

What is claimed is:

1. Use of a JAK inhibitor in the manufacture of a pharmaceutical composition for treating of a human subject having acute Graft-Versus-Host Disease (GvHD), wherein the human subject has been previously determined to have (i) a baseline concentration of
5 at least one protein selected from the group consisting of MCP-3, CA5A, IL8, CXCL10, IL6, CCL19, CTSL1, ACE2, ALDH1A1, TNFRSF6B, KYNU, FOSB, ALDH3A1, and DDAH1 in a biological sample obtained from the human subject that is lower than a control, and/or (ii) a baseline concentration of at least one protein selected from the group consisting of PON3, SCF, GH, SRC, and CR2 in a biological sample obtained from the
10 human subject that is higher than a control;

wherein the biological sample is blood, serum, or plasma;

wherein the reduced protein concentration of at least one protein selected from the group consisting of MCP-3, CA5A, IL8, CXCL10, IL6, CCL19, CTSL1, ACE2, ALDH1A1, TNFRSF6B, KYNU, FOSB, ALDH3A1, and DDAH1 compared to the
15 control, and/or the increased protein concentration of at least one protein selected from the group consisting of PON3, SCF, GH, SRC, and CR2 compared to the control, is predictive that the subject will respond to therapy comprising the JAK inhibitor; and

wherein the control is the concentration of the protein in a sample or samples obtained from one or more subjects that have not responded to treatment with the JAK
20 inhibitor.

2. The use according to claim 1, wherein the human subject has been previously determined to have the baseline concentration of MCP-3 in the biological sample obtained from the human subject that is lower than the control, wherein the
25 reduced protein concentration of MCP-3 compared to the control is predictive that the

subject will respond to therapy comprising the JAK inhibitor.

3. Use of a JAK inhibitor in the manufacture of a medicament for the treatment of a human subject having acute Graft-Versus-Host Disease (GvHD), wherein
5 the medicament is adapted for use in a method comprising the steps:

providing a biological sample obtained from the human subject, wherein the biological sample is blood, serum, or plasma;

measuring in the biological sample a reduced concentration, as compared to a control, of at least one protein selected from the group consisting of MCP-3, CA5A,
10 IL8, CXCL10, IL6, CCL19, CTSL1, ACE2, ALDH1A1, TNFRSF6B, KYNU, FOSB, ALDH3A1, and DDAH1, and/or an increased concentration, as compared to a control, of at least one protein selected from the group consisting of PON3, SCF, GH, SRC, and CR2; and

administering the medicament to the human subject;

15 wherein the reduced protein concentration of at least one protein selected from the group consisting of MCP-3, CA5A, IL8, CXCL10, IL6, CCL19, CTSL1, ACE2, ALDH1A1, TNFRSF6B, KYNU, FOSB, ALDH3A1, and DDAH1 compared to the control, and/or the increased protein concentration of at least one protein selected from the group consisting of PON3, SCF, GH, SRC, and CR2 compared to the control, is
20 predictive that the subject will respond to therapy comprising the JAK inhibitor; and

wherein the control is the concentration of the protein in a sample or samples obtained from one or more subjects that have not responded to treatment with the JAK inhibitor.

4. The use of claim 3, wherein the method comprises measuring in the biological sample the reduced concentration, as compared to the control, of MCP-3, wherein the reduced protein concentration of MCP-3 compared to the control is predictive that the subject will respond to therapy comprising the JAK inhibitor.

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5. The use according to any one of claims 1 to 4, wherein a second therapeutic agent is to be administered with the JAK inhibitor.

6. The use according to claim 5, wherein the second therapeutic agent is a corticosteroid, methotrexate, cyclosporine, mycophenolate mofetil, tacrolimus, sirolimus, everolimus, antithymocyte globulin, alemtuzumab, cyclophosphamide, ibrutinib, imatinib, infliximab, etanercept, tocilizumab, alemtuzumab, basiliximab, daclizumab, rituximab, denileukin diftitox, pentostatin, ciclosporin, thalidomide, halofuginone, hydroxychloroquine, or mesenchymal stem cells.

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7. The use according to claim 5, wherein the second therapeutic agent is a corticosteroid.

8. The use according to claim 7, wherein the second therapeutic agent is methylprednisolone or prednisone.

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9. An *in vitro* method of predicting the response of a human subject having acute Graft-Versus-Host Disease (GvHD) to a therapy comprising a JAK inhibitor, comprising:

providing a biological sample obtained from the subject before the therapy comprising the JAK inhibitor, wherein the biological sample is blood, serum, or plasma; and

measuring the concentration of at least one protein selected from the group consisting of PON3, SCF, GH, SRC, CR2, MCP-3, CA5A, IL8, CXCL10, IL6, CCL19, CTSL1, ACE2, ALDH1A1, TNFRSF6B, KYNU, FOSB, ALDH3A1, and DDAH1 in the biological sample,

wherein a reduced concentration, as compared to a control, of at least one of MCP-3, CA5A, IL8, CXCL10, IL6, CCL19, CTSL1, ACE2, ALDH1A1, TNFRSF6B, KYNU, FOSB, ALDH3A1, and/or DDAH1, and/or an increased concentration, as compared to a control, of at least one of PON3, SCF, GH, SRC, and/or CR2 is predictive that the subject will respond to the therapy comprising the JAK inhibitor, and

wherein the control is the concentration of the protein in a sample or samples obtained from one or more subjects that have not responded to treatment with the JAK inhibitor.

10. The method of claim 9, wherein the method comprises measuring the concentration of MCP-3 in the biological sample, wherein a reduced concentration, as compared to a control, of MCP-3 is predictive that the subject will respond to the therapy comprising the JAK inhibitor.

11. The use according to any one of claims 1 to 8, or the method of claim 9 or 10, wherein the concentration of the protein is measured by an immunological method.

12. The use according to claim 11, or the method according to claim 11,
wherein the immunological method is selected from the group consisting of enzyme-
linked immunosorbent assay, enzyme immunoassay, radioimmunoassay,
chemiluminescent immunoassay, electrochemiluminescence immunoassay, latex
5 turbidimetric immunoassay, latex photometric immunoassay, immuno-chromatographic
assay, and western blotting.

13. The use according to any one of claims 1 to 8, or the method of claim 9
or 10, wherein the concentration of the protein is measured by mass spectrometry.

14. The use according to any one of claims 1 to 8 and 11 to 13, or the
method of any one of claims 9 to 13, wherein the JAK inhibitor is itacitinib.

15. The use according to any one of claims 1 to 8 and 11 to 14, or the
method of any one of claims 9 to 13, wherein the JAK inhibitor is 4-[3-(cyanomethyl)-
3-(3',5'-dimethyl-1H,1'H-4,4'-bipyrazol-1-yl)azetidin-1-yl]-2,5-difluoro-N-[(1S)-2,2,2-
trifluoro-1-methylethyl]benzamide or a pharmaceutically acceptable salt thereof or
((2R,5S)-5-{2-[(1R)-1-hydroxyethyl]-1H-imidazo[4,5-d]thieno[3,2-b]pyridin-1-
yl}tetrahydro-2H-pyran-2-yl)acetonitrile or a pharmaceutically acceptable salt thereof.