

# 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    | <b>s 47F</b>  |
| Contact Made | <input checked="" type="checkbox"/> Company reached out<br><input type="checkbox"/> Australia reached out |

**s 47C, 47E(d)**

See also – **s 47C, 47E(d)**

## Product Information

|                  |   |
|------------------|---|
| Company Capacity | <input checked="" type="checkbox"/> Vaccine development <ul style="list-style-type: none"> <li><input type="checkbox"/> Inactivated or attenuated virus</li> <li><input type="checkbox"/> Viral vector</li> <li><input type="checkbox"/> Protein</li> <li><input checked="" type="checkbox"/> DNA <input checked="" type="checkbox"/> RNA – nucleic acid – four candidates being investigated</li> <li><input type="checkbox"/> with Adjuvant (details)</li> </ul> <input checked="" type="checkbox"/> Commercial scale manufacture <ul style="list-style-type: none"> <li><input type="checkbox"/> Inactivated or attenuated virus</li> <li><input type="checkbox"/> Viral vector</li> <li><input type="checkbox"/> Protein</li> <li><input type="checkbox"/> DNA <input checked="" type="checkbox"/> RNA – nucleic acid</li> <li><input type="checkbox"/> Adjuvant</li> </ul> <input type="checkbox"/> Fill and finish <ul style="list-style-type: none"> <li><input type="checkbox"/> Inactivated or attenuated virus</li> <li><input type="checkbox"/> Viral vector</li> <li><input type="checkbox"/> Protein</li> <li><input type="checkbox"/> DNA <input type="checkbox"/> RNA – nucleic acid</li> </ul> <input type="checkbox"/> Other (details) |
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s47C, 47E(d)

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| Related Entities | BioNTech- clinical development and commercialisation collaboration with Fosun Pharma in China |
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## Development and Manufacturing Expectations

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| Development Timeline (estimates) | <p>BNT162b2 selected from four mRNA vaccine candidates in preclinical work, phase 1/2a clinical trials</p> <p>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Pfizer and BioNTech announced preclinical data in mouse and nonhuman primate models from the BNT162b2 candidate (not yet peer reviewed or published).</p> <ul style="list-style-type: none"><li>• 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.</li><li>• Neutralising antibody responses and strong, antigen-specific CD4+ and CD8+ T cell responses were induced in nonhuman primates and mice.</li></ul> <p><b>Phase 1/2a clinical trials commenced 05/05/20</b></p> <p><b>12 August</b> – interim results for BNT162b1 published in Nature</p> <p>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.</p> <p><b>20 August</b> - Preliminary results comparing BNT162b1 and BNT162b2 available online (preprint) (see <a href="https://www.medrxiv.org/content/10.1101/2020.08.17.20176651v1">https://www.medrxiv.org/content/10.1101/2020.08.17.20176651v1</a>)</p> <p>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.</p> <p><b>Phase 2/3 clinical trial commenced 27/07/20</b></p> |
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|  | <p>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.</p> <p>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.</p> |
| Manufacturing facilities                 | <p>23 fill and finish facilities globally</p> <ul style="list-style-type: none"> <li>St Louis, MO (USA), Kalamazoo, MI (USA), Andover, MA (USA), Puurs (Belgium)– Pfizer</li> <li>Mainz Region (Germany), Idar Oberstein (Germany) – BioNTech</li> </ul>  |
| Manufacturing capacity and timelines     | 13/7/20 The companies currently expect to manufacture up to <b>s 47C</b> doses by the end of 2020 and 1.3 billion doses by the end of 2021.   |
| Any additional requirements for scale up |   |

s47, s47C, 47E(d)

### Relationships and Partnerships

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|---|---|
| Recipient of Australian funding                     | <input checked="" type="checkbox"/> No<br><input type="checkbox"/> Yes details - eg MRFF, Industry grants, public university                        |
| Contractual arrangements with Australian Government | <input type="checkbox"/> No<br><input checked="" type="checkbox"/> Yes – for other medications/vaccines, details TBC                                |
| Other Australian link                               | <input type="checkbox"/> No<br><input checked="" type="checkbox"/> Yes – non RNA manufacturing facilities in Mulgrave, Victoria, Perth and Adelaide |

