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File Title:	PAUL TIBOR HORSKY AND OIL SURVEILLANCE AUSTRALIA PTY LTD ATF D.A LYNCH SUPERFUND v MESOBLAST LIMITED ACN 109 431 870
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Important Information

This Notice has been inserted as the first page of the document which has been accepted for electronic filing. It is now taken to be part of that document for the purposes of the proceeding in the Court and contains important information for all parties to that proceeding. It must be included in the document served on each of those parties.

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Form 33

Rule 16.32

AMENDED DEFENCE

No. VID 268 of 2022

FEDERAL COURT OF AUSTRALIA

DISTRICT REGISTRY: VICTORIA

DIVISION: GENERAL

PAUL TIBOR HORSKY

First Applicant

OIL SURVEILLANCE AUSTRALIA PTY LTD (ACN 092 979 498) ATF D. A. LYNCH SUPERFUND

Second Applicant

MESOBLAST LTD (ACN 109 431 870)

Respondent

In answer to the Amended Consolidated Statement of Claim (~~CSOC~~ACSOC) dated 20 ~~October 2022~~December 2023, the Respondent (**Mesoblast**) says as follows.

NOTE: Mesoblast uses the headings and defined terms in the ~~CSOC~~ ACSOC for convenience only and does not admit any allegations contained in, or implied by, such headings or defined terms.

Filed on behalf of (name & role of party)	Mesoblast Limited (ACN 109 431 870), the Respondent
Prepared by (name of person/lawyer)	David Taylor
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A. PARTIES

A.1. The Applicants and Group Members

1. Mesoblast admits paragraph 1.

2. In answer to paragraph 2, Mesoblast:

   (a) denies that the Applicants and Group Members have suffered loss and damage by or resulting from the alleged contravening conduct of Mesoblast described in the ~~CSOC~~ACSOC;

   (b) says further that any person who:

      (i) purchased or otherwise acquired Mesoblast publicly traded American Depository Shares (**ADSs**) between 13 December 2018 and 2 October 2020 (inclusive);

      (ii) held such ADSs on 11 August 2020 and/or 2 October 2020;

      (iii) claims to have been damaged thereby; and

      (iv) did not submit a request for exclusion that was accepted by the United States District Court for the Southern District of New York;

   is barred from bringing a claim against Mesoblast in respect of such ADSs by the Stipulation and Agreement of Settlement dated 28 March 2022 (the **Stipulation**); and

   Particulars

   The United States District Court for the Southern District of New York approved the settlement set forth in the Stipulation by a judgment dated 15 August 2022 (**Judgment**). As to paragraph 2(b)(iv) above, the two persons who submitted a request for exclusion that was accepted by the Court are listed in Exhibit 1 to the Judgment.

   (c) otherwise admits the paragraph.

3. Mesoblast admits paragraph 3.

4. Mesoblast admits paragraph 4.

A.2 The Respondent

5. In answer to paragraph 5, Mesoblast:

(a) denies that any of the following statutes has or had during the Claim Period any application to Mesoblast:

(i) the *Fair Trading (Australian Consumer Law) Act 1992* (ACT);

(ii) the *Fair Trading Act 1987* (NSW);

(iii) the *Fair Trading Act 1989* (Qld);

(iv) the *Australian Consumer Law (Tasmania) Act 2010* (Tas);

(v) the *Fair Trading Act 2010* (WA);

(vi) the *Fair Trading Act 1987* (SA); and

(vii) the *Consumer Affairs and Fair Trading Act* (NT);

Particulars

Each of the above statutes only applied to certain persons and Mesoblast is not, and was not during the Claim Period, one of those persons. Mesoblast refers to: section 11 of the *Fair Trading (Australian Consumer Law) Act 1992* (ACT); section 32 of the *Fair Trading Act 1987* (NSW); section 20 of the *Fair Trading Act 1989* (Qld); section 10 of the *Australian Consumer Law (Tasmania) Act 2010* (Tas); section 24 of the *Fair Trading Act 2010* (WA); section 18 of the *Fair Trading Act 1987* (SA); and section 31 of the *Consumer Affairs and Fair Trading* Act (NT).

(b) says further that section 18 of Schedule 2 to the *Competition and Consumer Act 2010* (Cth) (**CCA**) is and was during the Claim Period inapplicable to the supply, or possible supply, of Mesoblast Securities, by reason of section 131A(1) of the CCA and that, in the premises, section 18 of Schedule 2 to the CCA has no application to this proceeding;

(c) denies that the text of Schedule 2 to the CCA is and was at all material times during the Claim Period applied as a law of Victoria pursuant to section 12 of the *Australian Consumer Law and Fair Trading Act 2012* (Vic);

Particulars

Section 12 limits the persons to whom the Australian Consumer Law (Victoria) applies (and had that operation during the Claim Period). It does not (and did not during the Claim Period) apply Schedule 2 of the CCA as a law of Victoria (as to which, Mesoblast refers to paragraph 5(e) below).

(d) says further that, instead, the text of Schedule 2 to the CCA is and was during the Claim Period applied as a law of Victoria by section 8 of the *Australian Consumer Law and Fair Trading Act 2012* (Vic) and, as so applied, is and was during the Claim Period known (together with the text of certain regulations made under the CCA) as the Australian Consumer Law (Victoria);

Particulars

Mesoblast also refers to section 7 of the *Australian Consumer Law and Fair Trading Act 2012* (Vic).

(e) says further that section 236 of the Australian Consumer Law (Victoria) cannot operate of its own force in federal jurisdiction and can only operate in federal jurisdiction if picked up and applied by section 79(1) of the *Judiciary Act 1903* (Cth);

(f) says further that section 236 of the Australian Consumer Law (Victoria) is not picked up and applied by section 79(1) of the *Judiciary Act 1903* (Cth) because section 131A of the CCA, being a law of the Commonwealth, "otherwise provide[s]";

(g) says further that, in the premises, section 236 of the Australian Consumer Law (Victoria) has no application to this proceeding; and

(h) otherwise admits the paragraph.

6. In answer to paragraph 6, Mesoblast:

(a) denies that at all material times during the Claim Period MSB Shares were "financial products" within the meaning of section 763A of the Corporations Act; and

Particulars

During the Claim Period, MSB Shares were not caught by the general definition of "financial products" in section 763A of the

Corporations Act. Rather, they were deemed to be "financial products" for the purposes of that Act by reason of section 764A(1)(a) of the Corporations Act.

(b) otherwise admits the paragraph.

7. In answer to paragraph 7, Mesoblast:

(a) says that, at all times during the Claim Period, one of the necessary elements of a contravention of section 674(2) of the Corporations Act, prescribed by section 674(2)(b), was that the entity "had" the relevant information;

(b) says further that, consequently, Mesoblast could not during the Claim Period contravene section 674(2) of the Corporations Act unless and until it "had" the relevant information;

(c) says further that, during the Claim Period, the ASX Listing Rules did not determine whether an entity "had" information within the meaning of section 674(2)(b) of the Corporations Act;

(d) as to subparagraph (c)(iii), repeats paragraph 5(a)-(g) above; and

(e) otherwise admits the paragraph.

8. In answer to paragraph 8, Mesoblast:

(a) admits subparagraph (a);

(b) admits that, during the Claim Period, each MESO ADR represented 5 MSB Shares;

(c) admits subparagraph (c); and

(d) otherwise does not know and therefore cannot admit the paragraph.

B. MESOBLAST'S BUSINESS

B.1 Introduction

B.1.1 History

9. Mesoblast admits paragraph 9.

10. Mesoblast admits paragraph 10.

11. Mesoblast admits paragraph 11.

12. Mesoblast admits paragraph 12.

13. Mesoblast admits paragraph 13.

14. In answer to paragraph 14, Mesoblast:

    (a) admits that it had identified R-L as a potential treatment for paediatric patients suffering SR-aGVHD by the commencement of the Claim Period;

    (b) admits subparagraph (b); and

    (c) otherwise denies the paragraph.

15. Mesoblast admits paragraph 15.

16. Mesoblast admits paragraph 16.

17. Mesoblast admits paragraph 17.

18. Mesoblast admits paragraph 18.

19. Mesoblast admits paragraph 19.

20. Mesoblast admits paragraph 20.

21. In answer to paragraph 21, Mesoblast:

    (a) says that:

        (i) the FDA's approval of ruxolitinib in May 2019 to treat patients aged 12 years and over who suffer from SR-aGVHD was based on an open-label, single-arm, multicentre Phase 2 pivotal study of 49 patients with grades B to D (II to IV) SR-aGVHD known as REACH-1;

        (ii) Mesoblast's Study 001 was also an open-label, single-arm, multicentre (i.e., conducted at more than one site but according to a single protocol) pivotal study of patients with grades B to D (II to IV) SR-aGVHD, but had 55 patients and was a Phase 3 trial;

Particulars

A Phase 3 trial is a more advanced trial than a Phase 2 trial, with the latter classification suggesting that further trials will be required.

(iii) the primary endpoint of REACH-1 was, like the primary endpoint of Mesoblast's Study 001, a day 28 (**D28**) overall response rate (**ORR**), both being objective;

(iv) in REACH-1, ruxolitinib demonstrated a D28 ORR of 57.1% whereas, in Study 001, R-L demonstrated a better D28 ORR of 69.1%;

(v) the null hypothesis for Study 001 (45%) was similar to but more conservative than the null hypothesis for REACH-1 (40%);

(vi) the null hypotheses for REACH-1 and Study 001 were derived in a similar manner;

Particulars

In particular, the null hypothesis for REACH-1 was defined without reference to a historical comparator.

