Trans-PALLAS

Overview of PALLAS translational research program and call for research proposals
PALLAS status and timelines

• End of Treatment Phase: July 2020

• Final Endpoint Analysis (469 iDFS):
  → date of awareness 20-Nov-2020 (EC/SC data review in May 2021)

  → presentation of data planned at SABCS 2021 and manuscript in preparation

→ Protocol related research is followed by additional Research Project Proposals for surplus samples and associated data in the PALLAS network.

→ First Call for proposal submission open from 15 Sept 2021 – 15 Jan 2022
### Timepoints of Sample Collection per PALLAS Study Protocol (Schedule of Assessments)

<table>
<thead>
<tr>
<th>Type of Sample</th>
<th>Collection Timepoint(s)</th>
<th>Amount of Sample collected per timepoint (per Protocol)</th>
</tr>
</thead>
</table>
| FFPE Tumor Block (Core Biopsy and/or surgical specimen) | • Baseline (Randomization)  
• Timepoint of recurrence* | 1 specimen/ sample |
| Whole Blood | • Pre-treatment or Cycle 2/day 1 | 8.5 ml |
| Serum | • Pre-treatment | from 9 ml blood |
| Circulating cfDNA | • Pre-treatment  
• Cycle 6/day 1  
• End of treatment and/or timepoint of recurrence*  
• 5, 7 & 10 years post-randomization | from 2 x 10 ml blood (approx. 5 ml plasma) |
| Plasma | • Pre-treatment  
• Cycle 6/day 1  
• End of treatment and/or timepoint of recurrence*  
• 5, 7 & 10 years post-randomization | from 9 ml blood |

*only for patients with recurrence
Available trans-PALLAS Samples (combined in US and non-US Biobanks)

- 3381 patients randomized in non-US
- 2414 patient randomized in US
Ongoing & planned pre-defined trans-PALLAS Projects

Pre-defined Trans-PALLAS Projects

- RNA Sequencing of baseline tumor samples of all PALLAS patients - ongoing
- HTG Sequencing of selected PALLAS patients – ongoing
- ctDNA analysis of selected PALLAS patients – in planning
- GWAS and WES approaches addressing protocol defined objectives – in planning
- Validation of biomarker assays and pre-defined signatures - in planning

Additional envisioned approaches:
- Analysis of bulk RNA-Seq profiles
- Analysis of immune infiltration and immunogenicity
- Digital pathology approaches
Ongoing & planned pre-defined Clinical Science Research Projects

Pre-defined Clinical Science Research Projects

- PRO analysis – *ongoing*
- Analysis of chemotherapy induced amenorrhea - *planned*
- Discontinuation and adherence analyses - *ongoing*
- BMI analysis - *ongoing*

Additional planned protocol-specified analyses:
- Analysis of COVID outcomes - *ongoing*
- Analysis of post-recurrence treatments - *planned*
- Overall survival analysis - *planned*
- Stage IIa subgroup analysis - *planned*
Research Project Proposals (RPP) – addressing objectives not defined in the study Protocol

- **Research Project Proposals (RPP)**
  - Include study data and samples as well as data generated from samples (e.g. sequencing data)
  - Globally harmonized review process and approval by EC and SC committees
  - Workflow and review defined in “PALLAS Policy for Access to Study Data or Surplus Samples for Research Projects not related to the Protocol”

- **2 types of proposals can be submitted:**
  - Clinical Science Research Projects (CSRP): Data only
  - Trans-PALLAS Translational Research Projects (TRP): Data and surplus samples or data generated from those samples

- **Summary of Review and approval process:**
  - Translational Research Committee (TRC)
    - Review and recommendations of “trans-PALLAS” TRPs
  - Executive Committee (EC):
    - Evaluation of all CSRP and trans-PALLAS TRP proposals and recommendations to SC or endorsement of TRCs recommendations
  - Steering Committee (SC):
    - Final endorsement of all proposals
Call for Research Project Proposals

First RPP Call open for submission from 15-Sep-2021 until 15-Jan-2022

Review of all submitted proposals and feedback to investigators in Q1 2022

RPP submission is open to all PALLAS Investigators

Please address proposal submissions and inquiries to pallas.research@abcsg.at

Dr. Jana Link (ABCSG) coordinates proposal administration, submission status, progress of RPPs, and reports to the study sponsors

Submission form and further information can be downloaded from the PALLAS Study Portal ➔ https://www.pallasportal.com/Investigator/News/StudyUpdates

(access only for assigned non-US PALLAS Site Staff)

or requested via email.