

**AGREEMENT**

**FOR THE INCORPORATION**

**OF**

**EUFEMED ASBL**

**DATED**

**31 MARCH 2015**

## AGREEMENT FOR THE INCORPORATION OF EUFEMED ASBL

**Between:**

1. **The Belgian Federation of Phase I Units (BAPU)**, an association validly incorporated under the laws of Belgium, with registered office at Lange Beeldekensstraat 267, 2060 Antwerpen, enterprise number : 0873.655.640,

Represented by Dr. Jan de Hoon, President of BAPU,

2. **Club Phase I**, an association validly incorporated under the laws of France, with registered office at Service de Pharmacologie, Hôpital Pitié-Salpêtrière, Boulevard de l'Hôpital 83, 75013 Paris, France,

Represented by Dr. Yves Donazzolo, President of Club Phase I,

3. **The Association for Applied Human Pharmacology (AGAH)**, an association validly incorporated under the laws of Germany, with registered office at Matthias-Claudius-Str. 2 A, 41564 Kaarst, Germany,

Represented by Dr. Hildegard Sourgens, President of AGAH,

4. **The Association of Human Pharmacology in the Pharmaceutical Industry (AHPPI)**, a grouping established at PO Box 3325, South Croydon, CR2 1LA, United Kingdom,

Represented by Dr. Peter Dewland, President of AHPPI,

**And:**

5. **Alain Costantini**, attorney, residing at 1200 Woluwe-Saint-Lambert, avenue Georges Henri 29,

BAPU, Club Phase 1, AGAH, AHPPI and Alain Costantini are hereinafter collectively referred to as the "**Parties**" or individually as a "**Party**".

**WHEREAS:**

Under the conditions and terms of this agreement, the Parties intend to incorporate a not for profit association organised under Belgian law, named "**EUFEMED**", with the purpose and objectives defined hereinafter under article 3 of the Articles of Association.

## **IT HAS BEEN THEREFORE AGREED WHAT FOLLOWS:**

### **Article unique - Incorporation of an association**

The Parties hereby decide to incorporate among themselves a not for profit association organised under Belgian law (*a.s.b.l.*), named “**EUFEMED**”, with the following Articles of Association:

#### **CHAPTER I - Name, registered office, purpose and duration**

**Art. 1.** An association is hereby incorporated in accordance with the Title I of the Belgian law of 27 June 1921 on not for profit associations, foundations and international not for profit associations (the “**Law**”), under the name “**European Federation for Exploratory Medicines Development**”, abbreviated as “**EUFEMED**”, hereafter referred to as the “**Association**” or as “**EUFEMED**”. Both the full name and the abbreviated name can be used interchangeably.

All acts, invoices, announcements, publicity, letters, orders and other documents issued by the Association shall indicate the name of the Association preceded or followed by the words “*vereniging zonder winstoogmerk*” or “*association sans but lucratif*” or the abbreviation “*v.z.w.*” or “*a.s.b.l.*”.

**Art. 2.** The registered office of the Association is located at rue de l’Industrie 4, 1000 Brussels (District of Brussels).

The general assembly may move the registered office to anywhere in Belgium in compliance with the applicable legislation on languages.

Any change of registered office must be filed with the competent registry of the commercial court with a view to its publication in the Annexes to the Belgian Official Journal.

**Art. 3.** The not for profit purpose of the Association consists in the development, protection and promotion of the interests of early clinical medicines research and development in Europe.

To this end the Association will:

- represent National and European federations, organisations or associations active in early clinical medicines development;
- help the members it represents in all professional fields and use all means to promote the purpose of the Association, such as the organisation of meetings and conferences, courses and extra trainings, the contingent publication of a professional journal , etc. ... This list is unrestricted;
- promote the interest of early clinical medicines development in professional organisations, international organisations and public authorities;
- develop standards and guidances in early medicines development in order to improve European competitiveness.

