

CLAIMS

1. A urinary trypsin inhibitor (UTI) fusion protein comprising SEQ ID NO:1 for use as a medicament.
2. An isolated UTI fusion protein comprising SEQ ID NO:1 for use as a medicament.
3. The UTI fusion protein of claim 1 or 2 for use as a medicament, wherein the UTI fusion protein is a dimer comprising Fc domains that are associated covalently.
4. Use of a UTI fusion protein comprising SEQ ID NO:1 in the manufacture of a medicament for treating a UTI-related condition selected from the group consisting of pancreatitis, arthritis, SARS, systemic inflammatory response syndrome, acute circulatory failure, sepsis, hepatitis, appendicitis, colitis, organ failure, organ damage, reperfusion injury, Stevens-Johnson syndrome, toxic epidermal necrolysis, shock, ischemic injuries, acute lung injury, asthma, lung inflammation, pneumonia, disseminated intravascular coagulation, and acute respiratory distress syndrome, wherein a patient in need thereof is to be administered with an effective amount of said UTI fusion protein.
5. Use of an isolated UTI fusion protein comprising SEQ ID NO:1 in the manufacture of a medicament for treating a UTI-related condition selected from the group consisting of pancreatitis, arthritis, SARS, systemic inflammatory response syndrome, acute circulatory failure, sepsis, hepatitis, appendicitis, colitis, organ failure, organ damage, reperfusion injury, Stevens-Johnson syndrome, toxic epidermal necrolysis, shock, ischemic injuries, acute lung injury, asthma, lung inflammation, pneumonia, disseminated intravascular coagulation, and acute respiratory distress syndrome, wherein a patient in need thereof is to be administered with an effective amount of said isolated UTI fusion protein.
6. The use according to claim 4 or 5, wherein the UTI fusion protein is a dimer comprising Fc domains that are associated covalently.
7. A UTI fusion protein comprising SEQ ID NO:1 for use in treating a UTI-related condition selected from the group consisting of pancreatitis, arthritis, SARS, systemic inflammatory response syndrome, acute circulatory failure, sepsis, hepatitis, appendicitis, colitis, organ failure, organ damage, reperfusion injury, Stevens-Johnson syndrome, toxic epidermal necrolysis, shock, ischemic injuries, acute lung injury, asthma, lung inflammation, pneumonia, disseminated intravascular coagulation, and acute respiratory distress syndrome.
8. An isolated UTI fusion protein comprising SEQ ID NO:1 for use in treating a UTI-related condition selected from the group consisting of pancreatitis, arthritis, SARS, systemic inflammatory

response syndrome, acute circulatory failure, sepsis, hepatitis, appendicitis, colitis, organ failure, organ damage, reperfusion injury, Stevens-Johnson syndrome, toxic epidermal necrolysis, shock, ischemic injuries, acute lung injury, asthma, lung inflammation, pneumonia, disseminated intravascular coagulation, and acute respiratory distress syndrome.

9. The UTI fusion protein according to claim 7 or 8 for use in treating a UTI-related condition selected from the group consisting of pancreatitis, arthritis, SARS, systemic inflammatory response syndrome, acute circulatory failure, sepsis, hepatitis, appendicitis, colitis, organ failure, organ damage, reperfusion injury, Stevens-Johnson syndrome, toxic epidermal necrolysis, shock, ischemic injuries, acute lung injury, asthma, lung inflammation, pneumonia, disseminated intravascular coagulation, and acute respiratory distress syndrome, wherein the UTI fusion protein is a dimer comprising Fc domains that are associated covalently.

10. A UTI fusion protein comprising amino acids 1 to 149 of SEQ ID NO:1 linked to a wild-type Fc domain, wherein the Fc domain excludes the first constant region immunoglobulin domain, or fragment thereof that does not contain one or more substitutions.

11. A dimer comprising two isolated UTI fusion proteins of claim 10, wherein the Fc domains, or fragments thereof, are associated covalently.

12. A pharmaceutical composition comprising the UTI fusion protein of claim 10, or the dimer of claim 11, and a pharmaceutically acceptable excipient.

