Coronavirus Challenge Study Model

Released : 09 March 2020

RNS Number : 3586F
Open Orphan PLC
09 March 2020

09 March 2020

Open Orphan Plc

("Open Orphan" or the "Company")

Development of the World's First Human Coronavirus Challenge Study Model

Open Orphan, the rapidly growing specialist Clinical Research Organisation ("CRO") pharmaceutical services company whose London-based subsidiary hVIVO is the world leader in the provision of virology and vaccine challenge study services, is pleased to announce that it has commenced the development of the world's first commercial human coronavirus challenge study model, also known as a Controlled Human Infection Model (CHIM). The Company has Europe's only 24-bedroom quarantine clinic with onsite virology lab where the challenge model will be developed and used. The development of this coronavirus human challenge study model is being led by hVIVO's Chief Scientist Andrew Catchpole and his team in conjunction with Open Orphan's Scientific Advisory Board, which is led by world-renowned virologist Prof John Oxford, and builds upon work by hVIVO to potentially develop a Coronavirus challenge study model several years ago and hVIVO's extensive knowledge in developing human challenge models.

The Company is in early discussions with King & Wood Mallesons, acting on behalf of selected Chinese pharmaceutical and life science clients, to secure funding for the further development of this Coronavirus challenge study. It is intended that the major cost of developing this Coronavirus human challenge model will be primarily funded by new Chinese pharmaceutical partner companies who will get a return on their investment from royalties on the sale of this particular challenge study model.

Open Orphan will utilise common coronavirus strains such as OC43 and 229E which are from the same family of viruses as the newly emerging Covid-19 virus but unlike Covid-19 these common coronaviruses have been widespread in the community for many years and cause only a mild cold-like respiratory illness. Consequently, these common coronaviruses, while closely related to the Covid-19 strain can safely be administered to volunteers in hVIVO's highly controlled quarantine clinic, staffed by a highly experienced medical and scientific team who to date have already safely inoculated over 3,000 volunteers in hVIVO's current range of respiratory virus challenge models.

For the purposes of the human challenge study model, the common coronavirus strains such as OC43 and 229E, will provide an effective tool to obtain fast proof-of-concept data against this important family of viruses. It can be used to test the efficacy of both new novel and existing vaccines and anti-virals. This will allow the effective selection of the best candidates and the effective products to be fast-tracked for subsequent field testing against Covid-19. All of the human challenge studies can be run out of hVIVO's quarantine clinic with onsite virology lab in London. Once developed, hVIVO will offer its coronavirus challenge study model as both a standalone service to customers or as part of a combined Phase 1 and human challenge study that can both be run out of its London quarantine clinic. Furthermore, hVIVO can also offer services in early phase vaccine development.

This news follows an announcement on Friday 6 March that the Company had signed a contract with a new client, which is a European Biotech company, for the provision of an RSV human challenge study. This study is projected to deliver £3.2m in revenue, all of which is expected to be recognised in 2020. Furthermore, if that study is successful it is anticipated that an additional follow-on larger pivotal challenge study will commence end Q4 2020, delivering significant further revenue which is expected to be a minimum of £7m. This contract is significant as it the first that utilises the complementary in-house CRO services of both hVIVO and another of the Company's subsidiaries, Venn Life Sciences, following the completion of the Company's merger with hVIVO in late January and demonstrates the Company effectively converting its pipeline.

Cathal Friel, Executive Chairman of Open Orphan, commented:

"This is an important milestone in the development and evolution of Open Orphan and particularly the Company's subsidiary hVIVO which is based in London, UK. We are very happy to be able to try and assist in the battle against Covid-19. Our hVIVO scientists and virologists, and especially hVIVO's founder and the now Chairman of our Scientific Advisory Board Prof John Oxford, have a long history and experience of successfully developing challenge studies.

This development also reinforces the strength of hVIVO's reputation as a world leader in providing services to global vaccine and anti-viral production companies and is another example of the growth potential for Open Orphan. A considerable amount of the work around this project has already been carried out and the project takes advantage of the significant knowledge and experience gained from hVIVO's previous challenge virus manufacturing campaigns. We are delighted to be working with Mike Wang of the international law firm King & Wood Mallesons who is working with us to secure funders for this project from his network of Chinese pharmaceutical and life science companies."

