

# **Agreement of Understanding between EIGPC and Novartis Oncology regarding “A tuberous sclerosis clinical study program for EXIST-1 and EXIST 2 in Europe”.**

## **Introduction**

To improve the comfort of participants, as well as to support clinical research process, Novartis Oncology (Novartis) and an Experienced International Group of TSC Patient Consultants (EIGPC), coordinated by Eurordis, have decided to declare their intent to engage in principle in transparent collaboration for purposes that will benefit patients and that are associated with the studies called “EXIST-1 and EXIST-2” that are sponsored by Novartis Oncology. In accordance with the “Eurordis Charter for Collaboration between Sponsors and Patient Organisations for Clinical Trials in Rare Diseases”, the scope and conditions of this collaboration are described in this Agreement of Understanding.

This Agreement of Understanding is made further to and in accordance with the principles agreed by Novartis and by EIGPC on 8 February 2010

This Agreement of Understanding is made in principle, is not confidential and transparent, and is aimed to guarantee transparency in exploring possible collaboration between Novartis and EIGPC. It will be available from both the sponsor and all members of the EIGPC and Eurordis, including on their individual websites and on the Eurordis website.

This Agreement of Understanding will where relevant be attached to any documents mentioning this collaboration (for example in fundraising, submissions to ethics committees, information leaflets and brochures for participants and families, informed consent document).

For the purposes of this Agreement of Understanding, Three National TSC groups will coordinate contacts between Novartis and individual EIGPC members, and be responsible for the fulfilment by EIGPC members of the principles of this Agreement of Understanding.

This Agreement of Understanding and its aims are not dependent in any manner on the supply by Novartis of any current or future medicines, grant, inducement or other benefit. Eurordis and EIGPC members have independently considered the merits for patients of potential collaboration with Novartis and other sponsors, and have participated in this Agreement of Understanding on this basis.

## **A/ Initiators of this research project**

Eurordis has coordinated the EIGPC and will continue to do so, for example, by helping to expand its membership and remit.

## **B/ Protocol design**

EIGPC may make suggestions regarding future protocols, but no changes can be made to EXIST-1 and EXIST-2 at this point. Any feedback to the EIGPC will be provided in a timely manner.

EIGPC may have access to content of protocols for their use, and will keep it confidential as content may not be further distributed by any means.

## **C/ Implementation of research**

- This collaboration between EIGPC and Novartis covers the studies called EXIST-1 and EXIST-2, for the purpose of announcements, reviewing patient information documents, reviewing informed consent forms and reviewing patient brochures.
- Specifically, EIGPC will ensure that the information provided to both a potential participant and a

primary caregiver (if there is one) clearly states:

- the responsibilities and duties of both the patient/caregiver and investigators, ie, a clear IC form
  - the expenses involved and who will be reimbursed up to what amount
  - the studies are experimental and outcomes are not certain.
- Neither studies nor medication will be promoted by EIGPC or Novartis in any manner in information aimed at patients or their caregivers.
  - In all patient information materials (including informed consent forms), information about the major and known side effects will be set out clearly and in lay terms.
  - EIGPC is interested in working with Novartis to develop patient information on how to cope with certain side effects (fatigue, etc).
  - Novartis will request that where feasible and permissible, patient feedback be obtained anonymously by EIGPC at all sites, on the content of informed consent forms.
  - For information, EIGPC will provide anonymised data to Novartis of individuals who do not meet the inclusion criteria for studies or who are unable to participate due to their geographic location.
  - Where permissible and feasible within the limitations of Novartis' and government resources in such countries, Novartis is willing to consider submitting requests in countries in Europe that fall within EIGPC's remit, for programs to provide access to patients of medicines
  - Likely collaboration between EIGPC and Novartis is intended to apply initially to Europe, and this may be extended.

#### **D/ Conduct of research**

- EIGPC wishes to raise awareness about the EXIST studies, before and during the conduct of these studies.
- Novartis aims to provide timely information to EIGPC about patients' experiences in the studies and how these may be improved, as well as to respond to requests from EIGPC for other information.

#### **E/ Analysis and Dissemination of results**

- EIGPC will coordinate the dissemination of results to the patient community, dissemination of results to the general public and the date(s) of dissemination of results to the different target audiences in a timely fashion.

#### **F/ Anticipated projects**

- Novartis anticipates EIGPC may request support for:
  - Production of a new one-page brochure/leaflet on studies in participating country language
  - Where permissible and feasible, travel and accommodation to attend meetings to review the scope of this Agreement of Understanding and progress of the studies, where this is not practical by telephone or by e-mail (February 2010 and subsequent meetings)
  - Where permissible and feasible, caregivers' needs, and where support may be provided, Novartis shall follow it up with providers of clinical research services




- Any requests for support and its follow-up will be the subject of specific agreements

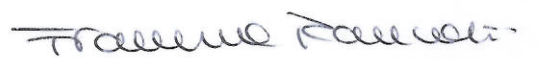
#### G/ Communication

- EIGPC and Eurordis may communicate this Agreement of Understanding on their website, and may also communicate other declarations after providing Novartis with a timely opportunity to comment on any proposed communication that refers to Novartis or to Novartis products
- EIGPC and Eurordis wish to participate in the dissemination of the results of these studies, and for this purpose Novartis where permissible and feasible will provide EIGPC and Eurordis with timely information on developments.

This Agreement of Understanding was made on 22 September 2010 by Novartis Oncology, Novartis Pharma AG and by EIGPC.

For  
Novartis Oncology

  
**SUSANNA LETO DI PRIOLO**  
Head of Patient  
Advocacy Relations

  
Med. Affairs  
Novartis Oncology IRE

For  
EIGPC

Céline BERTRAND - HARDY  
ASTB - France



YOLANDA PALOMO CASTAÑER  
A-E-S-T-U - Spain



STEPHEN TYLER  
TSA - UK

