

Langen, 10 September 2020

STATEMENT

CLINICAL TRIAL OF ASTRAZENECA PUT ON HOLD

Vaccine candidate: ChAdOx1 nCoV-19

The Phase II/III trial of Oxford University's COVID-19 vaccine candidate ChAdOx1 nCoV-19 and the UK-based company AstraZeneca has apparently been put on hold by the sponsor as a precautionary measure, and recruitment has been stopped. The company has not filed an application for approval of this clinical trial with the Paul-Ehrlich-Institut, Federal Institute of Vaccines and Biomedicines, so that no trial participants were included in the trial in Germany. In Europe, the study is only running in England. The Paul-Ehrlich-Institut therefore has no further information in addition to the data published in the European Register for Clinical Trials (www.clinicaltrialsregister.eu).

During the course of the study, a rare neurological disorder was diagnosed. Studies with the same vaccine candidate or a vaccine candidate with the same vector ChAdOx1 nCoV-19 are not conducted in Germany.

At this point in time, there is no need for action regarding the ongoing clinical trials with COVID-19 vaccines in Germany.

Putting studies on hold is a standard procedure in clinical trials and serves to protect study participants. Currently, intensive investigations are being conducted to determine whether the observed neurological disease is causally related to the vaccination or whether it occurred only by chance in temporal relation with the vaccination. Only when this question has been sufficiently clarified can a meaningful decision be made on any further measures.

How does the Paul-Ehrlich-Institut assess the significance of this interruption or recruitment stop of the clinical trial?

Studies put on hold, i.e. the temporary suspension of further recruitments for the evaluation of data, in particular data that could affect the safety of study participants, represent common precautionary measures in clinical trials and serve



to protect study participants. A resumption of the clinical trial is possible after evaluation and approval by the UK Medicines and Healthcare Products Regulatory Agency (MHRA).

On the basis of the information currently available, the Paul-Ehrlich-Institut is unable to make a final assessment of the suspected adverse reaction from the Phase II/III trial of the COVID-19 vaccine candidate ChAdOx1, but will continue to monitor the situation together with the European Medicines Agency. At this point in time, there is no need for action regarding the ongoing clinical trials with COVID-19 vaccines in Germany.

Further Information

- EU Clinical Trials Register – Phase II/III study AstraZeneca
www.clinicaltrialsregister.eu/ctr-search/trial/2020-001228-32/GB