

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

(19) World Intellectual Property
Organization
International Bureau

(43) International Publication Date
10 June 2021 (10.06.2021)



(10) International Publication Number
WO 2021/113770 A1

(51) International Patent Classification:

G01N 33/50 (2006.01) A61K 35/17 (2015.01)
G01N 33/574 (2006.01) A61K 39/00 (2006.01)
G01N 33/68 (2006.01)

(21) International Application Number:

PCT/US2020/063486

(22) International Filing Date:

04 December 2020 (04.12.2020)

(25) Filing Language:

English

(26) Publication Language:

English

(30) Priority Data:

62/945,105 06 December 2019 (06.12.2019) US

(71) Applicant: JUNO THERAPEUTICS, INC. [US/US]; 400
Dexter Ave. N, Suite 1200, Seattle, Washington 98109
(US).

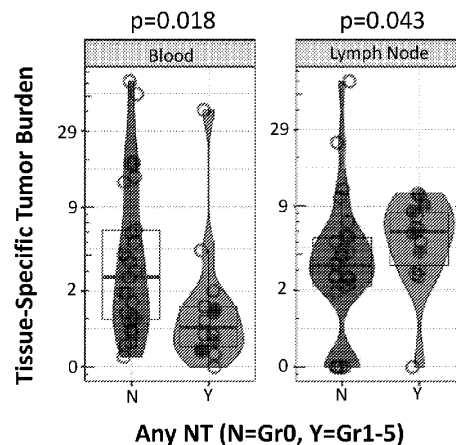
(72) Inventors: DUBOVSKY, Jason A.; 400 Dexter Ave.
N, Suite 1200, Seattle, Washington 98109 (US). RY-
TLEWSKI, Julie; 400 Dexter Ave. N, Suite 1200, Seattle,
Washington 98109 (US). THOMPSON, Ethan; 86 Mor-
ris Avenue, Summit, New Jersey 07901 (US). THORPE,
Jerill; 400 Dexter Ave. N, Suite 1200, Seattle, Washington
98109 (US).

(74) Agent: RICE, Rachel et al.; Morrison & Foerster LLP,
12531 High Bluff Drive, Suite 100, San Diego, California
92130-2040 (US).

(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, 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,

(54) Title: METHODS RELATED TO TOXICITY AND RESPONSE ASSOCIATED WITH CELL THERAPY FOR TREATING
B CELL MALIGNANCIES

FIG. 7A



(57) Abstract: Provided are methods for determining the risk of toxicity (e.g., neurotoxicity) and/or the likelihood of response to a cell therapy. In some aspects, the methods generally involve assessing parameters or biomarkers (e.g., blood analytes) that are associated with toxicity and/or response. In some aspects, the methods relate to adoptive cell therapy involving the administration of doses of cells for treating subjects with certain B cell malignancies, such as chronic lymphocytic leukemia (CLL), such as relapsed or refractory CLL, or small lymphocytic lymphoma (SLL). The cells for the adoptive cell therapy generally express recombinant receptors such as chimeric antigen receptors (CARs). In some aspects, the methods can be used to identify or select subjects for treatment, for example, with a cell therapy.

[Continued on next page]

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, 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).

Declarations under Rule 4.17:

- *as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii))*

Published:

- *with international search report (Art. 21(3))*
- *with sequence listing part of description (Rule 5.2(a))*