(vii) REACH-1 permitted enrolment of subjects who (a) progressed after 1 mg/kilogram methylprednisolone for skin GVHD and (b) could not tolerate steroid taper (viz., subjects who were not truly steroid refractory), whereas Study 001 did not permit the enrolment of such subjects, meaning the results of REACH-1 may have been based in part on the treatment of patients with less severe disease than the patients enrolled in Study 001;

(viii) ruxolitinib had only a 16-day duration of response (**DOR**), causing the FDA to conduct its own post-hoc analyses in an effort to find an indication of durability, whereas the durability of R-L was demonstrated using the prespecified (i.e., not post hoc) analysis in Study 002, which followed all subjects in Study 001 to day 180 (**D180**) and demonstrated a median DOR of 70.5 days;

(ix) the frequency of GVHD assessments in Study 001 (weekly through day 100 and then every 20 days thereafter) was greater that the frequency of GVHD assessments in REACH-1 (weekly through day 56 and then every 28 days thereafter);

(x) both Study 001 and REACH-1 included measures of survival as secondary endpoints, with reported D180 overall survival (**OS**) better for R-L (69%) than for ruxolitinib (42%);

(xi) both Study 001 and REACH-1 used Intention-to-Treat principles;

(xii) the size of the safety database for R-L was substantially larger than that for ruxolitinib and the safety profile for R-L was better than that for ruxolitinib;

Particulars

The safety of ruxolitinib was assessed across 617 patients whereas the safety of R-L was assessed across 1,114 patients.

The FDA has never expressed safety concerns regarding R-L. By contrast, ruxolitinib carries labelled risks of thrombocytopenia, anaemia, neutropenia, infection, non-melanoma skin cancer and lipid elevations. An adverse reaction resulting in treatment discontinuation occurred in 31% of subjects in REACH-1, with infection the most common adverse reaction leading to treatment discontinuation (10%).

(xiii) the FDA identified the following as factors justifying approval of ruxolitinib based on an open label, single-arm, multicentre Phase 2 pivotal study:

(A) the condition being studied was life-threatening;

(B) there were no approved therapies;

(C) there was no optimal therapy;

(D) the efficacy endpoint of the pivotal study was objective;

(E) there was a substantial safety database;

Particulars

FDA Clinical Evidence Briefing Document, page 8.

(xiv) each of the above factors is and was during the Claim Period true of R-L;

(xv) in the premises:

(A) the FDA's approval of ruxolitinib in 2019 confirmed that a single-arm pivotal study was capable of being the basis for the FDA's approval of an SR-aGVHD treatment;

(B) there are, and were during the Claim Period, substantial similarities between the data on the basis of which the FDA approved ruxolitinib as a treatment for SR-aGVHD and the data submitted by Mesoblast in support of its BLA for R-L as a treatment for paediatric SR-aGVHD;

Particulars

Mesoblast refers to paragraph 21(b)(i), (ii), (iii), (iv), (v), (vi), (x), (xi), (xiii) and (xiv) above.

(C) to the extent there are and were during the Claim Period differences, the data are and were objectively stronger for R-L, weighing in favour of the approval of Mesoblast's BLA; and

Particulars

Mesoblast refers to paragraph 21(b)(ii), (iv), (v), (vii), (viii), (ix), (x) and (xii) above.

(b) otherwise admits the paragraph.

22. Mesoblast admits paragraph 22.

B.1.2 Acute Graft Versus Host Disease

23. Mesoblast admits paragraph 23.

24. Mesoblast admits paragraph 24.

25. Mesoblast admits paragraph 25.

26. Mesoblast admits paragraph 26.

27. In answer to paragraph 27, Mesoblast:

(a) says that Fast Track designation was granted on 28 February 2017;

(b) says further that Fast Track designation conveyed that the FDA recognised paediatric SR-aGVHD as a life-threatening disease;

(c) says further that the FDA did not, following Fast Track designation, place any clinical holds on the BLA and, on 30 March 2020, the FDA accepted Mesoblast's BLA for filing; and

(d) otherwise admits the paragraph.

28. In answer to paragraph 28:

(a) says that the BLA number was 125706, not 1256706 as alleged by the Applicants;

(b) says further that on 5 April 2019 the FDA accepted Mesoblast's proposal to submit a BLA on a rolling basis;

Particulars

The FDA conveyed its acceptance of Mesoblast's proposal for a rolling submission of its application at a "pre-BLA meeting" with Mesoblast on 5 April 2019.

(c) says further that it was the final module of the BLA that was submitted on 31 January 2020 and that the first module was submitted on 29 May 2019;

(d) says further that the FDA accepted the submission for filing on 30 March 2020, granting the BLA priority review and setting a decision date for 30 September 2020;

(e) says further that acceptance of the BLA for filing by the FDA meant that the BLA was capable of being approved;

(f) denies that the results of Study 001 were relied on as the sole basis of efficacy;

(g) says further that, instead, the efficacy results of Study 001 were supported by EAP 275 and Protocol 280; and

Particulars

Mesoblast refers to the facts and matters set out in the Executive Summary of the Mesoblast ODAC Briefing Submission under the heading "Efficacy" and to the more detailed discussion in Section 5 headed "Clinical Efficacy". Further particulars will be provided following the service of Mesoblast's evidence.

(h) otherwise admits the paragraph.

B.1.4 COVID-19

29. Mesoblast admits paragraph 29.

30. Mesoblast admits paragraph 30.

31. Mesoblast admits paragraph 31

B.2 Governance of Mesoblast

B.2.1 Mesoblast Governance Protocols

32. In answer to paragraph 32, Mesoblast:

    (a) admits that at all material times during the Claim Period Mesoblast had a Materials Review Committee/External Communications Review Committee (the name "External Communications Review Committee" being used from about December 2019);

    (b) denies that at all material times during the Claim Period the Materials Review Committee/External Communications Review Committee, acting in conjunction with the Chief Executive Officer, was responsible for overseeing disclosure of information to the ASX; and

    (c) says further that, instead, at all material times during the Claim Period the Chief Executive Officer, acting in conjunction with the Global Head of Corporate Communications, the General Counsel, the Company Secretary and the Materials Review Committee/External Communications Review Committee, was responsible for overseeing the disclosure of information to the ASX.

B.2.2 Chief Executive Officer

33. Mesoblast admits paragraph 33.

B.2.3 Chief Medical Officer

34. Mesoblast admits paragraph 34.

35. Mesoblast admits paragraph 35.

B.2.4 Chief Financial Officer

36. Mesoblast admits paragraph 36.

37. Mesoblast admits paragraph 37.

B.2.5 Chief Operating Officer

38. Mesoblast admits paragraph 38.

B.2.6 General Counsel

39. Mesoblast admits paragraph 39.

B.2.7 Head of Regulatory Affairs and Quality Management

40. Mesoblast admits paragraph 40.

B.2.8 Head of Research and New Product Development

41. In answer to paragraph 41, Mesoblast:

    (a) admits subparagraph (a) save that Dr Simmons became "Chief Scientific Advisor" on 4 April 2022 and still holds that position; and

    (b) denies subparagraph (b).

B.2.9 The knowledge of Mesoblast Officers is knowledge of Mesoblast

42. In answer to paragraph 42, Mesoblast:

    (a) admits that, during the Claim Period, any information that had, or ought reasonably to have, come into the possession of a member of the board of directors of Mesoblast or any of the persons in paragraphs 33 to 40 of the ~~CSOC~~ACSOC in the course of the performance of that person's duties as an officer of Mesoblast, within the meaning of ASX Listing Rule 19.12, was information of which Mesoblast was "aware", within the meaning of ASX Listing Rule 3.1; and

    (b) otherwise denies the paragraph.

C. RELEVANT INFORMATION AND MESOBLAST'S KNOWLEDGE

C.1 Information concerning trials related to the SR-aGVHD Application

C.1.1 Protocol 280 and Protocol 280 Information

43. In answer to paragraph 43, Mesoblast:

    (a) says that Protocol 280 was a multicentre study; and

(b) otherwise admits the paragraph.

44. In answer to paragraph 44, Mesoblast:

(a) says that participants in Study 280 were aged six months to 70 years, not six months to 60 years as alleged by the Applicants;

(b) says further that participants in Study 280 had failed to respond to steroid treatment; and

(c) otherwise admits the paragraph.

45. Mesoblast admits paragraph 45.

46. In answer to paragraph 46, Mesoblast:

(a) admits subparagraphs (a), (b) and (c);

(b) admits subparagraph (d) insofar as the allegation is made in respect of the difference between R-L and placebo study arms assessed across the totality of subjects in Protocol 280, as distinct from the difference between R-L and study arms assessed across subgroups of subjects containing those with the most severe disease among the total cohort (viz., those with grade C or grade D disease); and

(c) otherwise denies the paragraph.

