based on the Mayo four stage prognostic staging system discussed in Kumar et al., 2012 (Kumar et al., Revised Prognostic Staging System for Light Chain Amyloidosis Incorporating Cardiac Biomarkers and Serum Free Light Chain Measurements, J Clin Oncol 30:989-995 2012), with the outcome for Stage IV patients being quite dire.

Current treatment of patients with AL amyloidosis is aimed at reducing or eliminating the bone marrow disorder, *i.e*. the plasma cells that are responsible for producing the light chains, thereby limiting or halting the production of amyloid. The most aggressive treatment options include stem cell transplant and high-dose chemotherapy for those patients who can tolerate it. Other treatment regimens include combinations of drugs often used to treat hematological malignancies, such as melphalan, prednisone, dexamethasone and proteosome inhibitors such as bortezomib, in an attempt to reduce light chain production. There are no currently approved treatments for AL amyloidosis, and none that directly target potentially toxic forms of the amyloidogenic proteins. While some treatment options may ameliorate some of the morbidity associated with AL amyloidosis, few if any have been demonstrated to improve the prognosis in patients. Furthermore, Mayo Stage IV patients with AL amyloidosis represent a patient subset with a very high burden of morbidity and mortality, with no currently approved treatments, and population estimates of approximately 2,760 patients in the U.S., and from 6,900 to 10,350 patients in the U.S. and the European Union combined.

Thus, there is an unmet need for therapies that improve health status, including reducing the risk of mortality or enhancing the quality of life in patients with AL amyloidosis.

SUMMARY

The present disclosure relates to methods of treating certain AL amyloidosis patients.

In one aspect, provided herein is a use of an antibody which competes for binding to human amyloid A peptide or human kappa or lambda light chain immunoglobulin with 2A4 (ATCC Accession Number PTA-9662) or 7D8 (ATCC Accession Number PTA-9468), or competes for binding to kappa light chain immunoglobulin with 11-1F4 (ATCC Accession Number PTA-105), in the manufacture of a medicament for treating a patient having AL amyloidosis, wherein the patient has (a) Mayo Stage IV AL amyloidosis, (b) a 6 minute walk distance (6MWD) ≥ 150 meters and EF > 50%, (c) Mayo Stage IV and an EF > 50% or (d) Mayo Stage IV and a 6MWD ≥ 150 meters and EF > 50%.

In one aspect, provided herein is a use of an antibody which competes for binding to human amyloid A peptide or human kappa or lambda light chain immunoglobulin with 2A4 (ATCC Accession Number PTA-9662) or 7D8 (ATCC Accession Number PTA-9468), or competes for binding to kappa light chain immunoglobulin with 11-1F4 (ATCC Accession Number PTA-105) in the manufacture of medicament for treating a patient with AL amyloidosis who has a demonstrated 6 minute walk distance (6MWD) of greater than or equal to 150 meters and an ejection fraction (EF) of more than 50%.

In one aspect, provided herein is a use of an antibody which competes for binding to human amyloid A peptide or human kappa or lambda light chain immunoglobulin with 2A4 (ATCC Accession Number PTA-9662) or 7D8 (ATCC Accession Number PTA-9468), or competes for binding to kappa light chain immunoglobulin with 11-1F4 (ATCC Accession Number PTA-105), in the manufacture of a medicament for reducing the risk of mortality in a patient with AL amyloidosis by at least 45%, wherein the patient has Mayo Stage IV AL amyloidosis and/or has a demonstrated 6 minute walk distance (6MWD) of greater than or equal to 150 meters and an ejection fraction (EF) of more than 50%, or the patient has Mayo Stage IV AL amyloidosis and an EF of > 50%.

In one aspect, provided herein is a use of an antibody which competes for binding to human amyloid A peptide or human kappa or lambda light chain immunoglobulin with 2A4 (ATCC Accession Number PTA-9662) or 7D8 (ATCC Accession Number PTA-9468), or competes for binding to kappa light chain immunoglobulin with 11-1F4 (ATCC Accession Number PTA-105) in the manufacture of a medicament for improving a 6 minute walk distance (6MWD) in a patient having AL amyloidosis.

