



10 September 2021

European Clinical Trials Database (EudraCT)
European Medicines Agency
Domenico Scarlattilaan 6
1083 HS Amsterdam
The Netherlands

Subject: Change in Sponsor Name and Early Study Termination Update

References:

Product Number: QR-313

Protocol Number: PQ-313-002

Protocol Title: A First in Human, Double-Blind, Randomized, Intra-subject, Placebo-controlled, multiple dose study of QR-313 Evaluating Safety, Proof of Mechanism, Preliminary Efficacy and Systemic Exposure in Subjects with Recessive Dystrophic Epidermolysis Bullosa (RDEB) due to Mutation(s) in Exon 73 of the COL7A1 Gene.

EudraCT Number: 2017-004806-17

Sponsor: Phoenixis Therapeutics

EU Legal Representative: IDEA Regulatory

Dear Sir/Madam,

On behalf of Phoenixis Therapeutics, IDEA, the applicant is hereby submitting notification of the change in sponsor name from Wings Therapeutics to Phoenixis Therapeutics for the above mentioned study.

Study PQ-313-002, which was originally undertaken by the Dutch company ProQR, was terminated early in September 2019 due to lack of enrollment. There were no safety-related issues that occurred with the drug. Only 2 patients had been enrolled in the study, one in the US and one in Spain, when the asset was transferred to Wings Therapeutics in the US which was subsequently acquired by Phoenixis Therapeutics. There are no plans to resume studies with the formulation used in Study PQ-313-002 and no final clinical study report will be generated for the PQ-313-002 study; therefore, results will not be available for posting in the EudraCT database.

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Please do not hesitate to contact me at the contact information list below if you have any questions or require further information regarding this notification.

Best regards,

Hal Landy, MD

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