

TARGET RECRUITMENT REACHED

The **POSITIVE trial** (IBCSG 48-14/BIG 8-13) met its target accrual, enrolling 518 patients from 203 centres from 20 countries around the world. The study expects to provide an answer to the question of whether women can interrupt their endocrine treatment to try to have a baby, without increasing the risk of cancer recurrence. Women will be followed up for 10 years after enrolment.

The **AURORA research programme** (BIG 14-01) enrolled 1,000 patients, an important milestone for this international academic study aiming to understand the biological evolution of metastatic breast cancer. This was made possible through the efforts of researchers and patients from 11 European countries, 10 BIG groups and 66 hospitals and cancer centres. The study will continue recruiting patients if sufficient funding is secured.

FIRST ENCOURAGING RESULTS

PYTHIA (IBCSG 53-14/BIG 14-04), a downstream trial of the AURORA programme, revealed its first results and showed that serum thymidine kinase activity (TKa) may be an independent prognostic biomarker in patients with luminal metastatic breast cancer treated with palbociclib and fulvestrant, helping doctors to identify those patients who will develop primary resistance to the treatment.

The **DCIS study** (TROG 07.01/BIG 3-07) demonstrated the importance of tailoring radiation treatment of patients with DCIS according to their risks of recurrence to avoid over- or under-treatment. It showed that, after breast conserving surgery, higher radiation doses to the part of the breast where the DCIS was found, in addition

to radiotherapy of the whole breast, significantly reduced its risk of returning in patients with higher-risk DCIS. Compared to 5 weeks of whole breast radiotherapy, the study also showed that the shorter, more convenient 3 weeks of radiotherapy did not increase recurrence.

The DCIS results will likely have a significant impact on how patients with DCIS are best managed worldwide

INVESTIGATING THE BENEFITS OF PALBOCICLIB IN EARLY BREAST CANCER

The results of **PALLAS** (BIG 14-03), presented in September 2020, showed that the addition of two years of palbociclib to endocrine therapy had no effect on invasive disease-free survival (iDFS) compared to standard of care (endocrine therapy alone) in patients with hormone receptor-positive (HR+), HER2-negative, early-stage breast cancer.

Despite the unexpected negative results, PALLAS is a great example of worldwide collaboration between academia and industry to run a huge pivotal clinical trial and advance breast cancer research.

The 5,796 patients enrolled in PALLAS will be followed for at least 10 years, and both clinical data and collected biomaterial build a huge treasure for future translational research

Later in 2020, these results were corroborated by the findings of **PENELOPE-B** (GBG 78 / BIG 1-13), which showed that the CDK4/6 inhibitor palbociclib did not improve iDFS when given in addition to standard endocrine therapy for a period of one year to patients with HR+, HER2-negative primary breast cancer who are at high risk of recurrence following neoadjuvant chemotherapy.