주요 백신 임상 논문들

(Updated at 2020.1.29)

(**추가된 내용은 붉은 색으로 표시**)

1. Pfizer/BioNTech (BNT162b1 and BNT162b2, mRNA vaccine)

(1) **Phase 1/2**

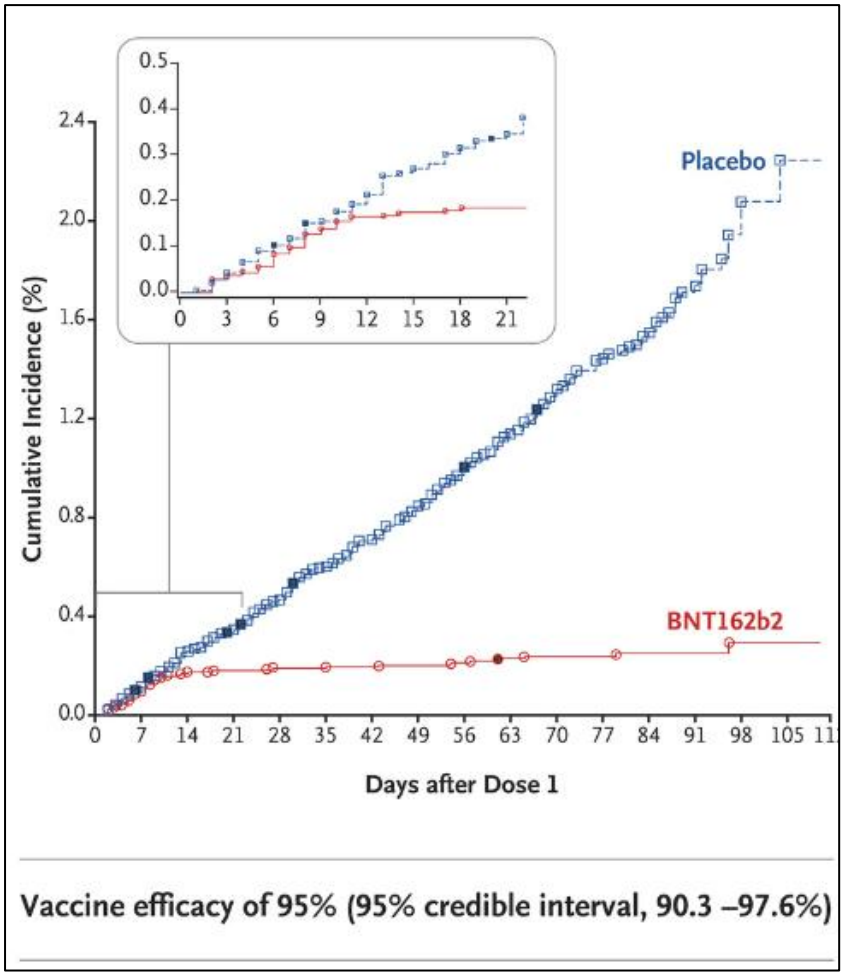
- NEJM 2020;383:2439-2450. **https://doi.org/10.1056/NEJMoa2027906**
- Nature 2020;586(7830):589-593 **https://doi.org/10.1038/s41586-020-2639-4**

(2) **BNT162b2** (Efficienty and safety in an ongoing multinational, placebo-controlled, observer-blinded, pivotal efficacy trial)

- NEJM. 2020;383:2603-2615 . **https://doi.org/10.1056/NEJMoa2034577**

(3) BNT162b2 Phase 3

- NEJM Published Online December 31, 2020. **https://doi.org/10.1056/NEJMoa2034577**
  - 43,548 명 대상, 1:1 ratio randomization, 16 세 이상
  - **COVID-19 illness 발생**
    - **Placebo group: 162 cases**
    - **vaccine group: 8 cases**
  - **BNT162b2 – 95% efficacy in preventing COVID-19**
  - **Subgroup analyses (age, sex, race, ethnity, baseliune BMI, coexising condition 동반)에서 vaccine efficacy 는 유사하였음.**