13. Use of the UTI fusion protein of claim 10 or the dimer of claim 11 in the manufacture of a medicament for treating a UTI-related condition selected from the group consisting of pancreatitis, arthritis, SARS, systemic inflammatory response syndrome, acute circulatory failure, sepsis, hepatitis, appendicitis, colitis, organ failure, organ damage, reperfusion injury, Stevens-Johnson syndrome, toxic epidermal necrolysis, shock, ischemic injuries, acute lung injury, asthma, lung inflammation, pneumonia, disseminated intravascular coagulation, and acute respiratory distress syndrome, wherein a patient in need thereof is to be administered with an effective amount of said UTI fusion protein, or said dimer.

14. The UTI fusion protein of claim 10 or the dimer of claim 11 for use in treating a UTI-related condition selected from the group consisting of pancreatitis, arthritis, SARS, systemic inflammatory response syndrome, acute circulatory failure, sepsis, hepatitis, appendicitis, colitis, organ failure, organ damage, reperfusion injury, Stevens-Johnson syndrome, toxic epidermal necrolysis, shock, ischemic injuries, acute lung injury, asthma, lung inflammation, pneumonia, disseminated intravascular coagulation, and acute respiratory distress syndrome.

15. A nucleic acid encoding the UTI fusion protein of claim 10, or the dimer of claim 11.

16. An expression vector comprising the nucleic acid of claim 15.
17. A recombinant host cell comprising the expression vector of claim 16.
18. A method of producing a UTI fusion protein, the method comprising placing the recombinant host cell of claim 17 in a growth medium such that a recombinant fusion protein is expressed, and isolating the recombinant fusion protein from the cell or growth medium.
19. A method of producing a UTI fusion protein, wherein (i) a UTI fusion protein comprising SEQ ID NO:1, (ii) a UTI fusion protein comprising SEQ ID NO:1 or an isolated UTI fusion protein comprising SEQ ID NO:1, wherein the UTI fusion protein is a dimer comprising Fc domains that are associated covalently, (iii) the UTI fusion protein of claim 10, or (iv) the dimer of claim 11 is produced in a transgenic animal.
20. (i) An isolated UTI fusion protein comprising SEQ ID NO:1, (ii) an isolated UTI fusion protein comprising SEQ ID NO:1, wherein the UTI fusion protein is a dimer comprising Fc domains that are associated covalently, (iii) the isolated UTI fusion protein of claim 10, or (iv) the dimer of claim 11, wherein the Fc domain is selected from the group consisting of an IgG1, an IgG2 and an IgG4 Fc domain.
21. (i) An isolated UTI fusion protein comprising SEQ ID NO:1, (ii) an isolated UTI fusion protein comprising SEQ ID NO:1, wherein the UTI fusion protein is a dimer comprising Fc domains that are associated covalently, (iii) the isolated UTI fusion protein of claim 10, or (iv) the dimer of claim 11, wherein the Fc domain is an IgG1 Fc domain.
22. A recombinant host cell comprising an expression vector that comprises a nucleic acid comprising a polynucleotide sequence encoding SEQ ID NO:1 or the recombinant host cell of claim 17, wherein the cell is selected from the group consisting of a mammalian cell, an insect cell, an E. coli cell, a yeast cell, and a plant cell.
23. The recombinant host cell of claim 22, wherein the mammalian cell is selected from the group consisting of a Chinese hamster ovary (CHO) cell, an HEK 293 cell, an NSO cell, a HeLa cell, a baby hamster kidney (BHK) cell, a monkey kidney cell (COS) and a human hepatocellular carcinoma cell.
24. The use of any one of claims 4-6 or 13, the UTI fusion protein of any one of claims 7-9 or 14, or the dimer of claim 14, wherein the UTI-related condition is acute pancreatitis.
25. The use of any one of claims 4-6 or 13, the UTI fusion protein of any one of claims 7-9 or 14, or the dimer of claim 14, wherein the UTI-related condition is selected from the group consisting of endoscopy induced pancreatitis, pancreas damage, kidney damage, lung damage, lung injury caused by acute aortic dissection, and ventilator associated pneumonia.