47. In answer to paragraph 47, Mesoblast:

(a) as to subparagraph (a):

(i) admits that Protocol 280 did not meet its primary endpoint; and

(ii) otherwise denies subparagraph (a);

(b) as to subparagraph (b):

(i) says that the D28 ORR for subjects in Study 280 receiving R-L was 57.7% and the D28 ORR for subjects receiving placebo was 50.6%;

(ii) says that an analysis of a subset of paediatric patients showed a higher D28 ORR with R-L versus the control group (64% versus 36%);

(iii) refers to paragraph 47(c) below; and

(iv) denies subparagraph (b);

(c) as to subparagraph (c):

(i) says that, of those subjects with grade C or D aGVHD, the D28 ORR was 61.1% for the R-L group compared with 46.7% in the placebo group;

(ii) says further that post-hoc analyses evaluated D28 ORR using three different classifications of disease severity based predominantly on involvement of gastrointestinal tract and/or liver, namely, baseline International Bone Marrow Transplant Registry (**IBMTR**) aGVHD grade, baseline Glucksberg aGVHD and baseline Minnesota Risk Score;

Particulars

The IBMTR, Glucksberg and Minnesota Risk Score systems are different systems for grading the severity of aGVHD. Glucksberg grades aGVHD by patterns of organ involvement and clinical performance status (grades 0-IV). IBMTR regroups the patterns of organ involvement into five indexes (grades 0-D). Minnesota Risk Score involves High Risk and Standard Risk ratings.

(iii) says further that R-L treated subjects had higher D28 ORR than controls for each of IBMTR grade C/D (59.5% versus 49.5%), Glucksberg grade III/IV (56.2% versus 41.4%) and High Risk classified according to the Minnesota Risk Score (56.7% versus 32.6%);

(iv) says further that the foregoing data from Study 280 indicated that R-L:

(A) provided a treatment benefit in subjects with more severe disease, such as SR-aGVHD affecting the gastrointestinal tract and/or the liver; and

(B) provided a treatment benefit when given as a second-line therapy after systemic corticosteroid therapy in patients that were High Risk (classified according to the Minnesota Risk Score); and

(v) denies subparagraph (c);

(d) as to subparagraph (d):

(i) insofar as the Applicants allege that data from Protocol 280 did not, or could not, provide support for FDA Marketing Approval of R-L as a treatment for SR-aGVHD in paediatric patients:

(A) refers to paragraph 47(c) above; and

(B) denies the allegation; and

(ii) otherwise denies subparagraph (d).

C.1.2 Protocol 265 and Protocol 265 Information

48. In answer to paragraph 48, Mesoblast:

(a) says that Protocol 265 was a multicentre clinical trial; and

(b) otherwise admits the paragraph.

49. In answer to paragraph 49, Mesoblast:

(a) says that Protocol 265 consisted of 193 participants, of whom 192 were randomised to receive treatment;

(b) says further that the patient population for Protocol 265:

(i) did not include SR-aGVHD subjects;

(ii) was composed of newly diagnosed aGVHD patients (grades B to D, including skin-only grade B); and

(iii) primarily enrolled subjects with milder disease; and

(c) otherwise admits the paragraph.

50. In answer to paragraph 50, Mesoblast:

(a) admits subparagraphs (a) and (b);

(b) as to subparagraph (c):

(i) admits the subparagraph insofar as the allegation is directed at the difference between R-L and placebo study arms assessed across the totality of subjects in Protocol 265, as distinct from the difference

between R-L and placebo study arms assessed across subgroups of subjects containing those with the most severe disease among the total cohort (viz., those with grade C or grade D disease); and

(ii) otherwise denies the subparagraph.

51. In answer to paragraph 51, Mesoblast:

(a) admits subparagraph (a);

(b) as to subparagraph (b):

(i) admits that Protocol 265 did not meet its primary endpoint; and

(ii) otherwise denies subparagraph (b);

(c) as to subparagraph (c):

(i) admits the allegation insofar as it concerns response rates versus placebo assessed across all subjects of Protocol 265;

(ii) says further that post-hoc analyses of Protocol 265 data indicated meaningful R-L treatment benefit in subjects with the most severe disease (grades C or D) relative to placebo; and

Particulars

Compared with placebo, there was a trend towards a higher D28 ORR among R-L-treated subjects with grade C or D disease in the gut (77.8% R-L versus 50% placebo). Further particulars will be provided following service of Mesoblast's evidence.

(iii) otherwise denies subparagraph (c); and

(d) denies subparagraph (d).

C.1.3 EAP 275 and EAP 275 Information

52. In answer to paragraph 52, Mesoblast:

(a) says that the paediatric patients in EAP 275 were not just patients with SR-aGVHD who had failed to respond to systemic corticosteroids but also such patients who had failed to respond to multiple lines of treatment; and

(b) otherwise admits the paragraph.

53. In answer to paragraph 53, Mesoblast:

(a) says that an expanded access program is not a clinical trial; and

(b) otherwise admits the paragraph.

54. In answer to paragraph 54, Mesoblast:

(a) admits subparagraph (a);

(b) as to subparagraph (b):

(i) refers to paragraph 53(a) above and says that an expanded access program is not a trial for the purposes of the FDA regulatory regime; and

(ii) in the premises, admits subparagraph (b);

(c) as to subparagraph (c):

(i) says that data from EAP 275 indicated R-L showed efficacy when used as a salvage therapy for children with predominantly severe SR-aGVHD who had failed to respond to multiple lines of additional therapy;

Particulars

A high rate of OR at day 28 was observed despite an overwhelming number of subjects with severe disease (50.6% with IBMTR grade D disease and 80.1% with grade C/D disease). Mesoblast refers to Table 29 on page 91 of the Mesoblast ODAC Briefing Submission. Further particulars will be provided following service of Mesoblast's evidence.

(ii) insofar as the Applicants allege that data from EAP 275 did not, or could not, provide support for FDA Marketing Approval of R-L as a treatment for SR-aGVHD in paediatric patients:

(A) refers to paragraph 54(c)(i) above; and

(B) denies the allegation; and

(iii) otherwise denies subparagraph (c).

C.1.4 Study 001 and Study 001 Information

55. In answer to paragraph 55, Mesoblast:

(a) says that patients who had received any second-line therapy to treat aGVHD prior to screening were excluded from Study 001;

(b) says further that patients who had received systemic agents for primary treatment of aGVHD (other than steroids and prophylactic agents) were also excluded from Study 001; and

(c) otherwise admits the paragraph.

56. In answer to paragraph 56, Mesoblast:

(a) says that the null hypothesis was prespecified in the statistical analysis plan, which was provided to the FDA as early as 18 November 2014; and

(b) otherwise admits the paragraph.

57. In answer to paragraph 57, Mesoblast:

(a) as to subparagraph (a):

(i) admits that Study 001 was not a randomised study and says that ethical constraints in conducting a study of paediatric patients suffering SR-aGVHD meant that designing Study 001 as a randomised study would not have been appropriate; and

Particulars

Providing a placebo (i.e., not providing a treatment) to children suffering from a life-threatening condition would not have been ethically appropriate. Moreover, given the risk of death in young children suffering from SR-aGVHD, absent treatment, doctors would not have allowed such patients to participate in a randomised study.

(ii) says further that information that Study 001 was not a randomised study was generally available during the Claim Period;

Particulars

Information that Study 001 was a single-arm trial was publicly available during the Claim Period on, *inter alia*, the US National Library of Medicine's "Clinical.Trials.gov" website.

(iii) denies that Study 001 was not a controlled study; and

(b) as to subparagraphs (b) to (f):

(i) refers to paragraph 21(a) above;

(ii) says that it will rely on the full terms and effect of dealings between Mesoblast and the FDA in relation to Study 001 from 2014 to 2020 at trial; and

(iii) denies the subparagraphs.

C.1.5 MAGIC Database and MAGIC Comparison Data Information

58. Mesoblast admits paragraph 58.

59. In answer to paragraph 59, Mesoblast:

(a) says that the MAGIC Comparison Data was provided to the FDA in response to a query raised by the FDA at the pre-BLA meeting on 5 April 2019 regarding the 45% null hypothesis; and

(b) otherwise admits the paragraph.

60. In answer to paragraph 60, Mesoblast:

(a) as to subparagraph (a):

(i) repeats paragraph 59(a) above;

(ii) says that, because the FDA did not query the 45% null hypothesis until April 2019, the MAGIC Comparison Data was necessarily not part of the original statistical analysis plan for Study 001 and there was necessarily no *a priori* specified hypothesis;

(iii) denies that there was no hypothesis "for the utility of the data"; and

(iv) otherwise admits subparagraph (a);

(b) denies subparagraph (b);

(c) as to subparagraph (c):

(i) says that the cohort of paediatric patients from the MAGIC database matched the key eligibility criteria for Study 001; and

(ii) denies subparagraph (c);

(d) denies subparagraph (d); and

(e) as to subparagraph (e):

(i) says that Mesoblast primarily relied on the MAGIC Comparison Data as additional support for the 45% null hypothesis in the circumstances pleaded at paragraph 59(a) above;

(ii) says further that, in addition to providing additional support for the 45% null hypothesis, the MAGIC Comparison Data provided support for the efficacy of R-L; and

Particulars

The D28 ORR in the severity and age-matched MAGIC control population was 43% (95% CI: 25, 63).

(iii) says further that:

(A) the FDA expressly sought the input of ODAC as to the persuasiveness of the MAGIC Comparison Data as historical controls to establish the null hypothesis for the purpose of quarantining the treatment effect of R-L in paediatric patients with SR-aGVHD; and

Particulars

Mesoblast refers to page 6 of the FDA Clinical Evidence Briefing Document.

(B) ODAC voted 9-1 that the available data supported the efficacy of R-L in paediatric patients with SR-aGVHD; and

(iv) denies subparagraph (e).