2. Moderna (mRNA-1273 vaccine)

(1) **Preclinical (Nonhuman Primates)**

- NEJM 2020;383:1544-1555. **https://doi.org/10.1056/NEJMoa2024671**

(2) **Phase 1**

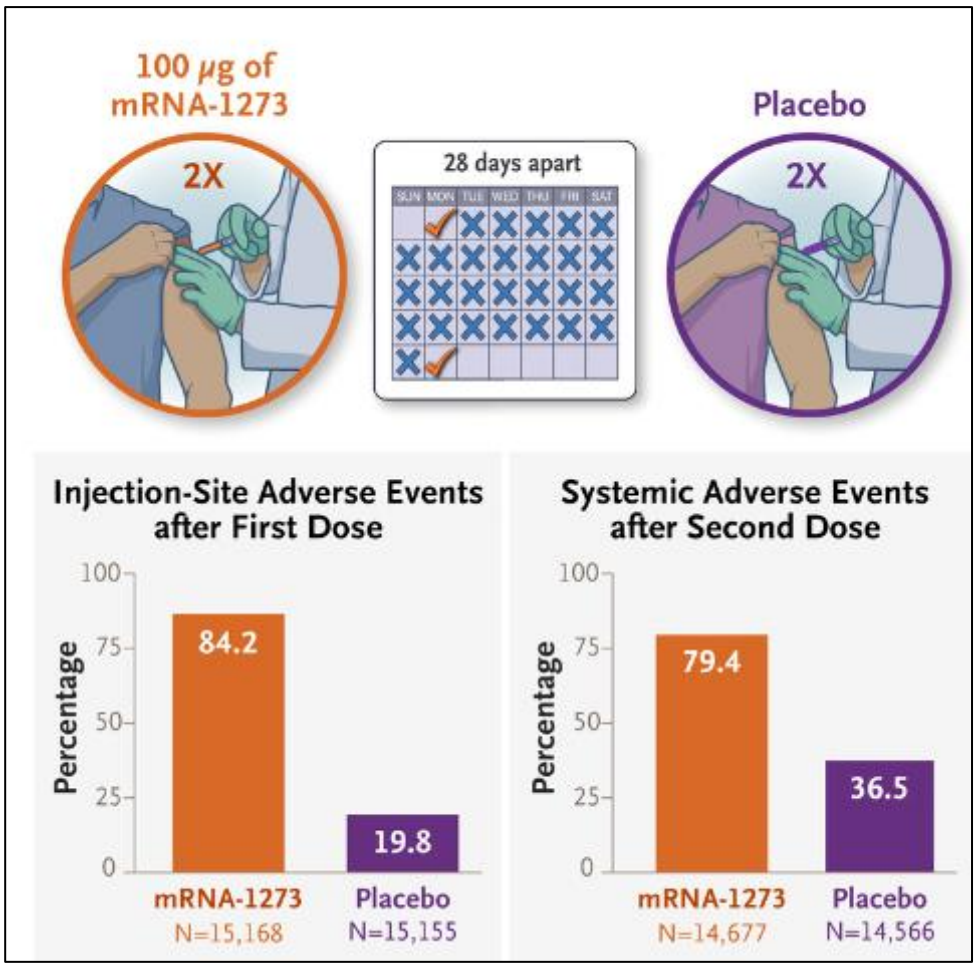
- NEJM 2020;383:1920-1931. **https://doi.org/10.1056/NEJMoa2022483**