Provided herein are methods of treating a patient having AL amyloidosis, comprising determining the Mayo Stage of the patient's AL amyloidosis, and/or the 6 minute walk distance (6MWD) and ejection fraction (EF) of the patient, or determining the Mayo Stage and EF of the patient, selecting the patient for treatment with an antibody which competes for binding to human amyloid A peptide or human kappa or lambda light chain immunoglobulin with 2A4 (ATCC Accession Number PTA-9662) or 7D8 (ATCC Accession Number PTA-9468), or competes for binding to human kappa (κ) or lambda light chain immunoglobulin with 11-1F4 (ATCC Accession Number PTA-105) if the patient has Mayo Stage IV AL amyloidosis, has a 6MWD ≥ 150 meters and an EF > 50% at baseline, has Mayo Stage IV and EF > 50% at baseline, or has Mayo Stage IV, a 6MWD ≥ 150 meters and an EF > 50% at

baseline, and administering an effective dosage of the antibody. In some examples, the patient has Mayo Stage IV AL amyloidosis. Some such Mayo Stage IV patients have an EF >50%, and some of such patients also have a 6MWD ≥ 150 meters.

Also provided herein are methods of treating a patient having AL amyloidosis, comprising administering an effective dosage of an antibody which competes for binding to human amyloid A peptide or human kappa or lambda light chain immunoglobulin with 2A4 (ATCC Accession Number PTA-9662) or 7D8 (ATCC Accession Number PTA-9468), or competes for binding to κ or lambda light chain immunoglobulin with 11-1F4 (ATCC Accession Number PTA-105), wherein the patient has (a) Mayo Stage IV AL amyloidosis (b) a 6 minute walk distance (MWD) ≥ 150 meters and an ejection fraction (EF) > 50%, (c) Mayo Stage IVC and an EF > 50% or (d) Mayo Stage IV and a 6MWD ≥ 150 meters and an EF > 50%. In some examples, the patient has Mayo Stage IV AL amyloidosis. In some examples, the patient has a 6MWD ≥ 150 meters and an EF > 50%, and some of such patients have Mayo Stage IV AL amyloidosis. In some examples, the Mayo Stage IV patients have an EF > 50%.

Provided herein are methods of treating a Mayo Stage IV patient with AL amyloidosis comprising administering an effective dosage of an antibody which competes for binding to human amyloid A peptide or human kappa or lambda light chain immunoglobulin with 2A4 (ATCC Accession Number PTA-9662) or 7D8 (ATCC Accession Number PTA-9468), or competes for binding to human kappa (κ) or lambda light chain immunoglobulin with 11-1F4 (ATCC Accession Number PTA-105). In some examples, the method reduces the risk of mortailtiy in the patient. In some examples, the method reduces the risk of all-cause mortality in the patient. In some examples, the method of treatment reduces the risk of cardiac mortality in the patient.

Provided herein are methods of treating a Mayo Stage IV patient with AL amyloidosis comprising administering an effective dosage of birtamimab. In some examples, the method reduces the risk of mortality in the patient. In some examples, the method reduces the risk of all-cause mortality in the patient. In some examples, the method of treatment reduces the risk of cardiac mortality in the patient. In some examples, the dosage is from about 0.5 mg/kg to about 30 mg/kg, and birtamimab is administered intravenously or subcutaneously at a frequency of from about weekly to about quarterly. In some examples, the dosage is about 24 mg/kg and birtamimab is administered intravenously every 28 days.

In some examples provided herein, antibody comprises a light chain variable region comprising three complementarity determining regions of 2A4, 7D8 or 11-1F4, and a heavy chain variable region comprising three complementarity determining regions of 2A4, 7D8 or 11-1F4, respectively. In some examples, the antibody is a humanized version of 2A4. In some examples the antibody is a humanized or chimeric version of 11-1F4.

In some examples, the antibody binds to the same epitope as 2A4, 7D8 or 11-1F4. In some examples the patient is administered an antibody which competes for binding to human amyloid A peptide or human kappa or lambda light chain immunoglobulin with 2A4 (ATCC Accession Number 9662) or or competes for binding to κ or lambda light chain immunoglobulin with 11-1F4 (ATCC Accession Number PTA-105). In some examples, the antibody binds to the same epitope as 2A4 or 11-1F4. In some examples, the antibody is a humanized version of 2A4. In some examples, the antibody is a humanized or chimeric version of 11-1F4. In some examples, the antibody is a humanized bispecific or multispecific version containing combinations of 11-1F4, 2A4, and/or 7D8.

