Company Liaison Template

Last updated by s 22 **on 11 September 2020**

Company and Contact Details

Company Name	Pfizer Inc /BioNTech SE
Nationality	USA / German
Location/s	Multiple
Contact/s	s 47F
Contact Made	☒ Company reached out ☐ Australia reached out

s 47C. 47E(d)

See also – s 47C, 47E(d)

Product Information

Company Capacity	☒ Vaccine development ☐ Inactivated or attenuated virus ☐ Viral vector ☐ Protein ☐ DNA ☒ RNA – nucleic acid – four candidates being investigated ☐ with Adjuvant (details) ☒ Commercial scale manufacture ☐ Inactivated or attenuated virus ☐ Viral vector ☐ Protein ☐ DNA ☒ RNA – nucleic acid ☐ Adjuvant ☐ Fill and finish ☐ Inactivated or attenuated virus ☐ Viral vector ☐ Protein ☐ DNA ☐ RNA – nucleic acid ☐ Other (details)

Related Entities	BioNTech- clinical development and commercialisation collaboration with Fosun Pharma in China

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Development and Manufacturing Expectations

Development Timeline (estimates)	BNT162b2 selected from four mRNA vaccine candidates in preclinical work, phase 1/2a clinical trials On 9 September, Pfizer and BioNTech announced preclinical data in mouse and nonhuman primate models from the BNT162b2 candidate (not yet peer reviewed or published). • BNT162b2 immunisation prevented lung and nasal infection in 100% rhesus macaques after challenge with SARS-CoV-2, with no viral RNA detected in the lower respiratory tract of immunised and challenged animals. • Neutralising antibody responses and strong, antigen-specific CD4+ and CD8+ T cell responses were induced in nonhuman primates and mice. ***Phase 1/2a clinical trials* commenced 05/05/20** **12 August** – interim results for BNT162b1 published in Nature Neutralising antibody titres reached greater than those observed in COVID-19 convalescent human sera. The safety profile was overall favourable and no serious adverse events were reported. **20 August** - Preliminary results comparing BNT162b1 and BNT162b2 available online (preprint) (see https://www.medrxiv.org/content/10.1101/2020.08.17.20176651v1) In both younger and older adults, the 2 vaccine candidates elicited similar dose-dependent SARS−CoV−2−neutralizing geometric mean titers (GMTs), comparable to or higher than the GMT of a panel of SARS−CoV−2 convalescent sera. BNT162b2 was associated with less systemic reactogenicity, particularly in older adults. These results support selection of the BNT162b2 vaccine candidate for Phase 2/3 large−scale safety and efficacy evaluation, currently underway. ***Phase 2/3 clinical trial* commenced 27/07/20**

	modRNA candidate BNT162b2 was chosen following safety and immunogenicity evaluation of four BNT162 RNA vaccine candidates. A two-dose regimen will be tested in up to 30,000 participants across an expected 120 study sites globally (except China), commencing in the USA. 11,000 of 30,000 participants in USA enrolled at 21 August. Pfizer announced on 3 September that preliminary results of the Phase 3 trial were expected as early as October 2020. As at 3 September, 23,000 participants were enrolled in the Phase 3 trial.
Manufacturing facilities	23 fill and finish facilities globally • St Louis, MO (USA), Kalamazoo, MI (USA), Andover, MA (USA), Puurs (Belgium)– Pfizer • Mainz Region (Germany), Idar Oberstein (Germany) – BioNTech
Manufacturing capacity and timelines	13/7/20 The companies currently expect to manufacture up to s 47C doses by the end of 2020 and 1.3 billion doses by the end of 2021.
Any additional requirements for scale up	

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Relationships and Partnerships

Recipient of Australian funding	☒ No ☐ Yes details - eg MRFF, Industry grants, public university
Contractual arrangements with Australian Government	☐ No ☒ Yes – for other medications/vaccines, details TBC
Other Australian link	☐ No ☒ Yes – non RNA manufacturing facilities in Mulgrave, Victoria, Perth and Adelaide

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<tr>
<td>Other partnerships</td>
<td>☐ No
☒ Yes – USA ‘Warp speed’ project
BioNTech- clinical development and commercialisation collaboration with Fosun Pharma in China

<table>
<tr><th>Date announced</th><th>Country</th><th>Doses/value</th></tr>
<tr><td>5 August 2020</td><td>Canada</td><td>Not announced</td></tr>
<tr><td>31 July 2020</td><td>Japan</td><td>120 million doses</td></tr>
<tr><td>22 July 2020</td><td>USA</td><td>100 million doses USD$1.95 billion</td></tr>
<tr><td>20 July 2020</td><td>UK</td><td>30 million doses</td></tr>
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Media and public commentary