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|--------------------|--|----------------|--|
| Other partnerships | <input type="checkbox"/> No<br><input checked="" type="checkbox"/> Yes – USA ‘Warp speed’ project<br>BioNTech- clinical development and commercialisation collaboration with Fosun Pharma in China |                |  |
|                    | <b>Date announced</b>  | <b>Country</b> | <b>Doses/value</b>                     |
|                    | 5 August 2020  | Canada         | Not announced                          |
|                    | 31 July 2020   | Japan          | 120 million doses                      |
|                    | 22 July 2020   | USA            | 100 million doses    USD\$1.95 billion |
|                    | 20 July 2020   | UK             | 30 million doses                       |
|                    |  |                |  |

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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<br><a href="https://www.reuters.com/article/us-health-coronavirus-canada/canada-signs-deals-with-pfizer-moderna-for-experimental-covid-19-vaccines-idUSKCN2511RH">https://www.reuters.com/article/us-health-coronavirus-canada/canada-signs-deals-with-pfizer-moderna-for-experimental-covid-19-vaccines-idUSKCN2511RH</a>  |
| 31/07/20 | Pfizer and BioNTech to supply Japan with 120 million doses of their BNT162 mRNA-based vaccine candidate<br><a href="https://www.businesswire.com/news/home/20200731005116/en/Pfizer-BioNTech-Supply-Japan-120-Million-Doses">https://www.businesswire.com/news/home/20200731005116/en/Pfizer-BioNTech-Supply-Japan-120-Million-Doses</a>   |
| 27/07/20 | Pfizer and BioNTech commence Phase 2/3 trial for BNT162b2<br><a href="https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-choose-lead-mrna-vaccine-candidate-0">https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-choose-lead-mrna-vaccine-candidate-0</a>   |
| 23/07/20 | US agrees to pay Pfizer \$2bn for Covid-19 vaccine doses by end of year<br>- 100m doses by Dec 2020, up to another 500m later<br><a href="https://www.theguardian.com/us-news/2020/jul/22/pfizer-coronavirus-covid-vaccine-us-deal">https://www.theguardian.com/us-news/2020/jul/22/pfizer-coronavirus-covid-vaccine-us-deal</a>   |
| 21/07/20 | UK secures 90 million doses of potential coronavirus vaccine<br><a href="https://www.abc.net.au/news/2020-07-20/uk-government-secures-90-million-coronavirus-vaccine-doses/12474814">https://www.abc.net.au/news/2020-07-20/uk-government-secures-90-million-coronavirus-vaccine-doses/12474814</a>  |
| 13/07/20 | <b>Pfizer and BioNTech Granted FDA Fast Track Designation for Two Investigational mRNA-based Vaccine Candidates Against SARS-CoV-2</b> <ul style="list-style-type: none"> <li>• BNT162b1 and BNT162b2 currently being evaluated in ongoing Phase 1/2 clinical studies in the United States and Germany</li> <li>• '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.</li> <li>• designation was granted based on preliminary data from Phase 1/2 studies</li> </ul> <a href="https://www.pfizer.com/science/coronavirus/vaccine">https://www.pfizer.com/science/coronavirus/vaccine</a>  |
| 1/07/20  | <b>BioNTech shows positive results</b> <ul style="list-style-type: none"> <li>• Pfizer/BioNTech are testing four different versions of the vaccine</li> <li>• BNT162b1 vaccine sparked immune response in adults 18 – 55</li> <li>• 10, 30 &amp; 100 microgram doses trialled</li> <li>• Caused fever and other side effects, especially at higher doses</li> <li>• Two doses required for immunity</li> <li>• Phase 1/2 Clinical data released on MedRxiv - not peer reviewed</li> </ul> <a href="https://www.medrxiv.org/content/10.1101/2020.06.30.20142570v1.full.pdf">https://www.medrxiv.org/content/10.1101/2020.06.30.20142570v1.full.pdf</a><br><br><a href="https://www.statnews.com/2020/07/01/covid-19-vaccine-from-pfizer-and-biontech-shows-positive-results/">https://www.statnews.com/2020/07/01/covid-19-vaccine-from-pfizer-and-biontech-shows-positive-results/</a> |