The Association may also perform all activities directly or indirectly related to its purpose. It may in particular cooperate and participate in any activity which corresponds to its purpose. It is also authorised to engage in ancillary commercial activities insofar as they are necessary to promote its purpose, and insofar as the resulting profits are also used to achieve its not for profit purpose .

**Art. 4.** The Association is incorporated for an unlimited period of time.

## CHAPTER II – Members

**Art. 5.** The Association consists of at least four (4) full members.

**Art. 6.** The founding members of the Association are:

- The Belgian Federation of Phase I Units (BAPU);
- The Club Phase I;
- The Association for Applied Human Pharmacology (AGAH);
- The Association of Human Pharmacology in the Pharmaceutical Industry (AHPPI);
- Alain Costantini.

The 5 founding members listed above are considered as the first full members of the Association.

**Art. 7.** Any new prospective member that would apply for full membership must be a national or European not for profit organisation or association that:

- (i) is validly incorporated and/or existing under the laws or customs of its country;
- (ii) is active in early clinical medicines development;
- (iii) commits to abide by the Articles of Association, Internal Regulations and decisions of the bodies of the Association.

The power to admit new full members is reserved exclusively to the board of directors. Applications to join the Association should be sent in writing to the board of directors. It decides whether to accept or reject the request. Its decision is final and need not be substantiated.

The full members undertake to:

- pay the annual membership fee, in accordance with Article 34, within one month after dispatch of the payment request;
- pay any additional special contributions, as stipulated in Article 34;
- attend and be represented at the general assembly.

**Art. 8.** Associate members

The Association may also admit associate members. To be accepted as an associate member the prospective member must not fulfill the criteria for full membership as described in Article 7 and must:

- (i) be validly incorporated and/or existing under the laws or customs of its country;
- (ii) be an organisation, association or any other form of legal entity, including but not limited to universities, foundations or commercial companies;
- (iii) be professionally and actively involved in early clinical development;
- (iv) commit to abide by the Articles of Association, Internal Regulations and decisions of the bodies of the Association.

The power to admit associate members is reserved exclusively to the board of directors. Applications to join the Association should be sent in writing to the board of directors. It decides whether to accept or reject the request. Its decision is final and needs not be substantiated.

The associate members undertake to:

- pay the annual membership fee, in accordance with Article 34, within one month after dispatch of the payment request;
- pay any additional special contributions, as stipulated in Article 34;
- attend and be represented at the general assembly; they have the right to voice their opinion, but do not have the right to vote.

The rights and obligations of full members described in the Law do not apply to associate members. Only the Articles of Association, the Internal Regulations and the decisions of the bodies of the Association will govern the rights and obligations of associate members. The rights and obligations of associate members may be amended without their consent.

**Art. 9. Loss of membership**

Any member may at any time leave the Association. The resigning member is obliged to pay all due contributions as well as the contribution for the current year.

The resignation is to be addressed to the president of the board of directors.

Membership automatically ends when a member no longer meets the conditions stipulated in Articles 7 or 8.

Members may be expelled in case of non-compliance with the Articles of Association, Internal Regulations or decisions of the bodies of the Association, or if they prejudice the Association's interests by their conduct.

The expulsion of a member can only be pronounced by the general assembly with a majority of two thirds of the members present or represented.

The member will be informed by registered mail of the intention to expel it. The letter sets forth the grounds on which the proposed expulsion is based. The member has the right to notify its remarks in writing to the general assembly, within fifteen (15) calendar days subsequent to the receipt of the letter. Upon its prior written request, the member involved shall be heard.

Resigning or expelled members lose all entitlement to the benefits of the Association and cannot claim refunding of contributions, nor can they exercise any right to the assets of the Association.

**CHAPTER III – Board of directors**

**Art. 10.** The Association is governed by a board of directors consisting of “members of the board”, elected by the general assembly upon proposal of full members.

If applicable, one member of the board may be elected by the general assembly upon joint proposal of associate members.

All members of the board are elected for two (2) years by simple majority of the votes cast.

The mandates are awarded in an individual capacity.