In some examples provided herein, the antibody comprises a light chain variable region comprising three complementarity determining regions set forth as SEQ ID NOs: 3, 4 and 5, or SEQ ID NOs: 16, 17, and 18, and a heavy chain variable region comprising three complementarity determining regions set forth as SEQ ID NOs: 6, 7 and 8, or SEQ ID NOs:19, 20, and 21. In some examples, the light chain variable region of the antibody comprises the amino acid sequence set forth as SEQ ID NO: 1 or 14. In some examples, the heavy chain variable region of the antibody comprises the amino acid sequence set forth as SEQ ID NO: 2 or 15. In some examples, the light chain variable region comprises the amino acid sequence set forth as SEQ ID NO: 1 or 14 and the heavy chain variable region comprises the amino acid sequence set forth as SEQ ID NO: 2 or 15. In some examples provided herein, the antibody comprises a light chain comprising the amino acid sequence set forth as SEQ ID NO:10 and a heavy chain comprising the amino acid sequence set forth as SEQ ID NO: 11, 12 or 13. In some examples, the antibody comprises a light chain comprising the amino acid sequence set forth as SEQ ID NO:10 and a heavy chain comprising the amino acid sequence set forth as SEQ ID NO:12. In some examples, the antibody is birtamimab.

In some examples provided herein, the patient is newly diagnosed and AL amyloidosis treatment naïve. In some examples, the patient previously received or concomitantly receives treatment with melphalan, prednisone, dexamethasone, bortezomib, cyclophosphamide, lenalidomide, doxorubicin, doxycycline, daratumumab, autologous

transplant or a combination thereof. In certain methods, the patient previously received or concomitantly receives treatment with humanized 2A4, 7D8, or 11-1F4 in advance of recreiving plasma cell therapy.

Provided herein are methods comprising administering to a Mayo Stage IV patient an effective dosage of an antibody which competes for binding to human amyloid A peptide or human kappa or lambda light chain immunoglobulin with antibody 2A4 (ATCC Accession Number 9662) or 7D8 (ATCC Accession Number PTA-9468), or competes for binding to kappa light chain immunoglobulin with 11-1F4 (ATCC Accession Number PTA-105), thereby reducing the patient's relative risk of mortality by at least about 35%.

Also provided herein are methods of treating a patient with AL amyloidosis, comprising determining that the patient has a 6 minute walk distance (6MWD) ≥ 150 meters and an ejection fraction (EF) > 50%, selecting the patient for treatment with an antibody which competes for binding to human amyloid A peptide or human kappa or lambda light chain immunoglobulin with antibody 2A4 (ATCC Accession Number PTA-9662) or 7D8 (ATCC Accession Number PTA-9468), or competes for binding to kappa light chain immunoglobulin with 11-1F4 (ATCC Accession Number PTA-105), and administering an effective dosage of the antibody.

Also provided herein are methods of treating a patient with AL amyloidosis who has a demonstrated 6 minute walk distance (6MWD) of greater than or equal to 150 meters and an ejection fraction (EF) of more than 50%, comprising administering to the patient an effective dosage of an antibody which competes for binding to human amyloid A peptide or human kappa or lambda light chain immunoglobulin with antibody 2A4 (ATCC Accession Number PTA-9662) or 7D8 (ATCC Accession Number PTA-9468), or competes for binding to κ light chain immunoglobulin with 11-1F4 (ATCC Accession Number PTA-105).

Also provided herein are methods of improving a 6 minute walk distance (6MWD) in a patient having AL amyloidosis, comprising administering to the patient an effective dosage of an antibody which competes for binding to human amyloid A peptide or human kappa or lambda light chain immunoglobulin with antibody 2A4 (ATCC Accession Number PTA-9662) or 7D8 (ATCC Accession Number PTA-9468), or competes for binding to kappa light chain immunoglobulin with 11-1F4 (ATCC Accession Number PTA-105). In some examples, the patient has Mayo Stage IV AL amyloidosis. In some examples, the patient has an EF > 50%. In some examples, the Mayo Stage IV patients have an EF > 50%.

