Erythematosus Classification Criteria (DLECC) score, Score of Activity and Damage in Discoid Lupus Erythematosus (SADDLE), onset of new discoid lesions, size of lesions, or dyspigmentation of a discoid lesion, as compared to a baseline level of the subject before the administering. In examples, the autoimmune disease is alopecia areata, and wherein the pharmaceutically effective amount is about 300 mg. In examples, the administering is effective in stabilizing or reducing hair loss in the subject as determined by a stable or reduced Severity of Alopecia Tool (SALT) score and/or Alopecia Density and Extent (ALODEX) score. In examples, the ILT7-binding protein is administered with one or more additional therapies. In examples, the one or more additional therapies comprises a corticosteroid. In examples, the corticosteroid is prednisone. In examples, the administration of the one or more additional therapies is tapered. In examples, the pharmaceutically effective amount of the ILT7-binding protein is from about 150-300 mg. In examples, the pharmaceutically effective amount of the ILT7-binding protein is from about 200-300 mg. In examples, the ILT7-binding protein is administered once about every four weeks or once about every twelve weeks. In examples, the pharmaceutically effective amount of the ILT7-binding protein is about 300 mg and the 300 mg is administered as two doses of 150 mg each.

[0006] Provided are methods of treating discoid lupus erythematosus (DLE) in a subject in need thereof, the method comprising administering to the subject a pharmaceutically effective amount of an immunoglobulin-like transcript 7 (ILT7)-binding protein, wherein the pharmaceutically effective amount of the ILT7-binding protein is from about 100 to about 300 mg.

[0006a] In one aspect, the present disclosure refers to use of an immunoglobulin-like transcript 7 (ILT7)-binding protein in the manufacture of a medicament for the treatment of discoid lupus erythematosus (DLE) in a subject in need thereof, wherein a pharmaceutically effective amount of an immunoglobulin-like transcript 7 (ILT7)-binding protein is to be administered to the subject, wherein the ILT7 binding protein is an antibody that comprises heavy chain Complementarity-Determining Regions (HCDRs) HCDR1, HDR2, HCDR3, and light chain Complementarity Determining Regions (LCDRs) LCDR1, LCDR2, and LCDR3 comprising the amino acid sequences of SEQ ID NOs: 3, 4, 5, 6, 7, and 8, respectively and wherein the pharmaceutically effective amount of the ILT7-binding protein is from 100 to 300 mg.

[0007] Provided are methods of treating systemic lupus erythematosus (SLE) in a subject in need thereof, the method comprising administering to the subject a pharmaceutically effective amount of an immunoglobulin-like transcript 7 (ILT7)-binding protein, wherein the pharmaceutically effective amount of the ILT7-binding protein is from about 200 mg.

[0008] Provided are methods of treating lupus nephritis in a subject in need thereof, the method comprising administering to the subject a pharmaceutically effective amount of an immunoglobulin-like transcript 7 (ILT7)-binding protein, wherein the pharmaceutically effective amount of the ILT7-binding protein is from about 300 mg.

[0009] Provided are methods of treating alopecia areata in a subject in need thereof, the method comprising administering to the subject a pharmaceutically effective amount of an

immunoglobulin-like transcript 7 (ILT7)-binding protein, wherein the pharmaceutically effective amount of the ILT7-binding protein is from about 300 mg.

[0010] Provided are methods of treating dermatomyositis in a subject in need thereof, the method comprising administering to the subject a pharmaceutically effective amount of an immunoglobulin-like transcript 7 (ILT7)-binding protein.

[0011] Provided are methods of treating Anti-Synthetase Inflammatory Myositis in a subject in need thereof, the method comprising administering to the subject a pharmaceutically effective amount of an immunoglobulin-like transcript 7 (ILT7)-binding protein.

[0012] In examples, the pharmaceutically effective amount of the ILT7-binding protein of any of the provided methods of treatment is from about 100 mg to about 300 mg. In examples, ILT7 binding protein is an antibody that comprises heavy chain Complementarity-Determining Regions (HCDRs) HCDR1, HDR2, HCDR3, and light chain Complementarity Determining Regions (LCDRs) LCDR1, LCDR2, and LCDR3 comprising the amino acid sequences of SEQ ID NOs: 3, 4, 5, 6, 7, and 8, respectively. In examples, ILT7 binding protein is an antibody comprising a variable heavy chain (VH) that is at least 85%, 90%, 95%, 96%, 97%, 98% or 99% identical to SEQ ID NO:1 and/or a variable light chain (VL) that is at least 85%, 90%, 95%, 96%, 97%, 98% or 99% identical to SEQ ID NO:2. In examples, the ILT7-binding protein is an antibody comprising a heavy chain variable region (VH) of SEQ ID NO:1 and a light chain variable region (VL) of SEQ ID NO:2. In examples, the ILT7 binding protein is afucosylated. In examples, the ILT7 binding protein is Daxdilimab. In examples, the administration is subcutaneous. In examples, the subject is administered the ILT7-binding protein every 4 weeks. In examples, the subject is administered the ILT7-binding protein every 12 weeks. In examples, prior to the administering, the subject is administered at least one initial dose of the ILT7-binding protein. In examples, the at least one initial dose is administered every 2 weeks for 1, 2, 3, 4, 5, or more doses. In examples, the at least one initial dose is about 100-300 mg.