C.2 Information concerning the SR-aGVHD Application

C.2.1 Unimproved Consistency in Manufactured Product Information

61. Mesoblast denies paragraph 61.

C.2.2 Differences in aGVHD Studies Information

62. In answer to paragraph 62, Mesoblast:

(a) admits that there were some differences between Study 001, on the one hand, and EAP 275, Protocol 280 and Protocol 265, on the other, in terms of patient populations, trial design, study conduct and primary endpoint evaluations;

(b) says that the existence of such differences did not mean that data, or subsets of data, from EAP 275, Protocol 280 and Protocol 265 could not provide support for the conclusion that Study 001 disclosed a treatment benefit of R-L in paediatric SR-aGVHD subjects;

(c) refers to paragraphs 47(c), 51(b)(ii) and 54(c) above; and

(d) otherwise denies the paragraph.

C.2.3 Non-compliance with FDA Advice Regarding SR-aGVHD Information

63. In answer to paragraph 63, Mesoblast:

(a) says that it did not commence dealings with the FDA in relation to R-L until 2014;

(b) denies that the matters pleaded in paragraph 63 of the ~~CSOC~~ACSOC accurately reflect the extent or the content of the dealings between Mesoblast and the FDA from 2014 to the filing of the final module of Mesoblast BLA on 31 January 2020, including as to the effect of the advice given by the FDA on the clinical development program for the treatment of aGVHD; and

(c) otherwise denies the paragraph.

64. In answer to paragraph 64, Mesoblast:

(a) refers to paragraph 63 above; and

(b) denies the paragraph.

C.2.4 Inadequately Designed Trial for aGVHD Information

65. In answer to paragraph 65, Mesoblast:

(a) refers to paragraph 21(a) above;

(b) refers to paragraph 66(b)-(d) below;

(c) says further that:

(i) the FDA expressly sought input from ODAC regarding:

(A) the persuasiveness of the MAGIC Comparison Data as historical controls to establish the null hypothesis for the purpose of quarantining the treatment effect of R-L in paediatric patients with SR-aGVHD;

(B) the suitability of the single-arm design of Study 001; and

(C) whether the results of Study 001 were adequate to allow one to conclude that remestemcel-L is effective in the treatment of SR-aGVHD in paediatric patients; and

Particulars

Mesoblast refers to pages 6 and 7 of the FDA Clinical Evidence Briefing Document.

(ii) ODAC voted 9-1 that the available data supported the efficacy of R-L in paediatric patients with SR-aGVHD; and

(d) denies the paragraph.

C.2.5 Unlikely to be Approved by FDA Information

66. In answer to paragraph 66, Mesoblast:

(a) refers to paragraph 21(a) above;

(b) repeats that, following the ODAC meeting on 13 August 2020 (which occurred after the final module of Mesoblast's BLA had been submitted on 31 January 2020), ODAC voted 9-1 that the available data supported the efficacy of R-L in paediatric patients with SR-aGVHD;

(c) says further that, prior to the FDA's issuing of the Complete Response Letter on 30 September 2020, the FDA had affirmed every ODAC vote in favour of approval of a therapy since 2006;

Particulars

From 1 January 2006 to 31 May 2019, ODAC voted on the approvability of therapies 61 times (excluding biosimilars, generics, and meetings involving the Paediatric Oncology Subcommittee). The FDA approved the therapy every time ODAC voted in favour of approval (30 out of 30). The FDA did not follow the vote of ODAC in seven instances when ODAC voted against approval and the FDA ultimately approved the treatment (7 out of 30). There was one instance of a tied ODAC vote and the FDA went on to approve the treatment.

(d) says further that, consequently, the non-approval of the BLA as articulated in the Complete Response Letter in the circumstances of a positive ODAC vote (9-1) had no precedent in at least the 14 years prior to that event; and

(e) denies the paragraph.

C.3 Information concerning trials related to the COVID-19 ARDS Application

C.3.1 Study 001 No Support for ARDS Treatment Information

67. Mesoblast denies paragraph 67.

C.3.2 Pilot Study and Pilot Study Information

68. In answer to paragraph 68, Mesoblast:

(a) says that the Pilot Study was conducted during the months of March and April 2020, not May 2020 as alleged by the Applicants; and

(b) otherwise admits the paragraph.

69. Mesoblast admits paragraph 69.

70. In response to paragraph 70, Mesoblast

(a) says that, for the purpose of the Pilot Study, Mesoblast recruited patients who met the ventilator-dependent criterion;

(b) says that age was not a criterion for the purpose of enrolment in the Pilot Study;

(c) says that the Pilot Study primarily enrolled patients between 34 and 67 years old; and

(d) otherwise denies the paragraph.

C.3.3 COVID-19 Trial and COVID-19 Trial Information

71. Mesoblast admits paragraph 71.

72. Mesoblast admits paragraph 72.

73. Mesoblast admits paragraph 73.

74. Mesoblast admits paragraph 74.

75. Mesoblast admits paragraph 75.

76. In answer to paragraph 76, Mesoblast:

    (a) denies that changes in the treatment regimens for COVID-19 patients occurred "at all material times" after the Pilot Study was conducted; and

    (b) otherwise admits the paragraph.

77. Mesoblast admits paragraph 77.

78. In answer to paragraph 78, Mesoblast:

    (a) admits that, by about 15 December 2020 when the Data Safety Monitoring Board (**DSMB**) delivered its advice following the third interim analysis, it had become more difficult to achieve improved reduction in mortality rates via R-L on top of maximal care during the COVID-19 Trial than it had been during the Pilot Study; and

Particulars

As to the DSMB's advice, Mesoblast refers to paragraph 80(a) below.

The DSMB is an independent board appointed by the National Heart, Lung, and Blood Institute (**NHLBI**), one of the National Institutes of Health of the United States Government. The DSMB serves in an advisory capacity to the NHLBI and its collaborators (such as Mesoblast), making recommendations based on its expert opinion. The principal role of the DSMB is to monitor data from the relevant clinical trial, review and assess the safety and performance of its operations, safeguard the interest of study participants, and make recommendations with respect to the same.

    (b) otherwise denies the paragraph.

79. Mesoblast denies paragraph 79.

C.3.4 Actual COVID-19 Trial Results Information

80. In answer to paragraph 80, Mesoblast:

(a) says that:

(i) on 3 September 2020, after review of the first interim analysis, the DSMB unanimously voted for the COVID-19 Trial to continue;

(ii) on 10 November 2020, after review of the second interim analysis, the DSMB unanimously voted for the COVID-19 Trial to continue; and

(iii) on 15 December 2020, after review of the third interim analysis, the DSMB noted that COVID-19 Trial met the pre-specified stopping criterion indicating a low likelihood of meeting the primary endpoint of 30-day mortality at full enrolment and unanimously recommended halting enrolment; and

(b) denies the paragraph.

81. In answer to paragraph 81, Mesoblast:

(a) repeats paragraph 80(a) above; and

(b) denies the paragraph.

82. In answer to paragraph 82, Mesoblast:

(a) refers to paragraphs 80 and 81 above; and

(b) otherwise does not plead to the paragraph as it contains no allegation.

C.3.5 Low Likelihood of COVID-19 Trial Success Information

83. Mesoblast denies paragraph 83.

C.4 Mesoblast's knowledge of information

C.4.1 Mesoblast knowledge of SR-aGVHD Trial Deficiencies Information

84. In answer to paragraph 84, Mesoblast:

(a) refers to paragraphs 47, 51, 54, 57, 62, 63, 64 and 65 above;

(b) denies that the SR-aGVHD Trial Deficiencies Information as pleaded by the Applicants existed during the SR-aGVHD Claim Period;

(c) says further that it never "had" the SR-aGVHD Trial Deficiencies Information within the meaning of section 674(2) of the Corporations Act during the SR-aGVHD Claim Period; and

(d) otherwise denies that it was "aware" of the SR-aGVHD Trial Deficiencies Information within the meaning of the ASX Listing Rules during the SR-aGVHD Claim Period.

C.4.2 Mesoblast's knowledge of the SR-aGVHD Approval Application Deficiencies Information

85. In answer to paragraph 85, Mesoblast:

(a) refers to paragraphs 60, 61, 63, 64 and 66 above;

(b) denies that the SR-aGVHD Approval Application Deficiencies Information as pleaded by the Applicants existed during the SR-aGVHD Claim Period;

(c) says further that it never "had" the SR-aGVHD Approval Application Deficiencies Information within the meaning of section 674(2) of the Corporations Act during the SR-aGVHD Claim Period; and

(d) otherwise denies that it was "aware" of the SR-aGVHD Approval Application Deficiencies Information within the meaning of the ASX Listing Rules during the SR-aGVHD Claim Period.

C.4.3 Mesoblast's knowledge of Study 001 No Support for ARDS Treatment Information

86. In answer to paragraph 86, Mesoblast:

(a) refers to paragraph 67 above;

(b) denies that the No Support for ARDS Treatment Information as pleaded by the Applicants existed during the SR-aGVHD Claim Period;

(c) says further that it never "had" the No Support for ARDS Treatment Information within the meaning of section 674(2) of the Corporations Act during the SR-aGVHD Claim Period; and

(d) otherwise denies that it was "aware" of the No Support for ARDS Treatment Information within the meaning of the ASX Listing Rules during the SR-aGVHD Claim Period.