Also provided herein are methods of reducing the risk of mortality in a patient with AL amyloidosis by at least 45% relative to control conditions (relative risk), comprising administering to the patient an effective dosage of an antibody which competes for binding to human amyloid A peptide or human kappa or lambda light chain immunoglobulin with antibody 2A4 (ATCC Accession Number PTA-9662) or 7D8 (ATCC Accession Number PTA-9468), or competes for binding to kappa light chain immunoglobulin with 11-1F4 (ATCC Accession Number PTA-105), wherein the patient has Mayo Stage IV AL amyloidosis and/or has a demonstrated 6 minute walk distance (6MWD) of greater than or equal to 150 meters and an ejection fraction (EF) of more than 50% or has Mayo Stage IV AL amyloidosis and an EF > 50%. In some examples, the method reduces the risk of all-cause mortality in the patient. In some examples, the risk of all-cause mortality is reduced by at least about 48.9% relative to control conditions. In some examples, the risk of all-cause mortality is reduced by at least about 50% relative to control conditions. In some examples, the risk of all-cause mortality is reduced by at least about 50.2% relative to control conditions. In some examples, the risk of all-cause mortality is reduced by at least about 60% relative to control conditions. In some examples, the risk of all-cause mortality is reduced by at least about 70% relative to control conditions. In some examples the risk of all-cause mortality is reduced by at least about 75% relative to control conditions. In some examples, the risk of all-cause mortality is reduced by at least about 79.9% relative to control conditions. In some examples, the risk of all-cause mortality is reduced by at least 81.5% relative to control conditions. In some examples, the method reduces the risk of cardiac mortality in the patient. In some examples, the risk of cardiac mortality is reduced by at least about 62.2% relative to control conditions. In some examples, the risk of cardiac mortality is reduced by at least about 75% relative to control conditions.

In some examples provided herein, the patient exhibits improvement in the 36-Item Short Form Survey Physical Component Score (SF-36 PCS) or SF-36v2 following treatment with the antibody. In some examples, after nine months of treatment the change in the patient's score on the SF-36 PCS or SF-36v2 is at least 5 points higher relative to a different patient at the same time point who has not been administered the antibody.

In some examples provided herein, the effective dosage of the antibody is administered from a pharmaceutical formulation comprising the antibody at a concentration within the range from about 1 mg/mL to about 100 mg/mL. In some examples provided herein, the effective dosage of the antibody is administered from a pharmaceutical

formulation comprising, histidine buffer at a concentration within the range from about 20 mM to about 30 mM, trehalose at a concentration within the range from about 210 mM to about 250 mM, and polysorbate 20 at a concentration within the range from about 0.005% to about 0.05% by weight, and the formulation has a pH within the range from about 6 to about 7. In some examples, the dosage is from about 0.5 mg/kg to about 30 mg/kg and the antibody is administered intravenously or subcutaneously at a frequency of from about weekly to about quarterly. In some examples, the antibody is present at a concentration of about 50 mg/mL. In some examples provided herein, the pharmaceutical formulation comprises, the histidine buffer at a concentration of about 25 mM, the trehalose at a concentration of about 230 mM, the polysorbate 20 at a concentration of about 0.2 g/L, and the pH is about 6.5.

In some examples provided herein, the dosage is administered subcutaneously without dilution from a vial containing the formulation. In some examples, the dosage is administered intravenously following the transfer of an amount of the formulation required for the dosage from a vial to an intravenous bag containing a liquid.

In some examples provided herein, the dosage is about 24 mg/kg and the antibody is administered intravenously every 28 days. In some examples provided herein, the dosage is administered intravenously (IV) at 24 mg/kg (dose not to exceed 2500 mg) once every 28 days (± 5 days). In some examples, the duration of the treatment is at least 9 months. In some examples, the duration of the treatment is at least 12 months. In some examples, the duration is effective to achieve or maintain at least about a 3 point increase from baseline in SF-36 PCS.

In some examples provided herein, the antibody is a Fab, Fab', $F(ab')_2$, F(ab)c, Dab, nanobody or Fv.