To the full extent permitted by the Law, the board of directors consists of at least four (4) members of the board and up to as many as twelve (12) members of the board.

The members of the board shall appoint from among its members a President, a President-Elect, a Secretary and a Treasurer. If the President is unable to attend, the President-Elect will act as President. In the spirit of the Association, consideration should be given to rotate the presidency and directorship among the full members.

**Art. 11.** The resigning members of the board are eligible for re-election.

**Art. 12.** The board of directors has the most extensive powers for the administration and management of the Association, unless the power is explicitly reserved by Law or the Articles of Association to the general assembly. It shall take all measures it deems necessary in the interest of the Association and decide in all contingencies.

**Art. 13.** The board of directors shall be convened at least once a year by the President and/or the Secretary by writing at least eight (8) calendar days in advance. This notice period may be shortened in the case of substantiated urgency. The President may convene the board of directors whenever required in the interest of the Association. He/she is obliged to convene the board of directors if at least two members of the board have requested so in writing.

**Art. 14.** Except for urgent matters, duly indicated and justified in the letter of notification, the board of directors may only deliberate and decide if at least half of the members of the board are present, in person, by telephone or video conference. Yet, when a new call to a meeting is made, the same agenda may be voted on, irrespective of the number of members of the board present. This new call is also done in writing. Decisions are taken by simple majority of the votes cast. In case of equality of votes, the person who is presiding has the casting vote, to the full extent permitted by the Law.

Decisions may also be taken by written resolutions provided that each member of the board has been informed at least eight (8) calendar days in advance of the decisions to be taken. The decisions come into effect on the date mentioned on the written resolutions and are deemed to be taken at the registered office of the Association.

**Art. 15.** When a member of the board, without valid reason, is not present at two consecutive meetings, as defined under Article 14, the board of directors may put forward his/her dismissal to the general assembly.

**Art. 16.** The members of the board fulfill their duties free of charge. However, they may be reimbursed for expenses they made, such as for travelling, accommodation and representation.

**Art. 17.** The President oversees the implementation of the Articles of Association, Internal Regulations and decisions of the bodies of the Association. He/she exercises supervision over the meetings and he/she shall take all necessary measures to implement the decisions of the board of directors. He/she gives the order to hold the meetings of the board of directors and the general assembly. The President may invite third parties as advisers to meetings of the board of directors.

**Art. 18.** The President-Elect shall assist the President in his/her office. If necessary, he/she replaces the President who may temporarily devolve his/her powers to him/her.

**Art. 19.** The Secretary is responsible for all the written documents of the Association, invitations to general assembly meetings and minutes of meetings. He/she has overall responsibility for the reports of the board of directors and the general assembly. He/she keeps the register of members.

**Art. 20.** The Treasurer is responsible for the funds of the Association and the assets that are entrusted to him/her. Payments made by him/her should be co-signed by the President or another member of the board, except for transactions of daily management, as described in the Internal Regulations, which he/she can carry out alone. He/she collects the contributions and other money owed to or to be received by the Association and provides receipts for this. He/she does all investments, transfers or withdrawals of funds pursuant to orders signed by the President or the person replacing him/her with specification of the sums to be invested, transferred or withdrawn.

**Art. 21.** The Association will be legally bound by the joint signatures of the President and the Secretary, or by the signature of either of them with the signature of one of the members of the board.

#### **CHAPTER IV - General assembly**

**Art. 22.** The general assembly is composed of full and associate members. Associate members have the right to voice their opinion, but do not have the right to vote.

The decisions of the general assembly are binding on all members.

**Art. 23.** The annual general assembly shall be convened in the course of the first two quarters. On the agenda of this general assembly the following required topics are mentioned:

- the election of the members of the board;
- the submission and review of the annual accounts prepared by the board of directors and ending on 31 December of the previous year;
- review of the budget for the coming year, also prepared by the board of directors;
- determining the amount of the annual membership fee up to € 10,000.00 per member;
- determining additional contributions for special services, to be established in the context of the mission of the Association;
- the election of one auditor.