[0013] Provided are methods of treating lupus nephritis in a subject in need thereof, the method comprising administering to the subject a pharmaceutically effective amount of an immunoglobulin-like transcript 7 (ILT7)-binding protein, wherein the pharmaceutically effective amount of the ILT7-binding protein is about 100 mg every 2 weeks for up to 4 weeks followed by 100 mg every 4 weeks for 1, 2, 3, 4, 5, 6, 7, 8, 9, 10 11, 12, 13, 14, 15 or more doses. In examples, the subject is further administered: 100 mg of the ILT7 binding protein every 12 weeks;

or 300 mg of the ILT7 binding protein every 12 weeks following the every 4 weeks administration. In examples, the 100 mg every 12 weeks or the 300 mg every 12 weeks are continued for at least about 104 weeks.

[0014] Provided are methods of treating lupus nephritis in a subject in need thereof, the method comprising administering to the subject a pharmaceutically effective amount of immunoglobulin-like transcript 7 (ILT7)-binding protein, wherein the pharmaceutically effective amount of the ILT7-binding protein is about 300 mg every 2 weeks for up to 4 weeks followed by 300 mg every 12 weeks for 1, 2, 3, 4, 5, 6, 7, 8, 9, 10 11, 12, 13, 14, 15 or more doses.

[0015] The methods of the present disclosure can be used for treating autoimmune disorders in a subject in need thereof, reducing pDCs in a tissue of a subject in need thereof, and for reducing a type I IFNGS in a subject in need thereof. The present disclosure also relates to methods of reducing plasmacytoid dendritic cells (pDCs), or reducing a type I interferon gene signature (IFNGS) in a tissue, of a subject in need thereof by administering an ILT7-binding protein to the subject.

[0016] The disclosure provides methods of treating an autoimmune disorder in a subject in need thereof. In the method, a pharmaceutically effective amount of an immunoglobulin-like transcript 7 (ILT7)-binding protein is administered to the subject. In examples, the effective amount of the ILT7-binding protein is about 200 mg. In examples, the subject is administered: (a) a first dose, (b) a second dose about four weeks after the first dose, (c) a third dose about twelve weeks after the first dose, and (d) subsequent doses about twelve weeks after the third dose. In examples, the ILT7-binding protein is administered once about every four weeks.

[0017] The disclosure also provides methods of reducing pDCs in a tissue of a subject in need thereof by administering an effective amount of an ILT7-binding protein to a subject. In examples, the effective amount of the ILT7-binding protein is about 200 mg.

[0018] The disclosure also provides methods for reducing a type I IFNGS in a subject in need thereof. In the method, a pharmaceutically effective amount of an ILT7-binding protein is administered to the subject in need thereof when the subject in need thereof's type I IFNGS is elevated relative to a normal subject's type I IFNGS. The pharmaceutically effective amount of the ILT7-binding protein is about 200 mg.

[0019] In examples, the disclosure provides a method of treating an autoimmune disorder in a subject in need thereof. In the method, a pharmaceutically effective amount of an ILT7-binding

least 85%, 90%, 95%, 96%, 97%, 98% or 99% identical to SEQ ID NOs: 3, 4, 5, 6, 7, and 8, respectively.

[0076] In aspects, the ILT7-binding proteins used in the methods described herein comprise a heavy chain of SEQ ID NO:10. In other aspects, the ILT7-binding proteins used in the methods described herein comprise a light chain of SEQ ID NO:9. In aspects, the ILT7-binding proteins used in the methods described herein comprise a heavy chain of SEQ ID NO:10 and a light chain of SEQ ID NO:9. In other aspects, the ILT7-binding proteins used in the methods described herein comprise a heavy chain that is at least 85%, 90%, 95%, 96%, 97%, 98% or 99% identical to SEQ ID NO:10 and/or a light chain that is at least 85%, 90%, 95%, 96%, 97%, 98% or 99% identical to SEQ ID NO:9.

