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

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
8 March 2012 (08.03.2012)

PCT

(10) International Publication Number
WO 2012/030939 A1

(51) International Patent Classification:
A61K 31/55 (2006.01) *A61P 3/04* (2006.01)

(21) International Application Number:
PCT/US2011/049936

(22) International Filing Date:
31 August 2011 (31.08.2011)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
61/402,628 1 September 2010 (01.09.2010) US
61/403,149 10 September 2010 (10.09.2010) US

(71) Applicant *(for all designated States except US)*: **ARENA PHARMACEUTICALS, INC.** [US/US]; 6166 Nancy Ridge Drive, San Diego, California 92121 (US).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: **ANDERSON, Christen M.** [US/US]; 756 Poinsettia Park South, Encinitas, California 92024 (US). **SHANAHAN, William R.** [US/US]; 4948 Rancho Viejo Drive, Del Mar, California 92014 (US).

(74) Agents: **CLARK, Melody E.** et al.; Arena Pharmaceuticals, Inc., 6166 Nancy Ridge Drive, San Diego, California 92121 (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, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, 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, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, 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, ML, MR, NE, SN, TD, TG).

Published:

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

(54) **Title**: ADMINISTRATION OF LORCASERIN TO INDIVIDUALS WITH RENAL IMPAIRMENT

Mean (±SD) Plasma Concentration-Time Profiles of Lorcaserin after a 10 mg Oral Dose of Lorcaserin•HCl, Groups 1-4

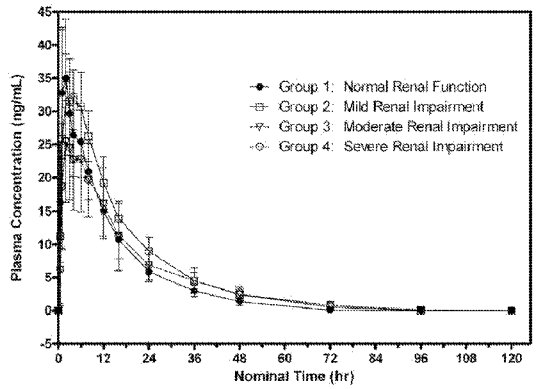


Figure 1A

(57) **Abstract**: The present disclosure relates to methods for weight management in an individual in need thereof by determining the level of renal sufficiency of the individual and prescribing or administering a therapeutically effective amount of (R)-8-chloro-1-methyl-2,3,4,5-tetrahydro-1H-3-benzazepine or a pharmaceutically acceptable salt, solvate or hydrate thereof to the individual, provided that the individual has a level of renal sufficiency selected from the group consisting of: no renal impairment, mild renal impairment, and moderate renal impairment. In addition, the disclosure relates to a method for selecting an individual for treatment with (R)-8-chloro-1-methyl-2,3,4,5-tetrahydro-1H-3-benzazepine or a pharmaceutically acceptable salt, solvate or hydrate thereof from a plurality of individuals in need of weight management by determining the level of renal sufficiency of the individual and selecting the individual for treatment with (R)-8-chloro-1-methyl-2,3,4,5-tetrahydro-1H-3-benzazepine or a pharmaceutically acceptable salt, solvate or hydrate thereof if the individual has a level of renal sufficiency selected from the group consisting of: no renal impairment, mild renal impairment, and moderate renal impairment.

WO 2012/030939 A1