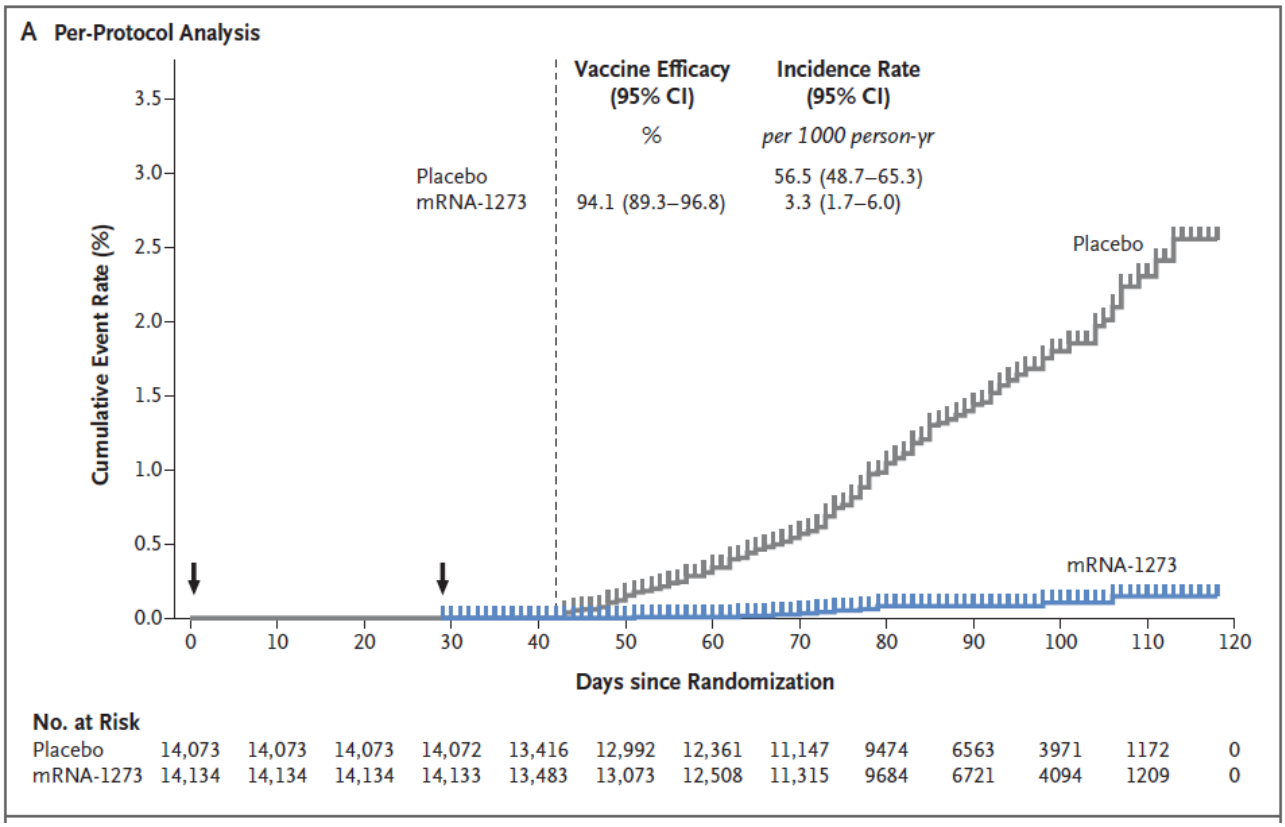
(3) **Older adults 대상 phase 1 -** 56 to 70 years or ≥71 years, 4 주 간격으로 25 μg or 100 μg 투여

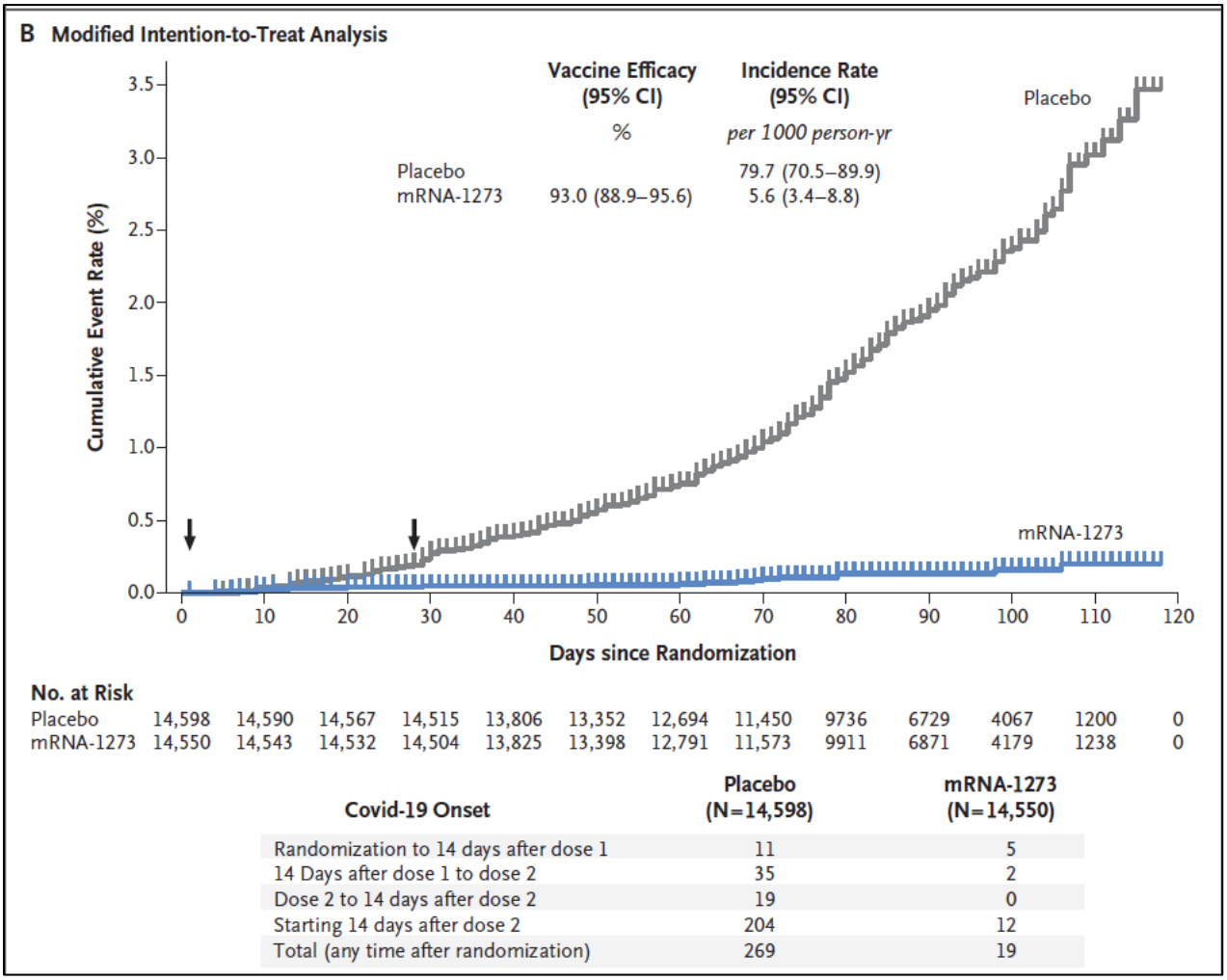
- NEJM 2020;383:2427-2438. **https://doi.org/10.1056/NEJMoa2028436**