C.4.4 Mesoblast's knowledge of COVID-19 Trial Deficiencies Information

87. In answer to paragraph 87, Mesoblast:

(a) as to subparagraph (a):

(i) says that there are no allegations of material fact in the ~~CSOC~~ACSOC corresponding with (or with the existence of) the "COVID-19 Comparative Study Data Information"; and

(ii) under cover of that objection, denies subparagraph (a);

(b) as to subparagraph (b):

(i) refers to paragraph 79 above;

(ii) denies that the COVID-19 Trial Information as pleaded by Applicants existed during the COVID-19 ARDS Claim Period;

(iii) says further that it never "had" the COVID-19 Trial Information within the meaning of section 674(2) of the Corporations Act during the COVID-19 ARDS Claim Period; and

(iv) otherwise denies that it was "aware" of the COVID-19 Trial Information within the meaning of the ASX Listing Rules during the COVID-19 ARDS Claim Period;

(c) as to subparagraph (c):

(i) refers to paragraph 78 above;

(ii) denies that the Difficulty with Primary Endpoint Information as pleaded by Applicants existed during the COVID-19 ARDS Claim Period;

(iii) says further that it never "had" the Difficulty with Primary Endpoint Information within the meaning of section 674(2) of the Corporations Act during the COVID-19 ARDS Claim Period; and

(iv) otherwise denies that it was "aware" of the Difficulty with Primary Endpoint Information within the meaning of the ASX Listing Rules during the COVID-19 ARDS Claim Period;

(d) as to subparagraph (d):

(i) refers to paragraph 83 above;

(ii) denies that the Low Likelihood of COVID-19 Trial Success Information as pleaded by Applicants existed during the COVID-19 ARDS Claim Period;

(iii) says further that it never "had" the Low Likelihood of COVID-19 Trial Success Information within the meaning of section 674(2) of the Corporations Act during the COVID-19 ARDS Claim Period; and

(iv) otherwise denies that it was "aware" of the Low Likelihood of COVID-19 Trial Success Information within the meaning of the ASX Listing Rules during the COVID-19 ARDS Claim Period.

C.4.5 Mesoblast's knowledge of the Actual COVID-19 Trial Results Information

88. In answer to paragraph 88, Mesoblast:

(a) refers to paragraphs 80 to 82 above;

(b) denies that the Actual COVID-19 Trial Results Information as pleaded by the Applicants existed during the COVID-19 ARDS Claim Period;

(c) says further that it never "had" the Actual COVID-19 Trial Results Information within the meaning of section 674(2) of the Corporations Act during the COVID-19 ARDS Claim Period; and

(d) otherwise denies that it was "aware" of the Actual COVID-19 Trial Results Information within the meaning of the ASX Listing Rules 19.12 during the COVID-19 ARDS Claim Period.

D. MISLEADING OR DECEPTIVE CONDUCT

D.1 Representations made by Mesoblast

89. Mesoblast admits paragraph 89.

D.1.1 The 22 February 2018 Representations

90. In answer to paragraph 90, Mesoblast:

(a) denies the paragraph; and

(b) says further that the 22 February 2018 Announcement contained, in the body of that announcement under the prominent heading "Forward-Looking Statements", extensive and express warnings as to forward-looking statements (as there defined) (**Extensive Forward-Looking Statements Warnings**) with the consequence that the representation alleged at subparagraph (d) was not conveyed to the Affected Market.

Particulars

The 22 February 2018 Announcement said as follows:

Forward-Looking Statements

This announcement includes forward-looking statements that relate to future events or our future financial performance and involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to differ materially from any future results, levels of activity, performance or achievements expressed or implied by these forward-looking statements. We make such forward-looking statements pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 and other federal securities laws. Forward-looking statements should not be read as a guarantee of future performance or results, and actual results may differ from the results anticipated in these forward-looking statements, and the differences may be material and adverse. Forward- looking statements include, but are not limited to, statements about: the initiation, timing, progress and results of Mesoblast's preclinical and clinical studies, and Mesoblast's research and development programs; Mesoblast's ability to advance product candidates into, enrol and successfully complete, clinical studies, including multi-national clinical trials; Mesoblast's ability to advance its manufacturing capabilities; the timing or likelihood of regulatory filings and approvals, manufacturing activities and product marketing activities, if any; the

> commercialization of Mesoblast's product candidates, if approved; regulatory or public perceptions and market acceptance surrounding the use of stem-cell based therapies; the potential for Mesoblast's product candidates, if any are approved, to be withdrawn from the market due to patient adverse events or deaths; the potential benefits of strategic collaboration agreements and Mesoblast's ability to enter into and maintain established strategic collaborations; Mesoblast's ability to establish and maintain intellectual property on its product candidates and Mesoblast's ability to successfully defend these in cases of alleged infringement; the scope of protection Mesoblast is able to establish and maintain for intellectual property rights covering its product candidates and technology; estimates of Mesoblast's expenses, future revenues, capital requirements and its needs for additional financing; Mesoblast's financial performance; developments relating to Mesoblast's competitors and industry; and the pricing and reimbursement of Mesoblast's product candidates, if approved. You should read this press release together with our risk factors, in our most recently filed reports with the SEC or on our website. Uncertainties and risks that may cause Mesoblast's actual results, performance or achievements to be materially different from those which may be expressed or implied by such statements, and accordingly, you should not place undue reliance on these forward-looking statements. We do not undertake any obligations to publicly update or revise any forward-looking statements, whether as a result of new information, future developments or otherwise.

91. Mesoblast denies paragraph 91.

92. Mesoblast denies paragraph 92.

D.1.2 20 September 2018 Representations

93. Mesoblast denies paragraph 93.

D.1.3 13 December 2018 Representations

94. Mesoblast denies paragraph 94.

D.1.4 20 February 2019 Representations

95. Mesoblast denies paragraph 95.

D.1.4A. 16 April 2019 Address Substantial Matters Future Representation

95A. In answer to paragraph 95A, Mesoblast:

(a) denies that the representation was as to a future matter; and

(b) otherwise admits paragraph 95A.

D.1.5 2 January 2020 Representations

96. Mesoblast denies paragraph 96.

97. Mesoblast denies paragraph 97.

D.1.6 Three Studies Confirmatory Evidence Representations

98. Mesoblast denies paragraph 98.

99. Mesoblast denies paragraph 99.

D.1.7 Study 001 Support for R-L Use in COVID-19 Patients Future Representation

100. In answer to paragraph 100, Mesoblast:

(a) denies the paragraph; and

(b) says further that the 6 April 2020 Announcement contained, in the body of that announcement under the prominent heading "Forward-Looking Statements", the Extensive Forward-Looking Statements Warnings with the consequence that the alleged Study 001 Support for R-L Use in COVID-19 Patients Future Representation was not conveyed to the Affected Market.

Particulars

The particulars to paragraph 90(b) are repeated.

D.1.8 R-L Efficacy Representation

101. Mesoblast denies paragraph 101.

102. Mesoblast denies paragraph 102.

D.1.9 24 April 2020 Representations

103. Mesoblast denies paragraph 103.

D.1.10 Pilot Study Future Representation

104. In answer to paragraph 104, Mesoblast:

(a) denies the paragraph; and

(b) says further that the 30 April 2020 Announcement contained, in the body of that announcement under the prominent heading "Forward-Looking Statements", the Extensive Forward-Looking Statements Warnings with the consequence that the alleged Pilot Study Future Representation was not conveyed to the Affected Market.

Particulars

The particulars to paragraph 90(b) are repeated.

D.1.11 Cleansing Notice Representation

105. Mesoblast admits paragraph 105.

106. Mesoblast admits paragraph 106.

107. Mesoblast denies paragraph 107.

D.1.12 30 July Representations

108. Mesoblast denies paragraph 108.

D.1.13 COVID-19 Trial Primary Endpoint Representation

109. Mesoblast denies paragraph 109.

110. Mesoblast denies paragraph 110.

D.2 SR-aGVHD Application Related Misleading Conduct

D.2.1 Conduct in trade or commerce

111. In answer to paragraph 111, Mesoblast:

(a) admits that, if Mesoblast engaged in the conduct pleaded in that paragraph, which is denied, it was conduct:

(i) in trade or commerce within the meaning of section 18 of the Australian Consumer Law (Victoria);

(ii) in trade or commerce, and in relation to financial services (being MSB Shares), within the meaning of section 12DA of the ASIC Act;

(iii) in relation to financial product or financial service (being MSB Shares) within the meaning of section 1041H of the Corporations Act;

(b) repeats paragraph 5(a)-(g) above; and

(c) otherwise denies the paragraph.

D.2.2 Continuing conduct

112. In answer to paragraph 112, Mesoblast:

(a) repeats that it denies making the SR-aGVHD Representations;

(b) says that, if Mesoblast made any of the SR-aGVHD Representations, which is denied, they were not continuing representations; and

(c) denies the paragraph.

D.2.3 Conduct was misleading

113. In answer to paragraph 113, Mesoblast:

(a) repeats that it denies making the Historical Control Rate Representation;

(b) repeats that it denies that the Study 001 Information and the Differences in aGVHD Studies Information existed during the SR-aGVHD Claim Period;

(c) as to the FDA Information and Advice Regarding SR-aGVHD Application, repeats paragraph 63 above;

(d) says that, if Mesoblast did make the Historical Control Rate Representation on 22 February 2018, which is denied, it was a representation of opinion which Mesoblast held and for which Mesoblast had a basis, alternatively a reasonable basis; and

Particulars

Mesoblast refers to the facts and matters set out under the heading "Calculation of Null Hypothesis and Determination of Sample Size" beginning on page 95 of the Mesoblast ODAC Briefing Submission. Further particulars will be provided following the service of Mesoblast's evidence.