**Art. 24.** Each meeting is held on the day, time and place specified in the invitation. All members must be invited to this meeting.

At least eight (8) calendar days before the general assembly, all members are to receive an invitation in writing. The agenda shall be attached to the invitation.

**Art. 25.** The President may convene the general assembly, whenever he/she deems it useful. He/she is obliged to convene them if at least one twentieth of the full members request so in writing, stating the topic they wish to be placed on the agenda.

**Art. 26.** Except as otherwise provided by the Law or the Articles of Association, the general assembly may validly deliberate and decide, irrespective of the number of full members present or represented and decisions of the general assembly are taken by simple majority of the votes cast. In case of equality of votes, the proposal is rejected.

Full and associate members may validly send several delegates to the meetings of the general assembly.

If a full member sends several delegates to a meeting of the general assembly, it must designate the delegate exercising the voting right. Failing so, the full member will not be allowed to cast its vote. The delegate of the full member holding the voting right may cast one (1) vote. Associate members have no voting right.

Decisions may also be validly taken by written resolutions provided that each member has been informed at least eight (8) calendar days in advance of the decisions to be taken. The decisions come into effect on the date mentioned on the written resolutions and are deemed to be taken at the registered office of the Association.

**Art. 27.** On an amendment to the Articles of Association, the general assembly may only validly deliberate and decide if the amendments are explicitly stated in the invitation and if at least two thirds of the full members are present or are validly represented at the meeting.

An amendment can only be adopted by a majority of two thirds of the votes cast.

In case less than two thirds of the full members are present or represented at the first meeting, a second meeting may be convened, which can validly deliberate and decide and adopt the amendments with the majorities provided for in the second paragraph, regardless of the number of full members present or represented. The second meeting cannot be held within fifteen (15) calendar days following the first meeting.

**Art. 28.** The decisions of the general assembly shall be kept by the Secretary and may be inspected by full members at the registered office of the Association. Third parties may inspect the decisions of the general assembly on condition that the board of directors has given its consent. The request for access shall be addressed to the President.

**Art. 29.** The President may invite third parties to the general assembly. They may under no circumstances take part in a vote.

**Art. 30.** The general assembly may vote on penalties for non-compliance of the Internal Regulations introduced by it in accordance with the Articles of Association

## **CHAPTER V – Internal Regulations and audit**

**Art. 31.** The board of directors is responsible for drawing up Internal Regulations for the implementation of the Articles of Association. Prior to its implementation, the Internal Regulations will be approved by the general assembly by a simple majority of the votes cast.

The same rule will be observed for any possible amendments to the Internal Regulations.

**Art. 32.** The review of the financial situation, the annual accounts and the verification that the transactions set out in the annual accounts comply with the legal requirements and the Articles of Association must be entrusted to one auditor ("auditeur"). The positive outcome of the audit is the basis for the discharge of the members of the board by the general assembly.

## **CHAPTER VI - Resources and assets of the Association**

**Art. 33.** The financial year of the Association runs from 1 January to 31 December.



**Art. 34.** The financial resources of the Association consist of membership fees of full members and associate members, the contributions for special services, incidental gifts, fines, potential entrance fees and the proceeds of investments of any kind. The unused funds of the Association may be invested in its name, either in securities or bonds guaranteed by the Belgian Government, or on a credit account in a bank to be designated by the board of directors.

**Art. 35.** The assets of the Association include all goods, fixed and flexible assets, for valuable or favorable consideration, for which the law allows possession.

**Art. 36.** The general assembly decides on the use of the assets and resources of the Association in accordance with the legal provisions.

#### **CHAPTER VII – Limited liability**

**Art. 37.** The members of the Association do not assume joint and several liability for the obligations of the Association, whether between themselves or with the Association. Their liability is limited to the settlement of their financial obligations.

The members of the board are not personally liable for the obligations of the Association. Their liability is limited to the proper performance of their mandate.