[0077] In aspects, the ILT7 binding protein comprises a VH comprising SEQ ID NO:1 and a VL comprising SEQ ID NO:2. In aspects, an isolated ILT7 binding protein is an ILT7 binding protein comprising a VH comprising SEQ ID NO:1. In aspects, an isolated ILT7 binding protein is an ILT7 binding protein comprising a VL comprising SEQ ID NO:2. In aspects, the ILT7 binding protein comprises a sequence with at least about 80%, 85%, 90%, 95%, 96%, 97%, 98% or 99% identity to SEQ ID NO: 9 and/or SEQ ID NO: 10. In aspects, the ILT7 binding protein comprises or consists of SEQ ID NO: 9 and/or SEQ ID NO: 10. In aspects, the ILT7 binding protein is Daxdilimab, a human immunoglobulin (Ig) G1 lambda (IgG1λ) afucosylated monoclonal antibody (mAb). Daxdilimab binds to ILT7 on the surface of pDCs, which leads to recruitment of macrophages and natural killer (NK) cells, thus inducing apoptosis and depletion of pDCs in vivo. The afucosylation of Daxdilimab is designed to enhance the potency of Daxdilimab for antibody-dependent cellular cytotoxicity (ADCC) against pDCs. Since pDCs are the major cell type that secretes type I interferons (IFNs) in response to nucleic acid-containing immune complexes, it is hypothesized that depletion of pDCs will reduce disease activity for subjects with autoimmune diseases (e.g., alopecia acreata) that are partially driven by abnormally high levels of type I IFNs.

[0078] In aspects, the ILT7 binding protein has ADCC activity against plasmacytoid dendritic cells (pDCs) in PMBCs.

[0079] In aspects, the ILT7 binding protein comprises a murine, human, chimeric, humanized, or resurfaced antibody or antigen-binding fragment thereof. In aspects, the ILT7

CLAIMS

What is claimed is:

1. Use of an immunoglobulin-like transcript 7 (ILT7)-binding protein in the manufacture of a medicament for the treatment of discoid lupus erythematosus (DLE) in a subject in need thereof, wherein a pharmaceutically effective amount of an immunoglobulin-like transcript 7 (ILT7)-binding protein is to be administered to the subject, wherein the ILT7 binding protein is an antibody that comprises heavy chain Complementarity-Determining Regions (HCDRs) HCDR1, HDR2, HCDR3, and light chain Complementarity Determining Regions (LCDRs) LCDR1, LCDR2, and LCDR3 comprising the amino acid sequences of SEQ ID NOs: 3, 4, 5, 6, 7, and 8, respectively and wherein the pharmaceutically effective amount of the ILT7-binding protein is from 100 to 300 mg.

2. The use of claim 1, wherein the pharmaceutically effective amount of the ILT7-binding protein is from 150 to 300 mg.

3. The use of claim 1, wherein the pharmaceutically effective amount of the ILT7-binding protein is 100 mg.

4. The use of claim 1, wherein the pharmaceutically effective amount of the ILT7-binding protein is 150 mg.

5. The use of claim 1, wherein the pharmaceutically effective amount of the ILT7-binding protein is 200 mg.

6. The use of claim 1, wherein the pharmaceutically effective amount of the ILT7-binding protein is 300 mg.

7. The use of any one of the preceding claims, wherein the ILT7 binding protein is an antibody comprising a variable heavy chain (VH) that is at least 85%, 90%, 95%, 96%, 97%, 98% or 99% identical to SEQ ID NO:1 and/or a variable light chain (VL) that is at least 85%, 90%, 95%, 96%, 97%, 98% or 99% identical to SEQ ID NO:2.

8. The use of claim 7, wherein the ILT7-binding protein is an antibody comprising a heavy chain variable region (VH) of SEQ ID NO:1 and a light chain variable region (VL) of SEQ ID NO:2.

9. The use of any one of the preceding claims, wherein the ILT7 binding protein is afucosylated.

10. The use of any one of the preceding claims, wherein the ILT7 binding protein comprises a heavy chain comprising SEQ ID NO: 10; and a light chain comprising SEQ ID NO: 9.

11. The use of any one of the preceding claims, wherein the administration is to be subcutaneous.

12. The use of any one of claims 1-11, wherein the subject is to be administered the ILT7-binding protein every 4 weeks.

13. The use of any one of claims 1-11, wherein the subject is to be administered the ILT7-binding protein every 12 weeks.

14. The use of any one of claims 1-13, wherein prior to the administration, the subject is to be administered at least one initial dose of the ILT7-binding protein.

15. The use of claim 14, wherein the at least one initial dose is to be administered every 2 weeks for 1, 2, 3, 4, 5, or more doses.

16. The use of any one of claims 14-15, wherein the at least one initial dose is 100-300 mg.