

20-MAY-2024

RE:	Request for Approval of Initial Clinical Trial Application with investigational medicinal product
EU CT Number:	2024-511482-11-00
Protocol Number:	SPIAM-301
Protocol Title:	ReNEW: A Phase 3, Randomized, Double-Masked, Placebo-Controlled Clinical Trial to Evaluate the Efficacy, Safety, and Pharmacokinetics of Subcutaneous Injections of Elamipretide in Subjects who have Dry Age-Related Macular Degeneration (Dry AMD)
Investigational Product Name:	Elamipretide hydrochloride
Sponsor:	Stealth BioTherapeutics Inc. 123 Highland Avenue Suite 201, Needham, MA, 02494, USA

Dear Sir/Madam,

On behalf of the Sponsor, Stealth BioTherapeutics Inc., and the EU legal representative IDEA Innovative Drug European Associates (Ireland) Limited, please find enclosed a request for the authorisation of a clinical trial application for the above referenced study.

The SPIAM-301/ReNEW study is to be conducted in Czech Republic, Germany, Hungary, Italy, Spain, the United Kingdom (UK), Australia, New Zealand and the United States (US).

The reference safety information can be found in Section 6.2. Reference Safety Information of the Investigators Brochure (IB) V15.0 dated 30 March 2023. Please see the attached memo dated 04-MAR-2024 for clarification on why the IB has not yet been updated in 2024.

I trust the information included in this submission is satisfactory. However, should any further information be required, please do not hesitate to contact me.

Please address all invoices to:

*Ora Europe, Ltd
10 John Street,
London,
United Kingdom,
WC1N 2EB*

Accounts Pay International accountspayinternational@oraclinical.com
Please quote the PO number 24867 on all invoices.

Yours Sincerely,



Ora Europe Limited, EU Regulatory Manager
On behalf of Stealth BioTherapeutics Inc.
Phone: 07904400274
email: oraeuroperegulatory@oraclinical.com