Safety Management and Advisory Council (SMAC)

for the PAS Study:

European Active Surveillance Study Comparing
Regimens of Administration in combined hormonal contraception
(EURAS-CORA)

Proposed Study Dates: November 2014 – June 2022

Investigational product: Lisvy® contraceptive transdermal patch containing 2.10 mg gestodene and 0.55 mg ethinylestradiol

Board Members:

The members of the SMAC shall be proposed by ZEG, based on the experience of the candidates, four European consultants and one based in the USA. Council Members will be finalised in October 2014, prior to study start.

The SMAC shall be responsible for:

- Supervising the conduct of the Study;
- Reviewing the safety relevant documents of the Study before implementation;
- Ensuring the transparency and the correctness of the results obtained during the performance of the Study;
- Reviewing the planned scientific publications, if requested by Gedeon Richter or ZEG;
- Developing and directing the plans for official publications;
- Any other similar pertinent and relevant task related to the performance of the Study, if requested by ZEG or Gedeon Richter.

The SMAC shall have regular meetings at 6 (six) months intervals during the Study.