Professor John Oxford, Chairman of Open Orphan's Scientific Advisory Board, commented:

"After almost 5 years' of absence from hVIVO, I'm delighted to be more involved again and particularly to be back involved as Chairman of the Scientific Advisory Board. Over the years, I have had extensive experience in dealing with novel and threatening viruses and in 2009 I was the first person, in conjunction with the hVIVO laboratory, to get permission from the government to bring the SARS virus into the country in order to analyse it as part of seeking a solution to the outbreak.

A couple of years ago, the hVIVO Scientific team started a project to potentially develop a Coronavirus challenge study model but after a certain amount of work and effort they suspended this project because they didn't see sufficient market demand for a Coronavirus challenge study model. However, in recent weeks, the hVIVO scientific team led by their Chief Scientist Andrew Catchpole have reopened their Coronavirus challenge study project and work files. Given the unfortunate circumstances of Covid-19 now spreading around the world they and I felt that there was an obligation on us to reactivate the project and to do our best to now swiftly and effectively make a Coronavirus challenge study model available to the market as soon as possible.

I'm looking forward to working with the team in the days and weeks ahead to do our best to make the world's first Coronavirus challenge study model available as soon as possible."

For further information please contact

Open Orphan plc

Cathal Friel, Executive Chairman **+353 (0)1 644 0007**

Trevor Phillips, Chief Executive Officer **+44 (0)20 7347 5350**

Arden Partners plc (Nominated Adviser and Joint Broker) **+44 (0)20 7614 5900**

John Llewellyn-Lloyd / Benjamin Cryer

Davy (Euronext Growth Adviser and Joint Broker) **+353 (0)1 679 6363**

Anthony Farrell

Camarco (Financial PR)

Tom Huddart / Daniel Sherwen **+44 (0)20 3757 4980**

Notes to Editors:

Open Orphan is a rapidly growing specialist CRO pharmaceutical services company which has a focus on orphan drugs and is a world leader in the provision of virology and vaccine challenge study services and viral laboratory services. It has Europe's only 24-bedroom quarantine clinic with onsite virology lab in London. hVIVO supports product development for customers developing antivirals, vaccines and respiratory therapeutics, all particularly relevant and topical in the environment of heightened awareness of the Coronavirus in 2020. The company also has a leading portfolio of 8 viral challenge study models which are: 2 FLU, 2 RSV, 1 HRV, 1 Asthma, 1 cough and 1 COPD viral challenge models. No other company in the world has such a portfolio, with only two competitors globally having 1 challenge study model each.

Open Orphan comprises of two commercial specialist CRO services businesses (Venn and hVIVO) and is developing an early stage orphan drug genomics data platform business. This platform captures valuable genetic data from patient populations

with specific diseases with designated orphan drug status and incorporating AI tools. In June 2019, Open Orphan acquired AIM-listed Venn Life Sciences Holdings plc in a reverse take-over and in January 2020 it completed the merger with hVIVO plc. Venn, as an integrated drug development consultancy, offers CMC (chemistry, manufacturing and controls), preclinical, phase I & II clinical trials design and execution. The merger with hVIVO created a European full pharma services company broadening the Company's customer base and with complementary specialist CRO services, widened the range of the Company's service offerings.

About Coronavirus

Coronaviruses are a family of viruses that can lead to respiratory illness, including Middle East Respiratory Syndrome (MERS-CoV) and Severe Acute Respiratory Syndrome (SARS-CoV). Coronaviruses are transmitted between animals and people and can evolve into strains not previously identified in humans. On January 7, 2020, a novel coronavirus (2019-nCoV) was identified as the cause of pneumonia cases in Wuhan City, Hubei Province of China, and additional cases have been found in a growing number of countries.[1,2]

[1]"Coronavirus." World Health Organization, https://www.who.int/health-topics/coronavirus.

[2]"2019 Novel Coronavirus, Wuhan, China." Centers for Disease Control and Prevention, https://www.cdc.gov/coronavirus/2019-nCoV/index.html.

END

CNTUPUCCWUPUPUR