Memorandum of Understanding

between

Boehringer Ingelheim International GmbH
Binger Straße 173
55216 Ingelheim am Rhein
Germany

- hereinafter referred to as "BI" -

and

Federation of European Scleroderma Associations – FESCA aisbl., Le Versailles
20/32 Avenue des États Unis
7500 Tournai
Belgium

- hereinafter referred to as "FESCA" -

and

The Scleroderma Society of Canada
41 King William St., Suite 206
Hamilton, Ontario L8R 1A2
Canada

- hereinafter referred to as "SSC" -

- Each party also referred to as a "Party" and the three parties collectively as the "Parties"-

Preamble

The Memorandum of Understanding ("MoU") summarizes the principal terms and conditions of the proposed collaboration between BI and FESCA/SSC regarding the SENSCIS™ Trial (BI trial 1199.214, EudraCT No: 2015-000392-28), its extension trial and areas of collaboration not related to the trial (the "Collaboration").

To improve satisfaction of trial participants, and patients in general, and to contribute to advance clinical research, BI and FESCA/SSC have decided to engage in a transparent Collaboration regarding the SENSCIS™ Trial, its extension trial and areas of Collaboration not related to the trial. 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 MoU. This MoU is made further to and in accordance with BI's Guiding Principles in the Collaboration with Patient Organisations (available at: http://www.boehringer-ingelheim.com).

This MoU is a non-confidential and non-legally binding document, aimed to guarantee transparency in the Collaboration between BI and FESCA/SSC. It will be available on request from FESCA and SSC, as well as BI, included on their websites and provided to EURORDIS for publication on their website.

This MoU will be attached to all documents and mentioned in all activities developed under the scope of this Collaboration.

For the purpose of this MoU, FESCA/SSC will coordinate contacts between BI and their individual members. FESCA/SSC are responsible for informing members involved in such additional contacts about the principles of this MoU and to ensure they respect those principles.

This MoU and its aims are not dependent, in any manner, on the supply by BI of any current or future medicines, grant, inducement or other benefit. FESCA and SSC have independently considered the merits for patients of potential collaboration with BI and other sponsors, and have participated in this MoU on this basis.

1. Scope of the potential Collaboration

1.1 It is intended that the Collaboration between BI and FESCA/SSC covers the SENSCIS™ Trial and its extension trial, in regards to:
   a) Implementation and conduct of the trial;
   b) Analysis and dissemination of results.

1.2 The Collaboration between BI and FESCA/SSC also cover other aspects not related to the trial.

1.3 The Parties agree that individual projects, including any financial or non-financial support provided by BI to FESCA/SSC, will be subject to separate agreements.

1.4 The Parties agree that the Collaboration between BI and FESCA/SSC is intended to apply initially to Europe and Canada, but this may be extended to other countries/regions.

1.5 The Collaboration between BI and FESCA/SCC will be acknowledged in all documents and activities developed under the scope of this MoU and in reference to it.

2. Implementation and conduct of the trial

The Collaboration between BI and FESCA/SSC covers:

2.1 Advice on the study announcement and dissemination of information about the trial to the patient community;

2.2 Announcement by FESCA/SSC of the study in its journal/newsletter and on its website, with reference to this MoU;

2.3 Support to physician education and training (e.g. collaboration in finding patients willing to volunteer for physician training to complete the modified Rodnan Skin Score [mRSS]);

2.4 Advice on and review of patient trial information and support materials;

2.5 Advice on and review of patient newsletter;

2.6 To the extent allowed under the applicable law, information about post-trial access to medication for patients;

2.7 The role of FESCA/SSC as an alternative source of information about the trial, as per the patient trial information and support materials developed under this MoU.

3. Analysis and dissemination of results

The collaboration between BI and FESCA/SSC covers:

3.1 Advice on and review of thank you letter which will be available to patients participating in the trial once the last patient has completed the trial and will provide the approximate timing of when the results will become available (to be provided by BI to study investigators for delivery to study participants);

3.2 Discussion of trial results. Evaluation of possible benefits, including those based on secondary endpoints and Quality of Life criteria;

3.3 Advice on and review of clinical trial results lay summary;

3.4 FESCA/SSC insights on trial results for inclusion in BI press releases;

3.5 Dissemination of results to the patient community and general public to the extent allowed under the applicable law, such as:

a) Development and publication of a leaflet for the dissemination of results, even if they are negative;
b) Announcement of results by FESCA/SSC in its journal/newsletter and on its website, with reference to this MoU.

4. Other aspects of the Collaboration not related to the study

In addition to the Collaboration concerning the SENSCIS™ Trial and its extension trial, BI and FESCA/SSC may extend their Collaboration to other fields of mutual interest, including:

4.1 Disease awareness and education

a) Distribution through BI of the awareness "So Rare" cards of systemic sclerosis symptoms developed by FESCA;
b) Awareness days and campaigns (traditional and social media);

4.2 Awareness videos (for BI);

4.3 Written interviews (for BI);

4.4 Surveys and epidemiological studies;

4.5 Early dialogue around patient access to medicines/HTA and healthcare services;

4.6 Discussion of healthcare policy topics.

5. Financial and non-financial support

The study is not financially supported by FESCA/SSC.

6. Confidentiality

The Parties confirm that a separate confidentiality agreement must be signed by each FESCA/SSC member before any confidential information is shared by BI with FESCA/SSC.

7. Conflict of interest

7.1. Any potential conflict of interest should be declared by each signing Party.

7.2. Restrictions may apply to FESCA/SCC members working on any aspects of this MoU and wishing to be involved as scientific committees' members or experts in medicinal product related activities at the European Medicines Agency (EMA), according to the "EMA policy on the handling of declarations of interests of scientific committees' members and experts". Similar restrictions could apply to national or European consultations on health technology assessment and/or in view of the reimbursement/coverage decision.

8. Non-binding nature

8.1. It is understood that the conditions set forth in this MoU merely state the present intention of the Parties and do not reflect all matters upon which agreement has to be reached.

8.2. Therefore this MoU is not intended to constitute a legally binding agreement to perform or consummate any of the projects described herein nor an agreement to enter into legally binding agreements as outlined herein or additional/ancillary agreements with respect to such projects, and it is expressly understood that no liability or obligation of any nature is intended to be created with such transactions.

8.3. It is further understood that the Parties will be bound to an agreement or any other suitable form of cooperation only if such agreement has been duly executed in writing by the Parties.

Ingelheim, April 6, 2016

Boehringer Ingelheim International GmbH

Wiesbaden, April 7, 2016

FESCA aisbl., Le Versailles

(Joep Welling)

Hamilton, April 28, 2016

The Scleroderma Society of Canada

(Maureen Sauve)