(4) **Phase 3:** NEJM Published Online December 30, 2020. **https://doi.org/10.1056/NEJMoa2035389**

- 30,420 명 대상, 1:1 ratio randomization
- **Symptomatic COVID-19 illness 발생**
  - **Placebo group: 56.5 / 1000 person-years**
  - **vaccine group: 3.3 / 1000 person-years**
- Efficacy 는 seconary analyses (first dose 14 일 후 평가, **65 세 이상 인구 집단)에서 유사**하였음.
- Severe COVID-19 disease 는 총 30 명의 참가자에서 발생하였는데 모두 placebo group 이었음.
- **Serious adverse events: rare**







Covid-19 Onset	Placebo (N=14,598)	mRNA-1273 (N=14,550)
Randomization to 14 days after dose 1	11	5
14 Days after dose 1 to dose 2	35	2
Dose 2 to 14 days after dose 2	19	0
Starting 14 days after dose 2	204	12
Total (any time after randomization)	269	19

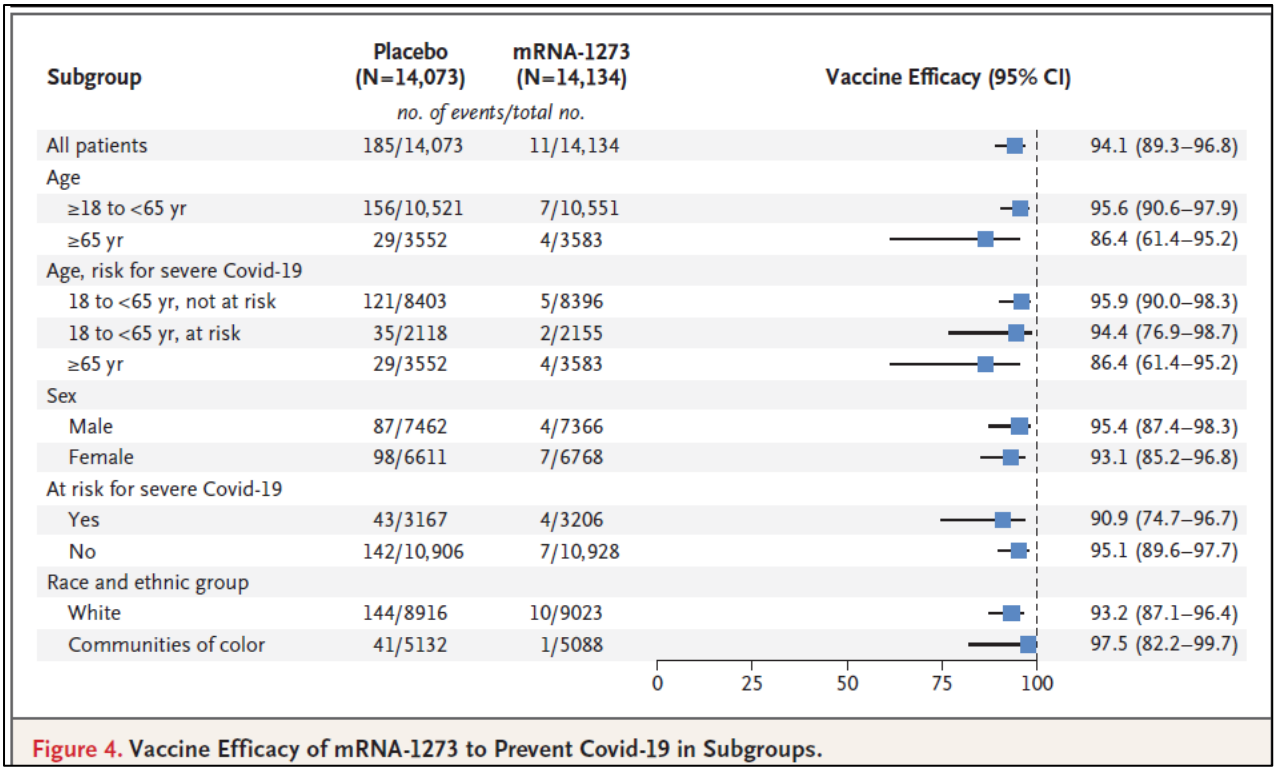


Figure 4. Vaccine Efficacy of mRNA-1273 to Prevent Covid-19 in Subgroups.

3. AstraZeneca (Chimpanzee adenovirus-vectored vaccine, ChAdOx1 nCoV-19)

(1) **Phase 1/2**

- Lancet 2020;396:467–478. https://doi.org/10.1016/S0140-6736(20)31604-4

(2) **Phase 2/3**

- Lancet. 2020;396:1979-1993 https://doi.org/10.1016/S0140-6736(20)32466-1

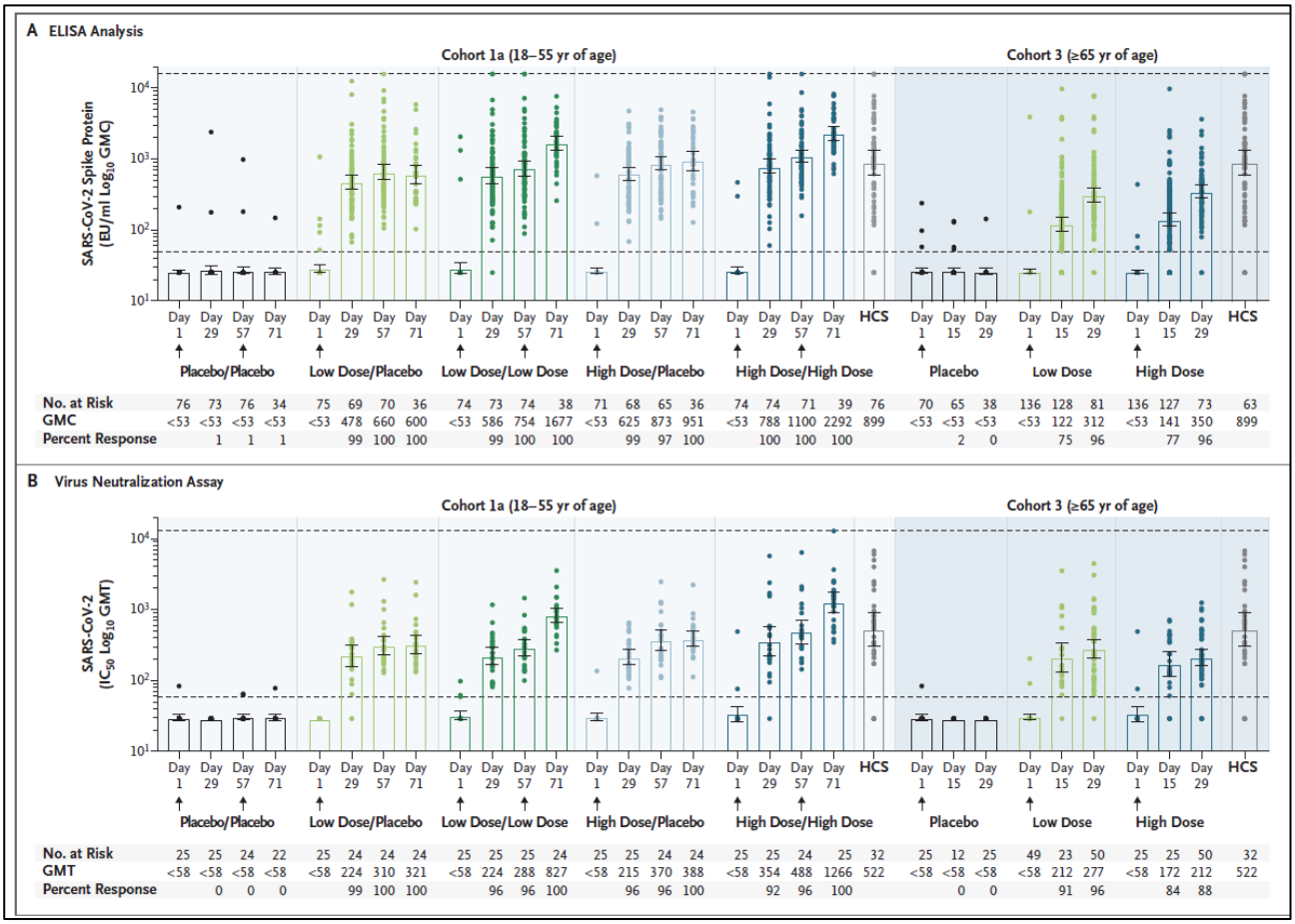
(3) **Interim analysis of ongoing blinded, randomised, controlled trials done across the UK, Brazil, and South Africa**