Also provided herein is an antibody which competes for binding to human amyloid A peptide or human kappa or lambda light chain immunoglobulin with antibody 2A4 (ATCC Accession Number PTA-9662) or 7D8 (ATCC Accession Number PTA-9468), or competes for binding to kappa light chain immunoglobulin with 11-1F4 (ATCC Accession Number PTA-105) for use in a method of treating a patient with Mayo Stage IV AL amyloidosis, a patient who has at baseline a demonstrated 6 minute walk distance (6MWD) of greater than or equal to 150 meters and an ejection fraction (EF) of more than 50%, a Mayo Stage IV patient who has at baseline an EF of more than 50%, or a Mayo Stage IV patient who has at baseline a 6MWD of greater than or equal to 150 meters and an EF of more than 50%. In some examples, the antibody is a humanized version of 2A4. Some such antibodies comprise

a light chain variable region comprising three complementarity determining regions set forth as SEQ ID NOs: 3, 4 and 5, or SEQ ID NO:16, 17, and 18, and a heavy chain variable region comprising three complementarity determining regions set forth as SEQ ID NOs: 6, 7 and 8,or SEQ ID NOs:19, 20 and 21. In some antibodies the light chain variable region comprises the amino acid sequence set forth as SEQ ID NO: 1 of 14. In some antibodies, the heavy chain variable region comprises the amino acid sequence set forth as SEQ ID NO: 2 or 15. In some antibodies the light chain variable region comprises the amino acid sequence set forth as SEQ ID NO: 1 or 14 and the heavy chain variable region comprises the amino acid sequence set forth as SEQ ID NO: 2 or 15.

Some antibodies provided herein are formulated as a pharmaceutical formulation comprising the antibody at a concentration within the range from about 1mg/mL to about 100 mg/mL, histidine buffer at a concentration within the range from about 20 mM to about 30 mM, trehalose at a concentration within the range from about 210 mM to about 250 mM, polysorbate 20 at a concentration within the range from about 0.005% to about 0.05% by weight, and the pharmaceutical formulation is characterized by a pH within the range from about 6 to about 7.

Some uses of the antibody comprise a dosage from about 0.5 mg/kg to about 30 mg/kg and wherein the antibody is administered intravenously or subcutaneously at a frequency of from about weekly to about quarterly. For some uses, the antibody is present at a concentration of about 50 mg/mL, the histidine buffer is present at a concentration of about

25 mM, the trehalose is present at a concentration of about 230 mM, the polysorbate 20 is present at a concentration of about 0.2 g/L, and the pH is about 6.5.

Also provided herein are methods of identifying a patient likely to receive a health benefit from treatment with an antibody which competes for binding to human amyloid A peptide or human kappa or lambda light chain immunoglobulin with antibody 2A4 (ATCC Accession Number PTA-9662) or 7D8 (ATCC Accession Number PTA-9468), or competes for binding to kappa light chain immunoglobulin with 11-1F4 (ATCC Accession Number PTA-105), comprising determining (a) whether the patient has Mayo Stage I, Stage II, Stage III or Stage IV AL amyloidosis, (b) the 6 minute walk distance (6MWD) of the patient, and/or (c) the ejection fraction (EF) of the patient, and selecting for treatment a patient with (i) Stage IV AL amyloidosis, (ii) a patient with a 6MWD ≥ 150 meters and an EF > 50%, (iii) Stage IV AL amyloidosis and a 6MWD ≥ 150 meters and an EF > 50%, or (iv) Stage IV AL amyloidosis and an EF > 50%. In some examples, the selected patient has Mayo Stage IV AL amyloidosis. In some examples, the selected patient has a 6MWD ≥ 150 meters and an ejection fraction > 50%. In some examples, the selected patient has Mayo Stage IV AL amyloidosis and a 6MWD ≥ 150 meters and an ejection fraction > 50%. Some methods further comprise administering intravenously to the patient a dose in the range of about 0.5 mg/m2 to about 500 mg/m2 of a chimeric or humanized version of 11-1F4, or a dose in the range of about 0.5 mg/kg to about 30 mg/kg of a humanized version of 2A4.

BRIEF DESCRIPTION OF THE DRAWINGS

Figures 1A-1B show the primary endpoint through 12 months (all-cause mortality or cardiac hospitalization ≥ 91 days) in AL amyloidosis patients treated with NEOD001 vs placebo in Mayo Stage I-III patients (Figure 1A) and Mayo Stage IV patients (Figure 1B), respectively.

Figures 2A-2B show the all-cause mortality in AL amyloidosis patients treated with NEOD001 vs placebo in Mayo Stage I-III patients (Figure 2A) and Mayo Stage IV patients (Figure 2B), respectively.

Figures 3A-3B show the cardiac mortality through 12 months in AL amyloidosis patients treated with NEOD001 vs placebo in Mayo Stage I-III patients (Figure 3A) and Mayo Stage IV patients (Figure 3B), respectively.

