Message

From: Van Tam, Jonathan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=D29C846FC8FA4678B419C6F0DC3836F3-JVANTAM]
Sent: 11/09/2020 20:44:28
To: NR @mhra.gov.uk]
CC: Name Redacted [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f02950ddfb2a448f831d41adba2da5e NR psmatthancock [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8dddc7f87798480280e3a7aa57cb8d62-psmatthanco]; PsBethell [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6f0a1735f9834b5ca9c02d2016d42e9f-PsBethell NR [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb0dcccccc0cf43b0842e42f061cbb55 NR Harpur, Matthew [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=854f042d836a406db4a10456d0a73331-MHarpur]; Alexander, Julie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a905975c1e054ec5a25140912b5528f0-JAlexander]; Reed, Emma [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=173f921982a14676bd2ddede2616bc10-EReed2]
Subject: Re: Oxford Vaccine Trials: Status Update

Dear NR

Dear NR

Thank you for the update. Participant safety and indeed the safety of any vaccine are of paramount importance and I thank MHRA for its independent oversight.

Of course it's a relief to hear the news given the global needs but that is secondary to the independence of the review irrespective of the outcome.

The only person I shall be passing this news to over the weekend is the CMO, Prof Whitty. Apart from that I can sit back and wait for more substantive announcements on Monday.

Regards

Jonathan

From: NR @mhra.gov.uk>
Sent: Friday, September 11, 2020 8:01 pm
To: Van Tam, Jonathan
Cc: Name Redacted psmatthancock; PsBethell; NR Harpur, Matthew; Alexander, Julie; Reed, Emma
Subject: Oxford Vaccine Trials: Status Update
OFFICIAL SENSITIVE
Dear Professor Van Tam,
I am writing with an update on the Oxford Vaccine trials pause.
As you will be aware, all trials (including UK, Brazil, South Africa, USA) with the Oxford ChAdOx1 vaccine were paused on 6th September, following an adverse event observed in one participant, so that a review of safety information could be conducted.
The independent Data Safety Monitoring Board (DSMB) set up by Oxford for this trial met on the 10th September 2020 and recommended that vaccination could resume, pending review by the MHRA of the data and the request to restart the trial, and by the ethics committee.

The MHRA has actively engaged with the Oxford Vaccine Centre and all available data, including the request to restart the trial, was received for review by 11th September. The information has been rigorously assessed by MHRA, with independent expert advice obtained from the Commission on Human Medicines (CHM), who met this afternoon.
The CHM discussed the clinical information available on the case in the context of all available safety data and agreed with the view of the DSMB and recommended to the MHRA that vaccination could restart, including a condition to provide the MHRA with further clinical information as soon as it is available and an expectation that the DSMB continues to closely monitor for events of special interest, in particular neurological events.
At the time of writing, the official notification to Oxford on their restart approval is pending review by the CHM Chair. Subsequent to this we will inform the investigators over the course of this evening. The usual procedure is that we would then update the status of the trials in the EU public register – this would mean a change in the public status of the trial from "temporarily halted" to "ongoing".
We understand that, logistically, the earliest Oxford can restart dosing is Monday 14th September. Given this, we propose that only holding lines are used until Oxford is in a position to formally confirm their restart; we would also then proceed to update the public database on 14th.
We are not aware of imminent decisions by other regulators regarding trials with the Oxford vaccine in their jurisdictions, and do not anticipate publicity over the weekend. We propose an initial reactive statement for use over the weekend should there be enquiries, and a second statement once the Oxford researchers have restarted the trial. These lines will be discussed and agreed with DHSC Comms in the normal way.

Initial Reactive statement:

MHRA Director of licensing, Dr Siu Ping Lam said;

"Participant safety in any clinical trial is our top priority. We have worked closely with the Oxford Vaccine Centre following the temporary pause of their COVID-19 vaccine trial to allow for a review of safety data. This is in line with the authorised protocol for the trial."

Once Oxford have confirmed the restart we will inform international regulators and update our reactive lines to the following:

Reactive statement from 14 September:

MHRA Director of licensing, Dr Siu Ping Lam said;

"Participant safety in any clinical trial is our top priority. We have worked closely with the Oxford Vaccine Centre following the temporary pause of their COVID-19 vaccine trial to urgently obtain and review the all available safety data.

We have now reviewed the data provided by the researchers and, after seeking independent expert advice from the Commission on Human Medicines, we agreed with the view of the Data and Safety Monitoring Board and approved the restart of the trials.

"Vaccine safety is of paramount importance and we continually monitor the safety of vaccines to ensure that the benefits outweigh any potential risks."

Please let me know if any further information or clarification would be helpful.

Best regards,

Name Redacted
Name Redacted PhD, MRPharmS
Unit Manager
Clinical Trials Unit
Licensing Division, MHRA

Medicines and Healthcare products Regulatory Agency

10 South Colonnade, Canary Wharf, London E14 4PU

NR @mhra.gov.uk
gov.uk/mhra
Stay connected