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- (71) Applicant (*for all designated States except US*): **ALK-ERMES CONTROLLED THERAPEUTICS, INC.** [US/US]; 64 Sidney Street, Cambridge, MA 02139 (US). Published: — *with international search report*
- (72) Inventors; and (88) Date of publication of the international search report: 14 February 2002
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(54) Title: MICROENCAPSULATION AND SUSTAINED RELEASE OF BIOLOGICALLY ACTIVE AGENT

(57) Abstract: This invention relates to sustained release compositions, and methods of forming and using said compositions, for the sustained release of biologically active acid-stable or free sulfhydryl-containing proteins, in particular β -IFN. The sustained release composition of this invention comprises a biocompatible polymer having dispersed therein a stabilized biologically active acid-stable or free sulfhydryl-containing protein formulation and a nonionic polymer surfactant. The method of the invention, for forming a composition for the sustained release of biologically active acid-stable or free sulfhydryl-containing protein, in particular β -IFN, includes dissolving a polymer in a polymer solvent to form a polymer solution, adding a stabilized biologically active acid-stable or free sulfhydryl-containing protein formulation and a nonionic surfactant to the polymer solution, and then solidifying the polymer to form a polymer matrix containing the stabilized biologically active acid-stable or free sulfhydryl-containing protein formulation, and a nonionic surfactant. The method of using the sustained release composition of the present invention comprises providing a therapeutically effective blood level of biologically active acid-stable or free sulfhydryl-containing protein in a subject for a sustained period by administering to the subject a dose of the sustained release composition described herein.

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A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61K38/21 A61K9/16 A61K47/34

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

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Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

WPI Data, PAJ, CHEM ABS Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
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| X | <p>WO 96 28143 A (BOEHRINGER MANNHEIM) 19 September 1996 (1996-09-19)</p> <p>claims page 5, line 19 -page 6, line 17 page 6, line 36 page 9, line 23 - line 24 ----- -/--</p> | <p>1,2, 5-10,14, 16,17, 19-21, 24,25, 27-30, 32,33, 36,37, 40,42, 43, 45-47, 50,51</p> |

Further documents are listed in the continuation of box C.

Patent family members are listed in annex.

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