Figures 4A-4B show the all-cause mortality in AL amyloidosis patients with a baseline 6MWD ≥ 150 meters and EF > 50% that are treated with NEOD001 vs placebo for all Mayo Stages (Figure 4A) and in Mayo Stage IV patients (Figure 4B), respectively.

Figure 5 shows Kaplan-Meier Estimate of Primary Composite Endpoint of Time to ACM or CH.

Figure 6 shows Kaplan-Meier Estimate of ACM in Stage IV (mITT).

CLAIMS

What is claimed is:

1. Use of an antibody which competes for binding to human amyloid A peptide or human kappa or lambda light chain immunoglobulin with 2A4 (ATCC Accession Number PTA-9662) or 7D8 (ATCC Accession Number PTA-9468), or competes for binding to kappa light chain immunoglobulin with 11-1F4 (ATCC Accession Number PTA-105), in the manufacture of a medicament for treating a patient having AL amyloidosis, wherein the patient has (a) Mayo Stage IV AL amyloidosis, (b) a 6 minute walk distance (6MWD) ≥ 150 meters and EF > 50%, (c) Mayo Stage IV and an EF > 50% or (d) Mayo Stage IV and a 6MWD ≥ 150 meters and EF > 50%.

2. The use of claim1, wherein the patient has Mayo Stage IV AL amyloidosis.

3. The use of claim1, wherein the patient has a 6MWD ≥ 150 meters and an EF > 50%.

4. The use of claim2, wherein the patient has a 6MWD ≥ 150 meters and an EF > 50%.

5. The use of claim2, wherein the patient has an EF > 50%.

6. The use of any of the preceding claims, wherein the antibody comprises a light chain variable region comprising three complementarity determining regions of 2A4, 7D8 or 11-1F4, and a heavy chain variable region comprising three complementarity determining regions of 2A4, 7D8 or 11-1F4, respectively.

7. The use of any of the preceding claims, wherein the antibody is a humanized version of 2A4.

8. The use of any of claims1-6, wherein the antibody is a humanized or chimeric version of 11-1F4.

9. The use of any of claims1-5, wherein the antibody comprises a light chain variable region comprising three complementarity determining regions set forth as SEQ ID NOs: 3, 4 and 5, or SEQ ID NOs: 16, 17, and 18, and a heavy chain variable region comprising three

complementarity determining regions set forth as SEQ ID NOs: 6, 7 and 8, or SEQ ID NOs: 19, 20, and 21.

10. The use of any of claims1-5, wherein the light chain variable region comprises the amino acid sequence set forth as SEQ ID NO: 1 or 14.

11. The use of any of claims1-5, wherein the heavy chain variable region comprises the amino acid sequence set forth as SEQ ID NO: 2 or 15.

12. The use of any of claims1-5, wherein the light chain variable region comprises the amino acid sequence set forth as SEQ ID NO: 1 or 14, and the heavy chain variable region comprises the amino acid sequence set forth as SEQ ID NO: 2 or 15.

13. The use of any of claims1-5, wherein the antibody comprises a light chain comprising the amino acid sequence set forth as SEQ ID NO:10, and a heavy chain comprising the amino acid sequence set forth as SEQ ID NO: 11, 12 or 13.

14. The use of any of claims1-5, wherein the antibody comprises a light chain comprising the amino acid sequence set forth as SEQ ID NO:10, and a heavy chain comprising the amino acid sequence set forth as SEQ ID NO:12.

15. The use of any of claims1-5, wherein the antibody is birtamimab.

16. The use of any of the preceding claims, wherein the patient is newly diagnosed and AL amyloidosis treatment naïve.

17. The use of any of claims1-5, wherein the patient previously received or concomitantly receives treatment with melphalan, prednisone, dexamethasone, bortezomib, cyclophosphamide, lenalidomide, doxorubicin, doxycycline, daratumumab, autologous transplant, or a combination thereof.

18. The use of any of claims2 or 4, wherein the patient's risk of mortality is reduced by at least about 35%.

19. Use of an antibody which competes for binding to human amyloid A peptide or human kappa or lambda light chain immunoglobulin with 2A4 (ATCC Accession Number PTA-9662) or 7D8 (ATCC Accession Number PTA-9468), or competes for binding to kappa light chain immunoglobulin with 11-1F4 (ATCC Accession Number PTA-105) in the manufacture of medicament for treating a patient with AL amyloidosis who has a demonstrated 6 minute walk distance (6MWD) of greater than or equal to 150 meters and an ejection fraction (EF) of more than 50%.

