19 February 2021
EMA/707383/2020 Corr.1*[1]
Committee for Medicinal Products for Human Use (CHMP)

Assessment report

Comirnaty

Common name: COVID-19 mRNA vaccine (nucleoside-modified)

Procedure No. EMEA/H/C/005735/0000

Note

Assessment report as adopted by the CHMP with all information of a commercially confidential nature deleted.

[1] * *Correction dated 19 February 2021 to clarify ERA statement*

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

Table 17 Number (%) of Subjects Reporting at Least 1 Adverse Event from Dose 1 to date cutoff date (14 Nov 2020) – Subjects with 2 months follow-up time after dose 2 for Phase 2/3 Analysis – Safety Population

	Vaccine Group (as Administered)		
Adverse Event	BNT162b2 (30 µg) (N[a]=9531) n[b] (%)	Placebo (N[a]=9536) n[b] (%)	Total (N[a]=19067) n[b] (%)
Any event	2044 (21.4)	1197 (12.6)	3241 (17.0)
Related[c]	1297 (13.6)	343 (3.6)	1640 (8.6)
Severe	105 (1.1)	69 (0.7)	174 (0.9)
Life-threatening	10 (0.1)	11 (0.1)	21 (0.1)
Any serious adverse event	57 (0.6)	53 (0.6)	110 (0.6)
Related[c]	2 (0.0)	0	2 (0.0)
Severe	32 (0.3)	33 (0.3)	65 (0.3)
Life-threatening	10 (0.1)	11 (0.1)	21 (0.1)
Any adverse event leading to withdrawal	1 (0.0)	0	1 (0.0)
Related[c]	0	0	0
Severe	0	0	0
Life-threatening	1 (0.0)	0	1 (0.0)
Death	1 (0.0)	0	1 (0.0)

a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event category. For "any event", n = the number of subjects reporting at least 1 occurrence of any event.
c. Assessed by the investigator as related to investigational product.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:48) Source Data: adae Table Generation: 17NOV2020 (16:28)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 IA P3 2MPD2/adae s091 all 2mpd2 p23 saf

Overall, in participants with 2 months follow up after dose 2, 21.4% / 12.6% (vaccine/placebo) and 13.6%/3.6% experienced at least 1 AE and 1 related AE, respectively. It is noted that the frequency of AEs and related AEs is lower compared to individuals with a median follow up of 2 months (27%/12.5% and 20.8%/5.1%).

The frequency of individuals experiencing AEs were slightly higher in the younger compared to older individuals (29.3% and 23.8% vaccine arm; 13.2% and 11.7% placebo arm). SAEs and deaths were however balanced in both study arms in both age groups.

The frequency of immediate AEs after dose 1 was low in participants with median 2 months of follow-up after Dose 2 (0.4%) and the whole population (≤0.5%), belonging mostly to the SOC general disorders and administration site conditions, primarily injection site reactions. No participant reported an immediate allergic reaction to vaccine.