Łomianki, 13.11.2019

Purchaser:

Celon Pharma S.A.
HQ address:
Ogrodowa 2A Street
05-092 Kiełpin/Łomianki
tel.: +48 22 751 59 33
KRS: 0000437778
NIP: 118 - 16 - 42 - 061
e-mail: anna.dulinska@celonpharma.com

Request for Quotation (RfQ) no. 04/2019/O/NoteSzHD/Z9

Attachment no. 3

Declaration confirming the fulfillment of the conditions from the RfQ

In connection with the implementation by Celon Pharma S.A. of the Project: "New therapy of psychotic disorders and Huntington's disease with particular focus on cognition deficits" under the Program Prevention and Treatment of Civilization Diseases - STRATEGMED - Competition II (hereinafter referred to as "the Project"), I declare that:

1. ……<Bidder's Name>…… runs a business with the capacity of conducting the activities which are the subject of the order and has knowledge, experience and technical capacity necessary to find and contract commercial Clinical Centres capable of conducting clinical trials and Laboratory/ies conducting medical laboratory tests.

   [ ] YES [ ] NO

   Substantiation:……
   ……
   ……

2. ……<Bidder's Name>…… commits to contract commercial Clinical Centres with the necessary medical and laboratory infrastructure to conduct the clinical trial according to GCP requirements. It is allowed to supplement the infrastructure in the Clinical Centre (in terms

of renting of e.g. centrifuges, refrigerators/freezers, cabinets) for the needs of the clinical trial which is the subject of this RfQ, if such a need arises

[ ] YES [ ] NO

Data of at least 3 Clinical Centers planned to be contracted:

……
……
……
……
……
……

Substantiation:……
……
……

3. Clinical Centres contracted by ……<Bidder's Name>…… must have employed experienced medical staff with a valid license to practice and Good Clinical Practice requirements training. It is allowed to conduct trainings on the requirements of GCP before starting a clinical trial.

[ ] YES [ ] NO

Substantiation:……
……
……

4. ……<Bidder's Name>…… must propose a Study Coordinator who has expertise and experience provided in the RfQ.

[ ] YES [ ] NO

Study Coordinator Data:

……
……
……

Substantiation:……
……
……

5. ……<Bidder's Name>…… has employed or will contract the Project Manager, or a person in different, adequate position, responsible for the implementation of the subject of the RfQ on the Bidder's side (including responsibility for communication with potential subcontractors and the Purchaser) who has experience provided in the RfQ.

[ ] YES [ ] NO

Data of the Project Manager (or a person in another adequate position):
……
……
……
Substantiation:……
……
……

6. ……<Bidder's Name>…… has employed or will contract a person with a fluent English, to write a Clinical Study Report in English, in accordance with the ICH E3 guideline "Structure and content of clinical study reports".

[ ] YES [ ] NO

Substantiation:……
……
……

7. Financial and economic situation of ……<Bidder's Name>…… ensures successful implementation of the order and there are no indications suggesting that this situation will change during the period covered by the agreement. The Bidder is not subject to insolvency proceedings initiated, nor his bankruptcy has not been declared, is not subject to liquidation proceedings, and his cases are not covered by a receivership or court order. The Bidder is not behind with taxes, fees or social insurance or health insurance contributions.

[ ] YES [ ] NO

.....	.....
(Place, date)	(Name, Surname, Signature of the Authorized Person)

Celon Pharma S.A.
Biuro: Ogrodowa 2A
05-092 Kiełpin / Łomianki
tel.: +48 22 751 59 33
e-mail: info@celonpharma.com
www.celonpharma.com

Organ rejestrowy: Sąd Rejonowy dla m. st. Warszawy,
XIV Wydział Gospodarczy Krajowego Rejestru Sądowego
Prezes Zarządu: Maciej Wieczorek
Numer KRS: 0000437778
Wysokość kapitału zakładowego: 4 500 000 PLN
NIP : 118 – 16 – 42 – 061, REGON : 015181033
BDO 000109582