Date	Article name, source, core points and hyperlink
5/08/20	Canada signs deals with Pfizer, Moderna for experimental COVID-19 vaccines https://www.reuters.com/article/us-health-coronavirus-canada/canada-signs-deals-with-pfizer-moderna-for-experimental-covid-19-vaccines-idUSKCN2511RH
31/07/20	Pfizer and BioNTech to supply Japan with 120 million doses of their BNT162 mRNA-based vaccine candidate https://www.businesswire.com/news/home/20200731005116/en/Pfizer-BioNTech-Supply-Japan-120-Million-Doses
27/07/20	Pfizer and BioNTech commence Phase 2/3 trial for BNT162b2 https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-choose-lead-mrna-vaccine-candidate-0
23/07/20	US agrees to pay Pfizer $2bn for Covid-19 vaccine doses by end of year - 100m doses by Dec 2020, up to another 500m later https://www.theguardian.com/us-news/2020/jul/22/pfizer-coronavirus-covid-vaccine-us-deal
21/07/20	UK secures 90 million doses of potential coronavirus vaccine https://www.abc.net.au/news/2020-07-20/uk-government-secures-90-million-coronavirus-vaccine-doses/12474814
13/07/20	**Pfizer and BioNTech Granted FDA Fast Track Designation for Two Investigational mRNA-based Vaccine Candidates Against SARS-CoV-2** • BNT162b1 and BNT162b2 currently being evaluated in ongoing Phase 1/2 clinical studies in the United States and Germany • 'Fast Track' is a process designed to facilitate the development, and expedite the review, of new drugs and vaccines intended to treat or prevent serious conditions that have the potential to address an unmet medical need. • designation was granted based on preliminary data from Phase 1/2 studies https://www.pfizer.com/science/coronavirus/vaccine
1/07/20	**BioNTech shows positive results** • Pfizer/BioNTech are testing four different versions of the vaccine • BNT162b1 vaccine sparked immune response in adults 18 – 55 • 10, 30 & 100 microgram doses trialled • Caused fever and other side effects, especially at higher doses • Two doses required for immunity • Phase 1/2 Clinical data released on MedRXiv - not peer reviewed https://www.medrxiv.org/content/10.1101/2020.06.30.20142570v1.full.pdf https://www.statnews.com/2020/07/01/covid-19-vaccine-from-pfizer-and-biontech-shows-positive-results/

Meetings

Date	Attendees, notes from discussion
11/9/20	s 47, 47C, 47E(d)
13/8/20	s 47C, 47E(d)
11/8/20	**Pfizer** s47F s47F – Legal Lead, Developed Markets s47F – Head, Regulatory Affairs, ANZ + Korea s47F – Vaccines Lead, ANZ + Korea **DoH** Lisa Schofield, Nick Henderson, s 22 Preliminary discussion of Draft Head of Terms. Under New York law for global consistency. Indemnity discussions, risk sharing to be reviewed by Legals. Pfizer seeking engagement with TGA, hoping for pre-submission meeting mid-September.
4/8/20	**Pfizer/BioNTech** s47 F – Director, Pfizer ANZ s47 F – Global Viral Vaccine s47 F – Director, Technical Projects (Manufacture and Supply) s47 F – Global Vaccine Market Access **Minister Hunt's Office** s 22 **DoH** Lisa Schofield, Professor John Skerritt, Dr Jane Cook, s 22 Pfizer provided an overview of the track record of Pfizer/BioNTech Established scientific discovery, clinical development, reg approval, manufacturing, supply chain, etc. <u>Science –</u> s 47F

Explanation of mRNA vaccines and advantages:

- adjuvant not needed
- less biosafety required
- lower production time

Seeking regulatory approval Q4 2020, as early as October

Phase 1/2 data ready for publication soon:

- 2 doses 3 weeks apart, 30 micrograms
- No SAEs, high level neutralising antibody titres, greater than those in sera from COVID-19-recovered patients aged 65-85 years

Phase 2/3 underway – 1:1 randomisation vaccine:placebo

- Primary endpoints = prevention of COVID-19 in those not previously infected; prevention in those previously infected
- Secondary endpoints = prevention of severe COVID-19
- Adults aged 18-85 years
- Sites – US, Argentina, Brazil, Germany

Manufacturing and supply chain – s 47F

23 fill and finish facilities globally

- St Louis, MO (USA), Kalamazoo, MI (USA), Andover, MA (USA), Puurs (Belgium)– Pfizer
- Mainz Region (Germany), Idar Oberstein (Germany) – BioNTech

US, EU supply chains planned
Shipping from Pfizer to dosing centres
975 vials per shipper (cold container)
-70 degrees C, stable for 10 days. Stability studies underway, development underway for stable lyophilised formulation
No plans at present for manufacturing in Australia

Principles of procurement proposal – s 47F

Value-based pricing

Upfront payment – nominal price of s s 47 (x doses over 2021)

- s 47

Full payment = s 47 (i.e. s 47 additional to upfront payment)

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10/7/20	Lisa Schofield s 22 s 47F
	Need to progress confidentiality agreements – s 22 working with Legal Provided overview of Pfizer/BioNTec work. Pfizer has strong history in vaccine development and production. 3 mRNA vaccine platforms 4 mRNA vaccine candidates Limited production by end 2020, higher in 2021. Early allocation to priority populations (health care workers etc). Clinical trials – see notes above (media) Pfizer wanted to know - Timeline for doses - ATAGI 'approval' processes Treatments: Two antiviral types/schools under development