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From: [redacted]
Sent: 11 March 2022 17:03
To: PHARMACO - Pirmohamed, Dr M (i)
Subject: OFF-SEN: Evusheld communications
Attachments: 050122_Evusheld press release and Q&A.docx

Hi Munir

I hope you're well.

Confidentially, we are looking to announce the approval of Evusheld on Tuesday morning (before 7am) subject to ministerial approval.

We've drafted a press release that includes a statement from you – could you please have a look over it and check you are happy? Feel free to make any edits as you see fit (to your statement or the rest of the communications). June hasn't cleared it yet so there may be further edits, but I'll make sure you have sight of any final version.

Grateful if you could get back to me by 3pm Monday.

Have a nice weekend.

[redacted]

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PRESS RELEASE: PUBLISHED ON GOV.UK

Evusheld approved by UK regulator to prevent COVID-19

A new COVID-10 medicine, Evusheld (tixagevimab/cilgavimab), has today been authorised by the Medicines and Healthcare products Regulatory Agency (MHRA) after meeting the UK regulator's expected standards of safety, quality and effectiveness.

The decision to grant approval for this treatment has been endorsed by the government's independent expert scientific advisory body, the Commission on Human Medicines, who has also carefully reviewed the data.

Developed by AstraZeneca, Evusheld is a combination of two long-acting antibodies that works by binding to the spike protein on the outside of the COVID-19 virus. This in turn prevents the virus from attaching to and entering human cells.

Unlike the other COVID-19 treatments approved by the UK regulator to date, it is authorised to prevent COVID-19 before infection (known as 'pre-exposure prophylaxis').

It has been authorised for use in adults who are unlikely to mount an immune response from COVID-19 vaccination or for whom COVID-19 vaccination is not recommended. Recipients should not be currently infected with or had recent known exposure to a person infected with the COVID-19 virus.

A single dose of the two medicines, tixagevimab and cilgavimab, should be given as two injections into a muscle by a healthcare professional.

In a clinical trial in adults, Evusheld was found to reduce the risk of developing symptomatic COVID-19 by 77%, with protection from the virus continuing for at least 6 months following a single dose.

There is not enough data to know how effective Evusheld is against Omicron or the duration of its effect against this variant, but the MHRA will work with the company to establish this.

POSSIBLE SoS STATEMENT

Dr June Raine, MHRA Chief Executive said:

"Today is an exciting day – after a careful review of the data, I am pleased to confirm that we have authorised another medicine to help protect against the effects of COVID-19.

"Evusheld is a "pre-exposure prophylaxis" treatment, meaning it is taken to prevent COVID-19 before infection. Just one dose has been found to provide long-lasting protection against this disease for up to 6 months.

“While the COVID-19 vaccines continue to be the first-line defence against COVID-19, we know that some people may not respond adequately to these vaccines and for a small number of individuals COVID-19 vaccines may not be recommended for other reasons, such as a previous allergic reaction to one of the vaccine ingredients.

“For these people, Evusheld could provide much needed protection against COVID-19..”

Professor Sir Munir Pirmohamed, Chair of the Commission on Human Medicines, said:

“The Commission on Human Medicines and its COVID-19 Therapeutics Expert Working Group has independently reviewed the data and endorses the MHRA’s regulatory approval of Evusheld.

“We have carefully reviewed data on the medicine’s safety, quality and effectiveness and are satisfied it meets the expected standards on all fronts.

“The recommended dosage is 300 mg of Evusheld but a higher dose of 600 mg may be more appropriate for some COVID-19 variants. All this is outlined in the Summary of Product Characteristics.”

Pre-exposure prophylaxis with Evusheld is not a substitute for vaccination in individuals for whom COVID-19 vaccination is recommended.

The government and the NHS will confirm how this treatment will be deployed to patients in due course.

Q&A - REACTIVE ONLY

Will repeat doses be required?
Evusheld has only been studied in single-dose studies.

As is common for newly authorised products, further data will become available through additional monitoring and post-authorisation studies that will add to our understanding of Evusheld in certain areas of interest, for example in regards to dosing.

Have any serious side effects been identified in the trials?
Serious hypersensitivity reactions, including anaphylaxis, have been observed with other monoclonal antibodies that are similar to Evusheld. Because of this, as a precautionary measure we are recommending a 1-hour observation period following administration of Evusheld.

A higher proportion of participants who received Evusheld reported heart-related side effects including heart attack and heart failure. All these individuals had risk factors for heart disease or a history of heart disease and there is no evidence to suggest that these events were related to administration of Evusheld.

As outlined in the Summary of Product Characteristics [link to], the risks and benefits in individuals at high risk of cardiovascular events should be considered by a healthcare professional prior to initiating Evusheld.

A small number of individuals who received Evusheld in the trials also reported blood clots but there is no evidence to suggest that these events were related to administration of Evusheld.

We will continue to keep the safety of Evusheld under close review.

If I receive Evusheld, does this mean I can never have a COVID-19 vaccination?
As outlined in the Summary of Product Characteristics [link to], data do not suggest an interaction between Evusheld and COVID-19 vaccination and therefore no specific interval is required between receipt of Evusheld and a COVID-19 vaccine.

Can I take Evusheld if pregnant or breastfeeding?
People should tell their doctor or nurse if they are pregnant, or if they might be pregnant. This is because there is not enough information to be sure that this medicine is safe for use in pregnancy. This medicine may be used during pregnancy where the expected benefit to the mother justifies the potential risk to the unborn child.

People should tell their doctor or nurse if they are breast-feeding. This is because it is not yet known whether this medicine passes into human breast milk - or what the effects might be on the baby or on milk production. Their doctor will help them decide whether to keep breast-feeding or to start treatment with this medicine.

What were the main side effects from the trials?
The most common side effects were injection site reactions (1.3%).

Does it contains any ingredients of animal origin?
Tixagevimab and cilgavimab are produced in Chinese hamster ovary (CHO) cells by recombinant DNA technology.

Can I have it if I've had COVID?
Evusheld is recommended for individuals who are not currently infected with or had recent known exposure to a person infected with the COVID-19 virus. If you have had COVID previously but it was not a recent infection, it will be for your healthcare professional to determine whether or not you are eligible to receive Evusheld, as per the official recommendations.

The data is based on a study conducted prior to Omicron SARS-CoV-2 variant. How do we therefore know this is effective in people with Omicron?
There is not enough data to know whether Evusheld is effective against Omicron.

For some COVID-19 variants, for example the Omicron variant, pre-clinical data (from the lab) has suggested that although it does blocks the virus completely, a higher concentration of Evusheld is needed compared to other variants: the SmPC allows some flexibility to use a higher dose to address this.

The company has committed to providing real-world data on effectiveness as soon as it is available.