of anti-cancer activity and which have the potential for added therapeutic value in clinical use.

The ReDO project identified a number of drugs in 2015 and published 3 articles. 2 additional articles on Diclofenac (doi:10.3332/ecancer.2016.610) and Propranolol (doi:10.3332/ecancer.2016.680) were published in 2016 in the *ecancermedicalscience*, an open access peer-reviewed cancer journal.

The Anticancer Fund team is continuously building expertise in the field of drug repurposing resulting in the design of 2 clinical trials (pancreatic cancer and rectal cancer). These trials were debated with experts in the field willing to take the trial on.

In November 2016, the Anticancer Fund publication 'Repurposing Drugs for cancer treatment: unlocking the potential' became available online. It summarises the need for innovative policy actions in the current medicines regulatory sphere, in order to unlock the enormous potential of drug repurposing for patients, health systems, and societies at large. The Anticancer Fund actively urges health policymakers at European and national level to engage with all relevant stakeholders, including not-for-profit foundations, researchers, patient organisations, regulators, health technology assessment (HTA) authorities, and payers to act collaboratively on these actions.



On December 12<sup>th</sup> 2016, Orphan Drug Designation (EU/3/16/1805) was granted by the European Commission to the Anticancer Fund for propranolol for the treatment of soft tissue sarcoma. Propranolol is commonly used to treat high blood pressure. The Orphan Drug Designation will allow the Anticancer Fund to obtain protocol assistance from EMA to design optimal confirmatory clinical trials, the next step in the process. If positive results are obtained from these trials, the drug label of propranolol could be extended to the treatment of soft tissue sarcoma.

## Patient support & information through the website

In 2016 165,000 users visited the Anticancer Fund website. The website contains information on the Anticancer Fund projects and information sheets for patients on therapies. On top of that over 150 patients received personalised information via [info@anticancerfund.org](mailto:info@anticancerfund.org). The guides for patients with general information were updated and new detailed information per cancer type was added.

## Partnerships



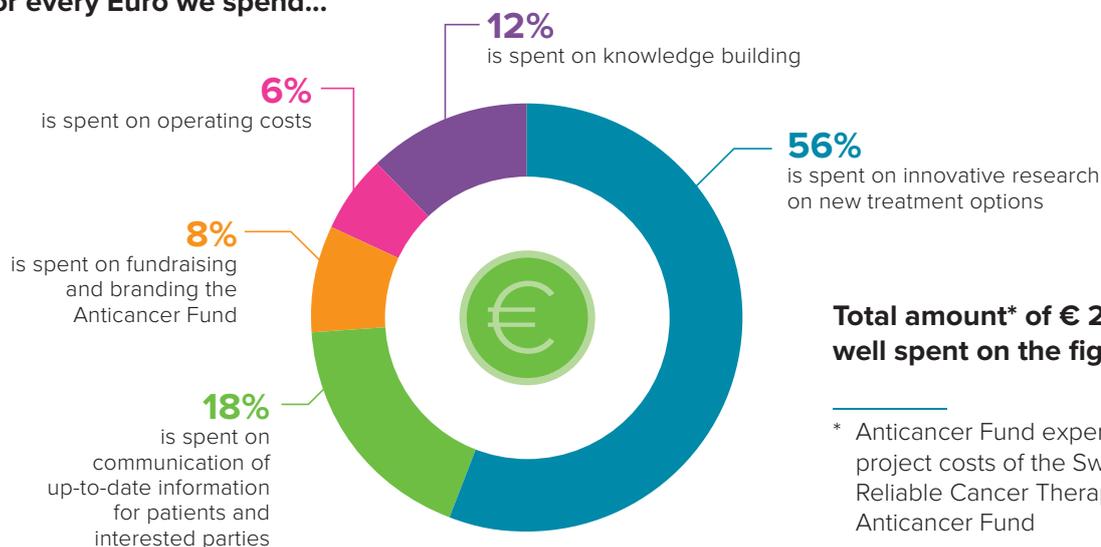
A new collaboration between Seerave, a UK-based foundation, and the Anticancer Fund has been established in 2016 to manage research on non-toxic interventions which could improve the survival and/or the quality of life of melanoma patients.



After a successful collaboration in 2015, the partnership between OvaCure (a Danish non-profit organisation focused on the fight against ovarian cancer) and the Anticancer Fund continued in 2016. The Anticancer Fund is the scientific strategy partner and a member of the OvaCure Scientific and Clinical Advisory Board. ([www.ovacure.org](http://www.ovacure.org))

## FINANCE

### For every Euro we spend...



**Total amount\* of € 2,0M well spent on the fight against cancer!**

\* Anticancer Fund expenses, which also covers all project costs of the Swiss, non-profit organisation Reliable Cancer Therapies managed by the Anticancer Fund



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