- Lancet. 2021;397:99-111. https://doi.org/10.1016/S0140-6736(20)32661-1

4. Ad26.COV2.S (Johnson & Johnson)

(1) **Phase 1-2a**: NEJM Published Online January 13, 2021. https://doi.org/10.1056/NEJMoa2034201

- Cohort 1 (ages 18-55 yr, n=402), Cohort 3 (ages ≥ 65 yr, n=403)
- Cohort 1 과 3 모두 low-dose (5×10^{10} viral particles) or high-dose (1×10^{11} viral particles) vacccine or placebo group 으로 randomization (single dose or two-dose schedule)
- 결과:
  a. 모든 participants 대상 분석에서 first vaccine dose 투여 29 일째의 중화항체 생성률은 90% 이상 (vaccine group, age group 에 따라 상이하지 않았음).
  b. Geometric mean titier 는 최소 71 일까지 안정적으로 유지되었음.
  c. Second-dose 투여 후 GMT 가 2.6-2.9 배 증가됨.
  d. 14 일째 CD4+ T-cell response 는 76-83% (cohort 1)과 60-67% (cohort 3)
  e. CD8+ T-cell reponse 도 전체적으로 충분히 관찰되었지만 cohort 3 (old age group)에서 낮았음.



5. Novavax (NVX-CoV2373: rSARS-CoV-2 spike protein nanoparticle vaccine)

(1) **Phase 1/2**

- NEJM 2020;383:2320-2332. https://doi.org/10.1056/NEJMoa2026920

6. Sinovac Life Sciences (CoronaVac, rAd5 vectored vaccine)

(1) **Phase 1**

- Lancet 2020;395:1845–54. https://doi.org/10.1016/S0140-6736(20)31208-3

(2) **Phase 2**

- Lancet 2020;396:479–88. https://doi.org/10.1016/S0140-6736(20)31605-6

(3) **Phase 1/2**

- Lancet Infect Dis 2021;21(2):181-192. https://doi.org/10.1016/S1473-3099(20)30843-4

7. BBIBP-CorV (National Program on Key Research Project of China)

(1) Development of an Inactivated Vaccine Candidate, BBIBP-CorV, with Potent Protectio against SARS-CoV-2

- Cell 2020:182,713–721. https://doi.org/10.1016/j.cell.2020.06.008

(2) **Phase 1/2**

- Lancet Infect Dis 2021;21(1):39-51. https://doi.org/10.1016/S1473-3099(20)30831-8

8. **Ministry of Health of the Russian Federation (rAd26- and rAd5-spike glycoprotein vaccine)**

(1) **Phase 1/2**

- Lancet 2020;396: 887–97. September 4, 2020. **https://doi.org/10.1016/S0140-6736(20)31866-3**