EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Dr Med. Peter Liese
Member of the European Parliament
European Parliament
Rue Wiertz
ASP 15 E 218
B-1047 Brussels
Belgium

27 January 2023
EMA/41105/2023

European Medicines Agency

Dear Dr Liese,

Re: The current RS-Virus Epidemic

Thank you for your letter of 16 January and for your compliments about the efforts of EMA's staff during the COVID-19 pandemic. In your letter you are highlighting the current challenges caused by the RS-Virus, and I can confirm that EMA is in close contact with companies that are developing vaccines against RSV and that for some of these vaccines a Marketing Authorisation Application has already been submitted as further detailed below.

Firstly, I would like to inform you that, based on EMA's assessment, on 31 October 2022 the European Commission granted authorisation in the EU for the monoclonal antibody Beyfortus[1] (nirsevimab) for the prevention of Lower Respiratory Tract Disease in newborn babies and infants during their first RSV season (i.e., when there is a higher risk of RSV infection in the community). Beyfortus was supported through EMA's PRIME scheme and was evaluated under accelerated assessment. This product is very likely to be marketed in the EU as of spring this year and so it might be a new option available for infants during the next winter season.

With regard to the Pfizer vaccine that you specifically refer to, EMA has had held several meetings with the company to facilitate the submission of a marketing authorization application, and which was received by EMA in December 2022. EMA's Committee for Medicinal Products for Human Use (CHMP), recognising the significant impact of RSV on respiratory diseases and especially in the current season, decided this week to evaluate the Pfizer vaccine under an accelerated assessment procedure[2]. Unfortunately, at this point I cannot provide further information on when the vaccine may potentially be authorised, as the evaluation is still ongoing. What I can say is that, as for any other procedure, the overall timeline depends on the robustness of the application and the timeliness with which the applicants can satisfactorily reply to EMA's questions. But I can assure you that our experts are fully committed to finalise the review within the shortest possible timelines.

I would also like to inform you that EMA is currently in close contact with three other companies that are developing vaccines against the RSV. One of these vaccines is also being assessed by the Agency

[1] https://www.ema.europa.eu/en/medicines/human/EPAR/beyfortus
[2] https://www.ema.europa.eu/en/committees/chmp/chmp-agendas-minutes-highlights

under 'accelerated assessment'[3] at present, while two others are currently being supported by the Agency via the PRIME scheme[4] but are not yet at the stage of marketing authorisation application.

I thank you again for your interest in EMA's activities and in raising awareness in this important area. I remain available should you have any further questions.

With kind regards,

Emer Cooke

Executive Director

[3] Recombinant respiratory syncytial virus pre-fusion F protein, adjuvanted with AS01E - EMEA/H/C/006054, Draft CHMP Agenda 23-26 January 2023, https://www.ema.europa.eu/en/documents/agenda/agenda-chmp-meeting-23-26-january-2023_en.pdf

[4] MVA-BN-RSV by Bavarian Nordic (for elderly) and VAC18193 by Janssen (for adults aged 60 years or older) List of products granted PRIME eligibility https://www.ema.europa.eu/en/human-regulatory/research-development/prime-priority-medicines#list-of-products-granted-eligibility-section