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## Meetings

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

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|  | <p>Explanation of mRNA vaccines and advantages:</p> <ul style="list-style-type: none"> <li>• adjuvant not needed</li> <li>• less biosafety required</li> <li>• lower production time</li> </ul> <p>Seeking regulatory approval Q4 2020, as early as October</p> <p>Phase 1/2 data ready for publication soon:</p> <ul style="list-style-type: none"> <li>• 2 doses 3 weeks apart, 30 micrograms</li> <li>• No SAEs, high level neutralising antibody titres, greater than those in sera from COVID-19-recovered patients aged 65-85 years</li> </ul> <p>Phase 2/3 underway – 1:1 randomisation vaccine:placebo</p> <ul style="list-style-type: none"> <li>• Primary endpoints = prevention of COVID-19 in those not previously infected; prevention in those previously infected</li> <li>• Secondary endpoints = prevention of severe COVID-19</li> <li>• Adults aged 18-85 years</li> <li>• Sites – US, Argentina, Brazil, Germany</li> </ul> <p><u>Manufacturing and supply chain – s 47F</u></p> <p>23 fill and finish facilities globally</p> <ul style="list-style-type: none"> <li>• St Louis, MO (USA), Kalamazoo, MI (USA), Andover, MA (USA), Puurs (Belgium)– Pfizer</li> <li>• Mainz Region (Germany), Idar Oberstein (Germany) – BioNTech</li> </ul> <p>US, EU supply chains planned</p> <p>Shipping from Pfizer to dosing centres</p> <p>975 vials per shipper (cold container)</p> <p>-70 degrees C, stable for 10 days. Stability studies underway, development underway for stable lyophilised formulation</p> <p>No plans at present for manufacturing in Australia</p> <p><u>Principles of procurement proposal – s 47F</u></p> <p>Value-based pricing</p> <p>Upfront payment – nominal price of s 47 (x doses over 2021)</p> <ul style="list-style-type: none"> <li>• s 47</li> </ul> <p>Full payment = s 47 (i.e. s 47 additional to upfront payment)</p> <p>s 47</p> <p>s 47, 47C, 47E(d)</p> |
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| 10/7/20<br>s 47F | <div data-bbox="339 192 520 255"> Lisa Schofield<br/> s 22 </div> <p data-bbox="339 584 1257 618">Need to progress confidentiality agreements – s 22 working with Legal</p> <p data-bbox="339 663 1362 734">Provided overview of Pfizer/BioNTec work. Pfizer has strong history in vaccine development and production.</p> <p data-bbox="339 779 689 813">3 mRNA vaccine platforms</p> <p data-bbox="339 817 711 851">4 mRNA vaccine candidates</p> <p data-bbox="339 855 970 889">Limited production by end 2020, higher in 2021.</p> <p data-bbox="339 893 1185 927">Early allocation to priority populations (health care workers etc).</p> <p data-bbox="339 972 858 1005">Clinical trials – see notes above (media)</p> <p data-bbox="339 1050 638 1084">Pfizer wanted to know</p> <ul data-bbox="389 1088 794 1164" style="list-style-type: none"> <li>- Timeline for doses</li> <li>- ATAGI 'approval' processes</li> </ul> <p data-bbox="339 1209 504 1243">Treatments:</p> <p data-bbox="339 1247 967 1281">Two antiviral types/schools under development</p> |
|                  |  |