

15580**COVID-19 vaccine in participants (ptcpts) with cancer: Subgroup analysis of efficacy/safety from a global phase III randomized trial of the BNT162b2 (tozinameran) mRNA vaccine**

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Background

Patients with cancer are at higher risk of developing COVID-19 disease, adverse outcomes, and increased mortality. Phase III COVID-19 vaccine trials have demonstrated safety/efficacy against COVID-19 and prevented hospitalizations and deaths; however, most excluded ptcpts with cancer. We present phase 3 tozinameran mRNA COVID-19 vaccine trial results from ptcpts with a cancer history at baseline, either ongoing or not, per the Charlson Comorbidity Index and up to 6 months of follow-up.

Methods

Between Jul 2020-Jan 2021, 46429 ptcpts ≥ 12 y at 152 sites in 6 countries were randomized in a placebo-controlled, observer-blinded trial of 2-dose tozinameran, showing 95% protection against COVID-19 and favorable safety (Polack et al *NEJM*, Dec 2020). After emergency use authorization, ptcpts were allowed to unblind and placebo recipients received vaccine. Data prior to unblinding for crossover up to 13 Mar 2021 are presented for ptcpts ≥ 16 y for safety and ≥ 12 y for efficacy. Adverse event (AE) data are controlled for follow-up time before unblinding and reported as incidence rate (IR) per 100-person-y of follow-up.

Results

Of ptcpts ≥ 16 y, 1647 had a prior diagnosis of cancer and were not on active immunosuppressive treatment (755 M; 892 F; median age 66 y [range 22-91]). Most common solid cancers included breast (n=458), prostate (n=360), and melanoma (n=210). AEs were reported at IRs of 94.0 (vaccine) and 49.3 (placebo) per 100-person-y; most common AEs were reactogenicity events (injection-site pain [IR: 40.2 vaccine; 4.2 placebo]; fatigue [IR: 21.4 vaccine; 7.6 placebo]; pyrexia [IR: 19.8 vaccine; 0.7 placebo]). 1 vaccine ptcpt withdrew due to a vaccine-related AE. No vaccine-related deaths were reported. Among ptcpts ≥ 12 y with cancer, 3 vaccine and 27 placebo recipients developed COVID-19 from 7 days post-Dose 2; vaccine efficacy (VE) was 89.7% (95% CI 66.5-98.0%). This compares favorably with overall VE of 91.1%. Updated results will be presented.

Conclusions

Tozinameran has similar efficacy/safety in ptcpts with cancer as in the overall population. These results inform tozinameran use in COVID-19 and in future trials in patients with cancer.

Clinical trial identification

NCT04368728.

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Legal entity responsible for the study

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Disclosure

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