(e) denies the paragraph.

114. In answer to paragraph 114, Mesoblast:

(a) repeats that it denies making the EAP 275 Comparison Representation;

(b) repeats that it denies that the EAP 275 Information and the 2014 FDA Meeting Information existed during the SR-aGVHD Claim Period;

(c) as to the FDA Information and Advice Regarding SR-aGVHD Application, repeats paragraph 63 above;

(d) as to the "Adequate and Well Controlled Trial Criteria" referred to in paragraph 114(c) of the ~~CSOC~~ACSOC:

(i) says that this expression is not defined or otherwise explained in the ~~CSOC~~ACSOC; and

(ii) under cover of that objection, denies that the "Adequate and Well Controlled Trial Criteria" rendered the conduct alleged in paragraph 114 of the ~~CSOC~~ACSOC misleading or deceptive, if that conduct occurred (which is denied);

(e) says that, if Mesoblast did make the EAP 275 Comparison Representation, which is denied, it was a representation of opinion which Mesoblast held and for which Mesoblast had a basis, alternatively a reasonable basis; and

Particulars

Mesoblast refers to the facts and matters set out in the Mesoblast ODAC Briefing Submission at pages 50-53, 63, 73, 92 and 112. Mesoblast also refers to the matters pleaded at paragraph 54(c)(i) above. Further particulars will be provided following the service of Mesoblast's evidence.

(f) denies the paragraph.

115. In answer to paragraph 115, Mesoblast:

(a) repeats that it denies making the Study 001 FDA Interactions Representation;

(b) as to the FDA Information and Advice Regarding SR-aGVHD Application, repeats paragraph 63 above;

(c) says that, if Mesoblast did make the Study 001 FDA Interactions Representation on 22 February 2018, which is denied, it was a representation of present fact that was true; and

~~(c)~~(d) says further that, if the Study 001 FDA Interactions Representation was continuing on 5 April 2019, which is denied, it remained true as at that date.

Particulars

As at 22 February 2018, the FDA had not raised critical issues with respect to the design of Study 001.

Further particulars will be provided following service of Mesoblast's evidence.

~~(d)~~(e) denies the paragraph.

116. In answer to paragraph 116, Mesoblast:

(a) repeats that it denies making the Study 001 Outcome Future Representation;

(b) repeats that it denies that the Study 001 Information, the Differences in aGVHD Studies Information, Inadequately Designed Trial for a-GVHD Information, the Non-Compliance with FDA Advice regarding a-GVHD Information and the Unlikely to be Approved by FDA Information existed during the SR-aGVHD Claim Period;

(c) as to the FDA Information and Advice Regarding SR-aGVHD, repeats paragraph 63 above;

(d) as to the "Adequate and Well Controlled Trial Criteria", repeats paragraph 114(d) above;

(e) says that, if it did represent on 22 February 2018 that "the results from Study 001 were likely to form the basis for a successful application for approval by the FDA to treat paediatric patients with SR-aGVHD with R-L", which is denied, it had reasonable grounds for making that representation; and

Particulars

Mesoblast refers to: each of the matters concerning R-L and Study 001 pleaded in paragraph 21(a) above; the fact that Study 001 met its primary endpoint; the facts and matters set out in Mesoblast's ODAC Briefing Submission at pages 92-107 under the heading "Study GVHD001/002" (excluding those matters discussing post-22 February 2018 data); and the particulars to paragraph 115(c) above. Further particulars will be provided following the service of Mesoblast's evidence.

(f) denies the paragraph.

117. In answer to paragraph 117, Mesoblast:

(a) repeats that it denies making the 22 February 2018 Basis Representation;

(b) refers to paragraphs 113 to 116 above; and

(c) denies the paragraph.

118. In answer to paragraph 118, Mesoblast:

(a) repeats that it denies making the R-L Quality Representation and the 20 September 2018 Basis Representation;

(b) repeats that it denies that the Unapproved Consistency in Manufactured Product Information existed during the SR-aGVHD Claim Period;

(c) says that, if it did make the R-L Quality Representation on 20 September 2018, which is denied, it was a representation of present fact that was true;

Particulars

Mesoblast refers to the facts and matters set out in Mesoblast's ODAC Briefing Submission at pages 24 to 35. Further particulars will be provided following the service of Mesoblast's evidence.

(d) says that, in the premises, if it did make the 20 September 2018 Basis Representation, it was also true; and

(e) denies the paragraph.

119. In answer to paragraph 119, Mesoblast:

(a) repeats that it denies making the EAP 275 Reliance Representation;

(b) insofar as the reference to the "EAP Information" in paragraph 119(a) of the ~~CSOC~~ACSOC is intended to be a reference to the EAP 275 Information, repeats that it denies that the EAP 275 Information existed during the SR-aGVHD Claim Period;

(c) as to the "2014 FDA Meeting Information" referred to in paragraph 119(b) of the ~~CSOC~~ACSOC:

(i) says that there are no allegations of material fact in the ~~CSOC~~ACSOC corresponding with (or with the existence of) the 2014 FDA Meeting Information; and

(ii) under cover of that objection, denies that the 2014 FDA Meeting Information rendered the conduct alleged in paragraph 119 of the ~~CSOC~~ACSOC misleading or deceptive, if that conduct occurred (which is denied);

(d) as to the "Adequate and Well Controlled Trial Criteria", repeats paragraph 114(d) above;

(e) as to the FDA Information and Advice Regarding SR-aGVHD, repeats paragraph 63 above;

(f) says that, if Mesoblast did make the EAP 275 Reliance Representation on 13 December 2018, which is denied, says that it was a representation of present fact that was true; and

Particulars

In a meeting with the FDA on 29 November 2018, the FDA advised Mesoblast on the presentation of analyses across all trials of R-L, including EAP 275, in the context of stating that a single-arm trial of R-L as a therapy in the paediatric population with SR-aGVHD could support a BLA submission. Further particulars will be provided following the service of Mesoblast's evidence.

(g) denies the paragraph.

120. In answer to paragraph 120, Mesoblast:

(a) repeats that it denies making the R-L Manufacturing Representation;

(b) repeats that it denies that the Unapproved Consistency in Manufactured Product Information existed during the SR-aGVHD Claim Period;

(c) says that, if it did make the R-L Manufacturing Representation on 13 December 2018, which is denied, it was a representation of opinion which Mesoblast held and for which Mesoblast had a basis, alternatively a reasonable basis; and

Particulars

In dealings between Mesoblast and the FDA on or about 28 September 2018 and 2 October 2018, the FDA expressed views consistent with the R-L Manufacturing Representation.

(d) denies the paragraph.

121. In answer to paragraph 121, Mesoblast:

(a) repeats that it denies making the 13 December 2018 Basis Representation;

(b) refers to paragraphs 119 and 120 above; and

(c) denies the paragraph.

122. In answer to paragraph 122, Mesoblast:

(a) repeats that it denies making the FDA Issues Addressed Representation and 20 February 2019 Basis Representation;

(b) repeats that it denies the Study 001 Information existed during the SR-aGVHD Claim Period;

(c) as to the "2014 FDA Meeting Information", refers to paragraph 119(c) above;

(d) as to the FDA Information and Advice Regarding SR-aGVHD, repeats paragraph 63 above;

(e) says that, if it did make the FDA Issues Addressed Representation on 20 February 2019, which is denied, it was a representation of opinion which Mesoblast held and for which Mesoblast had a basis, alternatively a reasonable basis;

Particulars

At that time, the FDA had not raised with Mesoblast any key questions on clinical matters that remained unaddressed. Further particulars will be provided following service of Mesoblast's evidence.

123. In answer to paragraph 123, Mesoblast:

(a) repeats that it denies making the Three Studies Reliance Representation;

(b) repeats that it denies that the EAP 275 Information, the Protocol 280 Information, the Study 001 Information and the Differences in aGVHD Studies Information existed during the SR-aGVHD Claim Period;

(c) as to the "2014 FDA Meeting Information", refers to paragraph 119(c) above;

(d) as to the FDA Information and Advice Regarding SR-aGVHD, repeats paragraph 63 above;

(e) says that, if it did make the Three Studies Reliance Representation on 2 January 2020, which is denied, it was a representation of opinion which Mesoblast held and for which Mesoblast had a basis, alternatively a reasonable basis; and

Particulars

Mesoblast refers to the facts and matters set out in Mesoblast's ODAC Briefing Submission at pages 51 to 64. Further particulars will be provided following the service of Mesoblast's evidence.

(f) denies the paragraph.

123A. In answer to paragraph 123A, Mesoblast:

(a) says that the 16 April 2019 Address Substantial Matters Future Representation was a representation of present opinion which Mesoblast held and for which it had a basis, alternatively a reasonable basis;

Particulars

The rolling BLA process afforded Mesoblast an opportunity to engage with the FDA periodically prior to any final decision on the BLA, and the nature of that process could reasonably be expected to allow Mesoblast to address any substantial concerns of the FDA in respect of the BLA. Further, there was nothing at the time of the representation to indicate to Mesoblast that it would not be able to address any such concerns.

