Innovate UK’s Response to the Science and Technology Committee’s Request for Comment on its Funding for the ‘INSPIRE’ Trial

I write with reference to a request of 08 December 2017 from the Committee asking Innovate UK to comment on its involvement in funding the “Stem cell-based 3D tissue engineered organ for tracheal replacement” project, an industry-led collaborative research and development project led by Videregen Ltd of which the INSPIRE trial formed part.

We understand that the INSPIRE trial was cited in evidence submitted by Professor Patricia Murray and Raphael Levy as an example of R&D activity that should be suspended pending investigations into the validity of related research into the transplantation of ‘tissue-engineered’ tracheas underpinning the trial.

We thank the Committee for the opportunity to clarify the extent of Innovate UK’s involvement with the project, from the original decision we took to fund the proposal up to the present.

The proposal was originally submitted to Innovate UK by a consortium comprising Videregen Ltd, the Cell and Gene Therapy Catapult and University College London in response to the 2013 “Supporting regenerative medicines and cell therapies” competitive call, seeking proposals from both single companies and collaborations for projects that would address the challenges of developing regenerative medicine and cell therapies as clinical treatments and commercial products. This project aimed to deliver validated manufacturing processes, an economic assessment of the potential therapy, and a 4-patient Phase 1 clinical trial.

The proposal underwent comprehensive and rigorous assessments against the established sets of scoring criteria that Innovate UK applies consistently across its competitions. The project was awarded funding on the basis of its alignment with the competition scope, and in accordance with the scientific consensus at the time that the above mentioned research underpinning the proposal was sound. The project formally commenced in 2014.

The Medicines and Healthcare products Regulatory Agency (MHRA) approved the use of the product in a first-in-human clinical trial in October 2015 and ethics approval of the trial was confirmed in January 2016.

The Cell and Gene Therapy Catapult is the sponsor of the INSPIRE trial element of the project, and it suspended the initiation of patient recruitment when they became aware of new information from investigation of Prof Macchiarini’s clinical cases, discussions with the UCL group and the UCL Special Inquiry to allow a thorough risk assessment. To this end, no patients have ever been recruited or treated on the INSPIRE trial. The suspension of site initiation and patient recruitment was agreed with the MHRA in December 2016, and it remains in effect.

In addition to its prompt suspension of the trial, the Catapult is committed to full transparency about the case and remains responsive to all requests for information on the matter from the relevant authorities. We would stress also that both Innovate UK and the Catapult continue to defer to the regulatory authorities when it comes to assessment of scientific evidence in clinical trials, as they have done in this case.

Innovate UK would remind the Committee that risks are inherent to all types of innovation, and this includes the risk that the scientific basis on which a successful application for funding is predicated, is later revised in light of new information. This does not minimise our resolve to rectify real or
suspected shortcomings with the delivery of a project we have funded thoroughly and without delay.

I trust this letter clarifies Innovate UK’s position on this subject.

January 2018