#### **CHAPTER VIII - Dissolution and liquidation of the Association**

**Art. 38.** The dissolution of the Association can only be validly decided on at a general assembly to which the invitation mentions this topic and at which at least two-thirds of the full members are present or validly represented.

If not at least two-thirds of the full members are present or represented at this general assembly, a second general assembly at which the dissolution and liquidation of the Association should be discussed may only be convened after fifteen (15) calendar days. The decision to dissolve the Association shall require a majority of at least four fifths of the votes cast.

**Art. 39.** The general assembly that pronounces the dissolution appoints the liquidators and determines their powers. Any surplus after liquidation is granted to a similar or related not for profit organisation, designated by a decision of the general assembly.

#### **CHAPTER IX – Final provisions**

**Art. 40.** These Articles of Association shall be drafted in French and English. The Internal Regulations shall be drafted in English only.

The French version of the Articles of Association shall take precedence. English shall be the working language of the Association.

**Art. 41.** Any dispute in connection with the Articles of Association of the Association, its Internal Regulations or any decision of one of its bodies, shall be governed by Belgian law and falls under the sole jurisdiction of the Brussels courts (French-speaking courts).

## **CHAPTER X – Temporary provisions**

### **1. First members of the board of directors**

As an exception to Article 10 of the Articles of Association, the Parties unanimously decide to appoint the following persons as first members of the board, who accept their mandate:

1. Dr. Jan de Hoon, President, Turnhout, 8/05/1964, Zandstraat 34, 2400 Mol, Belgium;
2. Dr. Ulrike Lorch, Secretary, Backnang (Germany), 23/12/1964, Kings Road 60, Richmond, Surrey, TW10 6EP, United Kingdom;
3. Dr. Yves Donazzolo, Treasurer, Grenoble, 3/10/1962, Rue de la Chaumière 8, 38180 Seyssins, France;
4. Dr. Hildegard Sourgens, President-Elect, Oberhausen, 19/02/1948, Hornstrasse 7, D-80797 München, Germany.

The mandate of the members of the board comes into force on the date the Association acquires legal personality and expires at the end of the meeting of the annual general assembly approving the annual accounts for the financial year 2016.

### **2. First financial year and first meeting of the annual general assembly**

As an exception to Article 33 of the Articles of Association, the Parties unanimously decide that the first financial year of the Association will begin on the date the Association acquires legal personality and expires on 31 December 2015. The first annual general assembly will be held in 2016.

### **3. Common attorney-in-fact of AHPPI**

As AHPPI does not dispose of a legal personality in accordance with the laws and the customs of its country of origin, it appoints Dr. Peter Dewland who will act on behalf and for the account of AHPPI, in his capacity of common attorney-in-fact. The replacement of the common attorney-in-fact requires the assent of the board of directors.

### **4. Full membership of Alain Costantini**

As an exception to Article 7 of the Articles of Association, the Parties unanimously decide to acknowledge the full membership of Alain Costantini even though he does not meet the criteria stated in Article 7 of the Articles of Association. His full membership will expire at the end of the first annual general assembly at the latest.

### **5. Power for publication formalities**

The Parties unanimously decide to grant a power of attorney to Mr Alain Costantini and Mr Julian Delplanche, lawyers, with offices at 1340 Ottginies, allée de Clerlande, 3, each of them empowered to act individually, to carry out all filing and publication formalities resulting from the decisions here above, including the filing of the Articles of Association with the clerk of the Commercial Court of Brussels.

Signed in 6 originals, each for one Party and one to be kept at the registered office of the Association.

Brussels, 31 March 2015

**For The Belgian Federation of Phase I Units (BAPU),**

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Dr. Jan de Hoon, President of BAPU

**For Club Phase I,**

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Dr. Yves Donazzolo, President of Club Phase I

**For The Association for Applied Human Pharmacology (AGAH),**

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Dr. Hildegard Sourgens, President of AGAH

**For The Association of Human Pharmacology in the Pharmaceutical Industry (AHPPI),**

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Dr. Peter Dewland, President of AHPPI

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**Alain Costantini**