(b) alternatively, says that, if (which is denied) the 16 April 2019 Address Substantial Matters Future Representation was a representation as to a future matter:

(i) it was made in the context of a prominent warning as to forward-looking statements set out in the main body of the 16 April 2019 Announcement; and

Particulars

Mesoblast refers to the text in the 16 April 2019 Announcement under the heading "Forward-Looking Statements". Insofar as the 16 April 2019 Address Substantial Matters is a representation as a to future matter, which is denied, it fell to be interpreted by the Affected Market in light of the information under that heading.

(ii) in any event, Mesoblast had reasonable grounds for the representation; and

Particulars

Mesoblast repeats the particulars subjoined to subparagraph (a).

(c) denies the paragraph.

124. In answer to paragraph 124, Mesoblast:

(a) repeats that it denies making the MAGIC Comparison Data Representation;

(b) repeats that it denies that the Study 001 Information and the MAGIC Comparison Data Information existed during the SR-aGVHD Claim Period;

(c) says that, if it did make the MAGIC Comparison Data Representation, which is denied, it was a representation of opinion which Mesoblast held and for which Mesoblast had a basis, alternatively a reasonable basis; and

Particulars

Mesoblast refers to the facts and matters set out in Mesoblast's ODAC Briefing Submission at page 108. Mesoblast also refers to paragraph 60(c) and (e)(iii) above. Further particulars will be provided following the service of Mesoblast evidence.

(d) denies the paragraph.

125. In answer to paragraph 125, Mesoblast:

(a) repeats that it denies making the 2 January 2020 Basis Representation;

(b) refers to paragraphs 123 and 124 above; and

(c) denies the paragraph.

126. In answer to paragraph 126, Mesoblast:

(a) repeats that it denies making the Three Studies Confirmatory Evidence Representations and the 24 February Basis Representation;

(b) repeats that it denies that the EAP 275 Information, the Protocol 280 Information, the Study 001 Information and the Differences in aGVHD Studies Information existed during the SR-aGVHD Claim Period;

(c) as to the "2014 FDA Meeting Information", refers to paragraph 119(c) above;

(d) as to the FDA Information and Advice Regarding SR-aGVHD, repeats paragraph 63 above; and

(e) denies the paragraph.

127. In answer to paragraph 127, Mesoblast:

(a) repeats that it denies making the R-L Efficacy Representation and the 9 April 2020 Basis Representation;

(b) repeats that it denies that the Protocol 280 Information, the Protocol 265 Information, the EAP 275 Information, the Study 001 Information, the Differences in aGVHD Studies Information, the Inadequately Designed Trial for a-GVHD Information, the Non-compliance with FDA Advice regarding a-GVHD Information and the Unlikely to be Approved by FDA Information existed during the SR-aGVHD Claim Period;

(c) as to the "2014 FDA Meeting Information", refers to paragraph 119(c) above;

(d) as to the "Adequate and Well Controlled Trial Criteria", repeats paragraph 114(d) above;

(e) as to the FDA Information and Advice Regarding SR-aGVHD, repeats paragraph 63 above; and

(f) says that, if Mesoblast did make the R-L Efficacy Representation on 9 April 2020, which is denied, it was a representation of opinion which Mesoblast held and for which Mesoblast had a basis, alternatively a reasonable basis;

Particulars

Mesoblast refers to the facts and matters set out in Mesoblast's ODAC Briefing Submission under the headings "Efficacy", "Safety" and "Benefit-Risk Summary" in the Executive Summary, and the more detailed facts and matters set out in Section 5 "Clinical Efficacy" and Section 6 "Clinical Safety". Further particulars will be provided following service of Mesoblast's evidence.

(g) says that, in the premises, if Mesoblast did make the 9 April 2020 Basis Representation, it was true; and

(h) denies the paragraph.

D.3 COVID-19 Misleading Conduct

D.3.1 Conduct in trade or commerce

128. In answer to paragraph 128, Mesoblast:

(a) admits that, if Mesoblast engaged in the conduct pleaded in that paragraph, which is denied, it was conduct:

(i) in trade or commerce within the meaning of section 18 of the Australian Consumer Law (Victoria);

(ii) in trade or commerce, and in relation to financial services (being MSB Shares), within the meaning of section 12DA of the ASIC Act;

(iii) in relation to financial product or financial service (being MSB Shares) within the meaning of section 1041H of the Corporations Act;

(b) repeats paragraph 5(a)-(g) above; and

(c) otherwise denies the paragraph.

D.3.2 Continuing conduct

129. In answer to paragraph 129, Mesoblast:

(a) repeats that it denies making the COVID-19 ARDS Representations;

(b) says that, if Mesoblast made any of the COVID-19 ARDS Representations, which is denied, they were not continuing representations; and

(c) denies the paragraph.

D.3.3 Conduct was misleading

130. In answer to paragraph 130, Mesoblast:

(a) repeats that it denies making the Study 001 Support for R-L Use in COVID-19 Patients Future Representation;

(b) repeats that it denies that the SR-aGVHD Trial Deficiencies Information and the SR-aGVHD Approval Application Deficiencies information existed during the COVID-19 ARDS Claim Period;

(c) says that, if it did make the Study 001 Support for R-L Use in COVID-19 Patients Future Representation, which is denied:

(i) it was not a representation with respect to a future matter, as alleged by the Applicants;

(ii) rather, it was a representation of opinion with respect to one of two alternative present matters pleaded by the Applicants, namely, whether Study 001 provided support for R-L being effective to treat COVID-19 ARDS and whether Study 001 improved the likelihood that R-L was effective to treat COVID-19 ARDS patients;

(iii) Mesoblast held that opinion and had a basis, alternatively a reasonable basis, for ~~that representation of~~holding that opinion;

Particulars

The results of Study 001 supported R-L being effective to treat COVID-19 because: (a) the results of Study 001 indicated R-L worked by regulating the body's inflammatory response, including by regulating cytokine storms; and (b) COVID-19 ARDS was (and is) characterised by a severe inflammatory response in the lung, including cytokine storms. Further particulars will be provided following service of evidence.

(iv) alternatively, if the representation was with respect to a future matter, which is denied, Mesoblast had reasonable grounds for making it; and

Particulars

Mesoblast repeats the particulars to paragraph 130(c)(iii) above.

(d) denies the paragraph.

131. In answer to paragraph 131, Mesoblast:

(a) repeats that it denies making the Comparative Survival Representation;

(b) repeats that it denies that the COVID-19 Comparative Study Data Information existed during the COVID-19 ARDS Claim Period;

(c) says that, if it did make the Comparative Survival Representation on 24 April 2020, which is denied, it was a representation of present fact that was true; and

Particulars

There was an 83% survival rate in ventilator-dependent COVID-19 patients (10/12) with moderate/severe acute respiratory distress syndrome (ARDS) in the Pilot Study treated during the period March-April 2020 with two intravenous infusions of R-L within the first five days. There was a 12% survival rate in ventilator-dependent COVID-19 patients at two major referral hospital networks in New York during the same time period. Further particulars will be provided following the service of Mesoblast's evidence.

(d) denies the paragraph.

132. In answer to paragraph 132, Mesoblast:

(a) repeats that it denies making the Adequate and Well Designed Trial Representation;

(b) repeats that it denies that the Pilot Study Information, the COVID-19 Trial Information, the COVID-19 Comparative Study Data Information, the Difficulty with Primary Endpoint Information and the Low Likelihood of COVID-19 Trial Success Information existed during the COVID-19 ARDS Claim Period; and

(c) denies the paragraph.

133. In answer to paragraph 133, Mesoblast:

(a) repeats that it denies making the 24 April 2020 Basis Representation;

(b) refers to paragraphs 131 and 132 above; and

(c) denies the paragraph.

134. In answer to paragraph 134, Mesoblast:

(a) repeats that it denies making the Pilot Study Future Representation;

(b) repeats that it denies that the Pilot Study Information, the COVID-19 Trial Information and the COVID-19 Comparative Study Data Information existed during the COVID-19 ARDS Claim Period; and

(c) says that, if Mesoblast did make the Pilot Study Future Representation, which is denied, it had reasonable grounds for making it; and

Particulars

The results of the Pilot Study were highly promising. There was an 83% survival rate in ventilator-dependent COVID-19 patients (10/12) with moderate/severe ARDS treated during the period March-April 2020 with two intravenous infusions of R-L within the first five days Further particulars will be provided following service of Mesoblast's evidence.

(d) denies the paragraph.

135. In answer to paragraph 135, Mesoblast:

(a) repeats that it denies making the 30 July 2020 Representation and the 30 July 2020 Basis Representation;

(b) repeats that it denies that the Pilot Study Information, the COVID-19 Trial Information and the COVID-19 Comparative Study Data Information existed during the COVID-19 ARDS Claim Period; and

(c) denies the paragraph.

136. In answer to paragraph 136, Mesoblast:

(a) repeats that it denies making the COVID-19 Trial Primary Endpoint Representation and the 4 September 2020 Basis Representation;

(b) repeats that it denies that the Pilot Study Information, the COVID-19 Trial Information, the COVID-19 Comparative Study Data Information, the Difficulty with Primary Endpoint Information, Low Likelihood of COVID-19 Trial Success Information and the Actual COVID-19 Trial Results Information existed during the COVID-19 ARDS Claim Period;

(c) says that, if it did make the COVID-19 Trial Primary Endpoint Representation on 4 September 2020, which is denied, it was a representation of present fact that was true;

Particulars

As at 4 September 2020, Mesoblast did not have any reason to doubt that the results of the COVID-19 Trial to date showed a reduction in mortality rate caused by R-L treatment that was not materially lower than the Pilot Study or the COVID-19 Trial Primary Endpoint. Further particulars will be provided following service of Mesoblast evidence.

