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

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
27 January 2022 (27.01.2022)

WIPO | PCT

(10) International Publication Number
WO 2022/020449 A1

(51) International Patent Classification:
A61K 31/44 (2006.01) *A61K 47/26* (2006.01)
A61K 9/00 (2006.01) *A61K 47/38* (2006.01)
A61K 9/19 (2006.01) *A61K 47/32* (2006.01)
A61K 9/10 (2006.01) *A61P 31/00* (2006.01)
A61K 9/16 (2006.01)

(21) International Application Number:
PCT/US2021/042543

(22) International Filing Date:
21 July 2021 (21.07.2021)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
63/055,786 23 July 2020 (23.07.2020) US

(71) Applicant: **CRITITECH, INC.** [US/US]; 1849 E. 1450 Road, Lawrence, KS 66044 (US).

(72) Inventors: **SITTENAUER, Jacob**; c/o Crititech, Inc., 1849 E. 1450 Road, Lawrence, KS 66044 (US). **FARTHING, Joseph**; c/o Crititech, Inc., 1849 E. 1450 Road, Lawrence, KS 66044 (US). **WILLIAMS, Mark**; c/o Crititech, Inc., 1849 E. 1450 Road, Lawrence, KS 66044 (US). **BALTEZOR, Michael**; c/o Crititech, Inc., 1849 E. 1450 Road, Lawrence, KS 66044 (US). **DIZEREGA, Gere**; c/o Crititech, Inc., 1849 E. 1450 Road, Lawrence, KS 66044 (US). **ABARCA, Aranza Barreda**; c/o Crititech, Inc., 1849 E. 1450 Road, Lawrence, KS 66044 (US). **CLARK, Shelby**; c/o Crititech, Inc., 1849 E. 1450 Road, Lawrence, KS 66044 (US).

(74) Agent: **HARPER, David S.**; McDonnell Boehnen Hulbert & Berghoff LLP, 300 South Wacker Drive, Chicago, IL 60606 (US).

(54) Title: SORAFENIB PARTICLES AND USES THEREOF

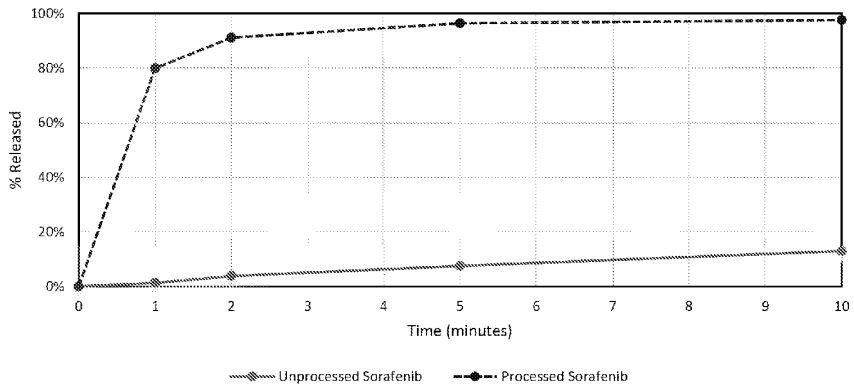


Figure 4

(57) Abstract: A composition comprising particles of at least 95% by weight of sorafenib, or a pharmaceutically acceptable salt thereof, wherein the particles have a specific surface area (SSA) of at least 2 m /g and have a mean particle size by volume distribution of between 0.7 um and 8 um. A method for making sorafenib particles, comprising: (a) introducing (i) a solution comprising at least one solvent, and at least one solute comprising sorafenib into a nozzle inlet, and (ii) a compressed fluid into an inlet of a vessel defining a pressurizable chamber; (b) passing the solution out of a nozzle orifice and into the pressurizable chamber to produce an output stream of atomized droplets, wherein the nozzle orifice is located between 2 mm and 20 mm from a sonic energy source located within the output stream, wherein the sonic energy source produces sonic energy with an amplitude between 10% and 100% during the passing, and wherein the nozzle orifice has a diameter of between 20 um and 125 um; (c) contacting the atomized droplets with the compressed fluid, to cause depletion of the solvent from the atomized droplets, to produce compound particles, wherein steps (a), (b), and (c) are carried out under supercritical temperature and pressure for the compressed fluid.

WO 2022/020449 A1

[Continued on next page]

(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, 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).

Published:

— *with international search report (Art. 21(3))*