20. Use of an antibody which competes for binding to human amyloid A peptide or human kappa or lambda light chain immunoglobulin with 2A4 (ATCC Accession Number PTA-9662) or 7D8 (ATCC Accession Number PTA-9468), or competes for binding to kappa light chain immunoglobulin with 11-1F4 (ATCC Accession Number PTA-105), in the manufacture of a medicament for reducing the risk of mortality in a patient with AL amyloidosis by at least 45%, wherein the patient has Mayo Stage IV AL amyloidosis and/or has a demonstrated 6 minute walk distance (6MWD) of greater than or equal to 150 meters and an ejection fraction (EF) of more than 50%, or the patient has Mayo Stage IV AL amyloidosis and an EF of > 50%.

21. The use of claim 20, wherein the risk of mortality is of all-cause mortality.

22. The use of claim 21, wherein the risk of all-cause mortality is reduced by at least about 48.9%.

23. The use of claim 21, wherein the risk of all-cause mortality is reduced by at least about 50%.

24. The use of claim 21, wherein the risk of all-cause mortality is reduced by at least about 50.2%.

25. The use of claim 21, wherein the risk of all-cause mortality is reduced by at least about 60%.

26. The use of claim 21, wherein the risk of all-cause mortality is reduced by at least about 70%.

27. The use of claim 21, wherein the risk of all-cause mortality is reduced by at least about 79.9%.

28. The use of claim 21, wherein the risk of all-cause mortality is reduced by at least about 81.5%.

29. The use of claim 20, wherein the risk of mortality is of cardiac mortality.

30. The use of claim 29, wherein the risk of cardiac mortality is reduced by at least about 75%.

31. The use of 29, wherein the risk of cardiac mortality is reduced by at least about 62.2%.

32. The use of any of claims 19-31, wherein the antibody is birtamimab.

33. The use of any of the preceding claims, wherein the patient exhibits improvement in the 36-Item Short Form Survey Physical Component Score (SF-36 PCS) or SF-36v2 following treatment with the antibody.

34. The use of claim 33, wherein after nine months of treatment the change in the patient's score on the SF-36 PCS or SF-36v2 is at least 5 points higher relative to a different patient at the same time point who has not been administered the antibody.

35. The use of any of the preceding claims, wherein an effective dosage of the antibody is to be administered from a pharmaceutical formulation comprising the antibody at a concentration within the range from about 1mg/mL to about 100 mg/mL.

36. The use of any of the preceding claims, wherein a dosage is from about 0.5 mg/kg to about 30 mg/kg and the antibody is to be administered intravenously or subcutaneously at a frequency of from about weekly to about quarterly.

37. The use of claim 35, wherein the antibody is present at a concentration of about 50 mg/mL.

38. The use of any of claims 35-37, wherein the dosage is to be administered intravenously following the transfer of an amount of the formulation required for the dosage from a vial to an intravenous bag containing a liquid.

39. The use of any claims 41-43, wherein the dosage is about 24 mg/kg and the antibody is to be administered intravenously every 28 days.

40. The use of any of the preceding claims, wherein the duration of the treatment is at least 9 months.

41. The use of claim 24, wherein the duration of the treatment is at least 12 months.

42. The use of any of the preceding claims, wherein the duration is effective to achieve or maintain at least about a 3 point increase from baseline in SF-36 PCS or SF-36v2.

43. The use of any of the preceding claims, wherein the antibody is a Fab, Fab', $F(ab')_2$, F(ab)c, Dab, nanobody, or Fv.

44. Use of an antibody which competes for binding to human amyloid A peptide or human kappa or lambda light chain immunoglobulin with 2A4 (ATCC Accession Number PTA-9662) or 7D8 (ATCC Accession Number PTA-9468), or competes for binding to kappa light chain immunoglobulin with 11-1F4 (ATCC Accession Number PTA-105) in the manufacture of a medicament for improving a 6 minute walk distance (6MWD) in a patient having AL amyloidosis.

45. The use of claim 44, wherein the AL amyloidosis is Mayo Stage IV AL amyloidosis.

46. The use of claim 44 or claim 45, wherein an ejection fraction (EF) of the patient is > 50%.

47. The use of any of claims 44-46, wherein the antibody in birtamimab.