(d) says that, in the premises, if it did make the 4 September 2020 Basis Representation, which is denied, it was true; and

(e) denies the paragraph.

D.4 Misleading Conduct Contraventions

137. In answer to paragraph 137, Mesoblast:

(a) refers to paragraphs 111-112, 113-127, 128-129 and 130-136 above; and

(b) denies the paragraph.

E. CONTINUOUS DISCLOSURE CONTRAVENTIONS

138. In answer to paragraph 138, Mesoblast:

(a) as to subparagraph (g)(ii):

(i) says that the Applicants have not pleaded any material facts capable of supporting the allegation that Mesoblast knew that, or was reckless or negligent with respect to whether, the Material Information, if it were generally available, would have a material effect on the price or value of MSB Shares, within the meaning of s 674(2)(c)(ii) of the Corporations Act; and

(ii) denies the subparagraph; and

(b) otherwise denies the paragraph.

139. In answer to paragraph 139, Mesoblast:

(a) says that, at all times during the Claim Period, the obligation in ASX Listing Rule 3.1 was not engaged if ASX Listing Rule 3.1A applied to the information;

(b) says that, to the extent that any of:

(i) the Inadequately Designed Trial for aGVHD Information;

(ii) the Unlikely to be Approved by FDA Information;

(iii) the Study 001 No Support for ARDS Treatment Information; and

(iv) the Low Likelihood of COVID-19 Trial Success Information;

existed during the SR-aGVHD Claim Period or the COVID-19 ARDS Claim Period, as the case may be, ASX Listing Rule 3.1A applied to that information during that period because:

(v) during that period, a reasonable person would not have expected Mesoblast to disclose the information;

(vi) during that period, the information was a matter of supposition or insufficiently certain to warrant disclosure; and

(vii) during that period, the information was confidential and the ASX had not formed the view that the information had ceased to be confidential; and

(c) denies the paragraph.

140. In answer to paragraph 140, Mesoblast:

(a) admits that it did not communicate the "Material Information" (as pleaded by the Applicants) to the ASX during the SR-aGVHD Claim Period or the COVID-19 ARDS Claim Period as the case may be;

(b) says that it did not communicate the "Material Information" (as pleaded by the Applicants) to the ASX during the SR-aGVHD Claim Period or the COVID-19 ARDS Claim Period, as the case may be, because that information did not exist during those periods; and

(c) otherwise denies the paragraph.

141. In answer to paragraph 141, Mesoblast:

(a) refers to paragraphs 138-140 above; and

(b) denies the paragraph.

142. In answer to paragraph 142 above, Mesoblast:

(a) admits that, if Mesoblast engaged in the conduct pleaded in that paragraph, which is denied, it was conduct:

(i) in trade or commerce within the meaning of section 18 of the Australian Consumer Law (Victoria);

(ii) in trade or commerce, and in relation to financial services (being MSB Shares), within the meaning of section 12DA of the ASIC Act;

(iii) in relation to financial product or financial service (being MSB Shares) within the meaning of section 1041H of the Corporations Act;

(b) repeats paragraph 5(a)-(g) above; and

(c) otherwise denies the paragraph.

143. In answer to paragraph 143, Mesoblast:

(a) repeats that it denies the Continuous Disclosure Contraventions;

(b) repeats that it denies making the Cleansing Notice Representation and the 18 May 2020 Basis Representation; and

(c) denies the paragraph.

144. In answer to paragraph 144, Mesoblast:

(a) refers to paragraphs 142 and 143 above; and

(b) denies the paragraph.

144A. In further or alternative answer to the alleged Continuous Disclosure Contraventions, Mesoblast says that, if and to the extent that this Court finds that Mesoblast contravened or may have contravened section 674(2) of the Corporations Act as alleged (which is denied):

(a) Mesoblast acted honestly;

(b) having regard to all the circumstances of the case, Mesoblast ought fairly to be excused for the contravention; and

(c) this Court ought in its discretion relieve Mesoblast from liability for such contravention, pursuant to section 1317S of the Corporations Act.

F. CORRECTIVE DISCLOSURES AND THEIR IMPACT

F.1 11 August 2020 Disclosure and Price Fall

145. In response to paragraph 145, Mesoblast

(a) admits paragraph 145; and

(b) says further that the FDA Clinical Evidence Briefing Document and the FDA Product Characterisation Briefing Document (**FDA Briefing Documents**) contained, in the body of those documents, an extensive disclaimer statement noting, amongst other things, that the FDA Briefing Documents contained assessments and/or conclusions and recommendations written by individual FDA reviewers, and that such conclusions and recommendations did not necessarily represent the final position of the individual reviewers, nor did they necessarily represent the final position of the Review Division or Office, and that the FDA would not issue a final determination on the issues at hand until input from the advisory committee process had been considered and all reviews had been finalized.

146. In answer to paragraph 146, Mesoblast:

(a) admits that:

(i) the price of MSB Shares traded on the ASX declined by 31.01% ($1.51) from a closing price of $4.87 on 10 August 2020 to a closing price of $3.36 on 11 August 2020; and

(ii) the price of MESO ADRs declined by 34.96% (USD 6.09) from a closing price of USD 17.42 on 10 August 2020 (ET) to a closing price of USD 11.33 on 11 August 2020 (ET);

(b) says further that, following ODAC's 9-1 vote in favour of the efficacy of R-L in paediatric patients with SR-aGVHD, the price of Mesoblast Securities increased materially; and

Particulars

(1) The price of MESO ADRs increased by 51.40% (USD 6.07) from a closing price of USD 11.81 on 12 August 2020 (ET) to a closing price of USD 17.88 on 14 August 2020 (ET).

(2) The price of MESO ADRs increased by 10.79% (USD 1.93) from a closing price of USD 17.88 on 14 August 2020 (ET) to a closing price of USD 19.81 on 17 August 2020 (ET).

(3) The price of MSB Shares traded on the ASX increased by 39.05%% (AUD 1.32) from a closing price of AUD 3.38 on 13 August 2020 to a closing price of AUD 4.70 on 14 August 2020.

(4) The price of MSB Shares traded on the ASX increased by a further 4.47% (AUD 0.21) from a closing price of AUD 4.70 on 14 August 2020 to a closing price of AUD 4.91 on 17 August 2020.

(c) otherwise denies the paragraph.

F.2 18 December 2020 Disclosure and Price Fall

147. Mesoblast admits paragraph 147.

148. In answer to paragraph 148, Mesoblast:

(a) admits that:

(i) the price of MSB Shares traded on the ASX declined by 36.07% ($1.36) from a closing price of $3.77 on 16 December 2020 to a closing price of $2.41 on 18 December 2020; and

(ii) the price of MESO ADRs declined by 31.69% (USD 4.30) from a closing price of USD 13.57 on 15 December 2020 (ET) to a closing price of USD 9.27 on 18 December 2020 (ET);

(b) says that:

(i) MSB Shares were placed in a trading halt from 16 December 2020 to 17 December 2020;

(ii) MESO ADRs were placed in a trading halt from 16 December (ET) to 17 December 2020 (ET); and

(c) otherwise denies the paragraph.

G. CONTRAVENING CONDUCT CAUSED GROUP MEMBERS' LOSS

G.1 Market-based causation (on-market acquisitions)

149. In answer to paragraph 149, Mesoblast:

(a) admits that the Applicants and some Group Members acquired their interests in MSB Shares in a market operated by the ASX; and

(b) otherwise denies the paragraph.

150. Mesoblast denies paragraph 150.

151. Mesoblast denies paragraph 151.

152. Mesoblast denies paragraph 152.

153. Mesoblast denies paragraph 153.

154. In answer to paragraph 154, Mesoblast:

(a) refers to paragraphs 149 and 153 above; and

(b) denies the paragraph.

G.2 Market-based causation (capital raising acquisition)

155. In answer to paragraph 155, Mesoblast:

(a) admits that it issued 43 million fully paid ordinary shares at an issue price of $3.20 per share; and

(b) otherwise denies the paragraph.

G.3 Reliance

156. Mesoblast denies paragraph 156.

G.4 Loss or damage suffered by the Applicants and Group Members

157. Mesoblast denies paragraph 157.

158. In answer to paragraph 158, Mesoblast:

(a) refers to paragraph 2 above;

(b) will at trial refer to the full terms and effect of the releases given by class members in the proceeding *Kristal v Mesoblast Limited, et al.* as recorded in the Stipulation and approved by the US Judgment (**Releases**); and

(c) otherwise does not plead to the paragraph as it contains no allegation.

Date: ~~16 December 2022~~16 February 2024

Signed by David Taylor

Lawyer for the Respondent

This pleading was prepared by H. C. Whitwell and K. A. Loxley of counsel and settled by R. G. Craig KC.

Certificate of lawyer

I, David Taylor, certify to the Court that, in relation to the amended defence filed on behalf of the Respondent, the factual and legal material available to me at present provides a proper basis for:

(a) each allegation in the pleading;

(b) each denial in the pleading; and

(c) each non-admission in the pleading.

Date: ~~16 December 2022~~16 February 2024

Signed by David Taylor

Lawyer for the Respondent