



(51) International Patent Classification:

A61K 9/00 (2006.01)

A61K 31/00 (2006.01)

A61K 9/16 (2006.01)

A61P 1/16 (2006.01)

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/SE2019/050603

(22) International Filing Date:

20 June 2019 (20.06.2019)

(25) Filing Language:

English

(26) Publication Language:

English

(30) Priority Data:

1850761-6

20 June 2018 (20.06.2018)

SE

1850762-4

20 June 2018 (20.06.2018)

SE

(71) Applicant: **ALBIREO AB** [SE/SE]; Arvid Wallgrens backe 20, 413 46 Göteborg (SE).(72) Inventors: **BYRÖD, Eva**; Smedsbergsgatan 3A, 431 39 Mölndal (SE). **GILLBERG, Per-Göran**; Södermalmsgatan 22, 431 69 Mölndal (SE). **TIVERT, Anna-Maria**; Ljunggatan 8, 413 21 Göteborg (SE). **BRYLAND, Rikard**; Rosengrens gata 27, 216 44 Limhamn (SE). **DAHLQUIST, Ann-Charlotte**; Norrängavägen 6B, 224 77 Lund (SE). **ELVERSSON, Jessica**; Veberödsvägen 5, 247 50 Dalby (SE). **GUSTAFSSON, Nils Ove**; Hippodromvägen 7, 246 50 Löddeköpinge (SE). **LUNDQVIST, Robert**; Varvsvägen 6, 475 50 Hälsö (SE). **YMÉN, Ingvar**; Gundersbergsvägen 8, 132 48 Saltsjö-Boo (SE). **BOHLIN, Martin**; Kalmgatan 23, 121 45 Johanneshov (SE).(74) Agent: **NOVITAS PATENT AB**; P.O.Box 55557, 102 04 Stockholm (SE).

(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, 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, 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, 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,

Published:

- with international search report (Art. 21(3))
- before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments (Rule 48.2(h))
- with sequence listing part of description (Rule 5.2(a))

(54) Title: PHARMACEUTICAL FORMULATION OF ODEVIXIBAT

(57) **Abstract:** The invention relates to a pharmaceutical formulation, e.g. a paediatric formulation, of odevixibat, which comprises a plurality of small particles. The formulation may be used in the treatment of liver diseases such as bile acid-dependent liver diseases, and particularly cholestatic liver diseases such as biliary atresia, progressive familial intrahepatic cholestasis (PFIC), Alagille syndrome (ALGS) and paediatric cholestatic pruritus. The invention also relates to a process for the preparation of the pharmaceutical formulation.