

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property
Organization

International Bureau

(43) International Publication Date
06 October 2022 (06.10.2022)



(10) International Publication Number
WO 2022/208118 A1

(51) International Patent Classification:

C12N 5/0775 (2010.01) C12N 5/00 (2006.01)
A61K 35/28 (2015.01) C12N 5/077 (2010.01)

EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV,
MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM,
TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW,
KM, ML, MR, NE, SN, TD, TG).

(21) International Application Number:

PCT/HU2022/050027

(22) International Filing Date:

29 March 2022 (29.03.2022)

(25) Filing Language:

English

(26) Publication Language:

English

(30) Priority Data:

P2100138 01 April 2021 (01.04.2021) HU

(71) Applicant: **STEM CELLX EUROPE KFT** [HU/HU]; Al-
só kikötő sor 11.D. ép., H-6726 Szeged (HU).

(72) Inventors: **KRISTON-PÁL, Éva**; Gyík u. 20/A 3/11,
H-6723 Szeged (HU). **SZUKACSOV, Valéria**; Felső
Tisza-part 19. 10/41, H-6723 Szeged (HU).

(74) Agent: **SBGK PATENT AND LAW OFFICES**; An-
drássy út 113., H-1062 Budapest (HU).

(81) Designated States (unless otherwise indicated, for every
kind of national protection available): AE, AG, AL, AM,
AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ,
CA, CH, CL, CN, CO, CR, CU, CZ, DE, DJ, DK, DM, DO,
DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN,
HR, HU, ID, IL, IN, IR, IS, IT, JM, JO, JP, KE, KG, KH,
KN, KP, KR, KW, KZ, LA, LC, LK, LR, LS, LU, LY, MA,
MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI,
NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU,
RW, SA, SC, SD, SE, SG, SK, SL, ST, SV, SY, TH, TJ, TM,
TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, WS, ZA, ZM,
ZW.

(84) Designated States (unless otherwise indicated, for every
kind of regional protection available): ARIPO (BW, GH,
GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ,
UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ,
TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK,

Declarations under Rule 4.17:

- as to the identity of the inventor (Rule 4.17(i))
- as to applicant's entitlement to apply for and be granted a
patent (Rule 4.17(ii))
- of inventorship (Rule 4.17(iv))

Published:

- with international search report (Art. 21(3))
- with amended claims and statement (Art. 19(1))
- in black and white; the international application as filed
contained color or greyscale and is available for download
from PATENTSCOPE

(54) Title: PROCESS FOR MANUFACTURE OF A COMPOSITION FOR THE TREATMENT OF OSTEOARTHRITIS IN A SUB-
JECT

(57) Abstract: The present invention relates to a process for the manufacture of a composition for the treatment of osteoarthritis in subject, in particular mesenchymal stem cells isolated, and propagated in a specific way, and use thereof. The present invention specifically relates to cell culture of mesenchymal stem cells (MSC) which: a. are derived from at least two healthy donors, wherein the donors are different from the subject to be treated, that is, allogeneic; b. are morphologically healthy, substantially free of senescent cells; c. are free of pathogens characteristic of the species; d. possess the main characteristics of MSCs, that is, they are CD105 and CD73 positive but do not carry surface markers characteristic of hematopoietic blood stem cells and progenitor cells and preferably do not carry surface markers characteristic of blood cell lineages, that is, the MSCs are preferably CD45, CD34, CD14, CD11b, CD31, CD79α, and CD19 negative; e. during propagation, the cumulative population doubling value, that is, CPD value of the said MSCs is preferably in the range of 3 to 14, more preferably in the range of 2 to 12, most preferably about 8; f. the level of kynurenine metabolite production of the MSCs is in the range 30 to 50 ng/ml, preferably about 30 ng/ml, and the level of THBS1 cytokine production of the MSCs is in the range of 50 to 80 ng/ml, preferably about 50 ng/ml; g. number of cells is in the range of 10⁵ to 5x10⁷.

WO 2022/208118 A1