INDIVIOR R&D PEER-REVIEWED PUBLICATIONS 2013-2017

Update April 2018

Peer-Reviewed Publications

Early Stage Discovery & Development

1. Heidbreder C (2013) Rationale in support of the use of selective dopamine D3 receptor antagonists for the pharmacotherapeutic management of drug addiction. *Naunyn-Schmiedeberg's Archives of Pharmacology*, 386: 167-176. http://dx.doi.org/10.1007/s00210-012-0803-6
2. Micheli F, Heidbreder C (2013) Selective dopamine D3 receptor antagonists 2007-2012: A patent review. *Expert Opin. Ther. Patents*, 23(3):363-381. http://dx.doi.org/10.1517/13543776.2013.757593
3. Rice OV, Heidbreder CA, Gardner EL, Schonhar C, Ashby CR Jr. (2013) The selective D3 receptor antagonist SB-277011A attenuates morphine-triggered reactivation of expression of cocaine-induced conditioned place preference. *Synapse*, 67(8):469-475. http://dx.doi.org/10.1002/syn.21653
4. Ashby C, Rice O, Heidbreder C, Gardner E (2015) The selective dopamine D3 receptor antagonist SB-277011A attenuates drug- or food deprivation reactivation of expression of conditioned place preference for cocaine in male Sprague-Dawley rats. *Synapse*, 69(6):336-345. http://dx.doi.org/10.1002/syn.21820
5. Ashby C, Rice O, Heidbreder C, Gardner E (2015) The Selective Dopamine D3 Receptor Antagonist SB-277011A Significantly Accelerates Extinction to Environmental Cues Associated with Cocaine-Induced Place Preference in Male Sprague-Dawley Rats. *Synapse*, 69(10):512-514. http://dx.doi.org/10.1002/syn.21839
6. Micheli F, Cremonesi S, Semeraro T, Tarsi L, Tomelleri S, Cavanni P, Zonzini L, Feriani A, Braggio S, Heidbreder C (2016) Novel morpholine scaffolds as selective dopamine (DA) D3 receptor antagonists. *Bioorganic & Medicinal Chemistry*, 26(4): 1329-1332. http://dx.doi.org/10.1016/j.bmcl.2015.12.081
7. Micheli F, Bernardelli A, Bianchi F, Braggio S, Castelletti L, Cavallini P, Cavanni P, Cremonesi S, Cin MD, Feriani A, Oliosi B, Semeraro T, Tarsi L, Tomelleri S, Wong A, Visentini F, Zonzini L, Heidbreder C (2016) 1,2,4-Triazolyl Octahydropyrrolo[2,3-b]pyrroles: A New Series of Potent and Selective Dopamine D3 Receptor Antagonists. *Bioorganic & Medicinal Chemistry*, 24(8): 1619-1636. http://dx.doi.org/10.1016/j.bmc.2016.02.031
8. Micheli F, Bacchi A, Bernardelli A, Braggio S, Castelletti L, Cavallini P, Cavanni P, Cremonesi S, Dal Cin M, Feriani A, Kajbaf M, Marchió L, Oliosi B, Pellacani A, Perdona E, Sava A, Semeraro T, Tarsi L, Tomelleri S, Wong A, Visentini F, Zonzini L, Heidbreder C (2016) 1,2,4-Triazolyl 5-Azaspiro[2.4]heptanes: Lead Identification and Early Lead Optimization of a New Series of Potent and Selective Dopamine D3 Receptor Antagonists. *J. Med. Chem.,* 59(18):8549-8576. http://dx.doi.org/10.1021/acs.jmedchem.6b00972

Treatment of Schizophrenia

9. Gomeni R., Heidbreder C, Fudala PJ, Nasser AF (2013) A model-based approach to characterize the population pharmacokinetics and the relationship between the pharmacokinetic and safety

profiles of RBP-7000, a new, long-acting, sustained-released formulation of risperidone. *J. Clin. Pharmacol.*, 53(10):1010-1019. http://dx.doi.org/10.1002/jcph.141

10. Laffont CM, Gomeni R, Heidbreder C, Fudala PJ, Nasser AF (2014) Population pharmacokinetics and prediction of dopamine D2 receptor occupancy after multiple doses of RBP-7000, a new sustained-release formulation of risperidone, in schizophrenia patients on stable oral risperidone treatment. *Clin. Pharmacokinetics*, 53(6):533-543. http://dx.doi.org/10.1007/s40262-014-0132-7
11. Laffont CM, Gomeni R, Zheng B, Heidbreder C, Fudala PJ, Nasser AF (2015) Population pharmacokinetic modeling and simulation to guide dose selection for RBP-7000, a new sustained-release formulation of risperidone. *J. Clin. Pharmacol.*, 55(1):93-103. http://dx.doi.org/10.1002/jcph.366
12. Nasser AF, Henderson DC, Fava M, Fudala PJ, Twumasi-Ankrah P, Kouassi A, Heidbreder C (2016) Efficacy, safety and tolerability of RBP-7000 once monthly risperidone for the treatment of acute schizophrenia: An 8-week, randomized, double-blind, placebo-controlled, multicenter Phase 3 study. *J. Clin. Psychopharmacology*, 36(2):130-140. http://dx.doi.org/10.1097/JCP.0000000000000479
13. Isitt JJ, Nadipelli VR, Kouassi A, Fava M, Heidbreder C (2016) Health-related quality of life in acute schizophrenia patients treated with RBP-7000 once monthly risperidone: An 8-week, randomized, double-blind, placebo-controlled, multicenter phase 3 study. *Schizophr Res*., 174(1-3):126-131. http://dx.doi.org/10.1016/j.schres.2016.03.020
14. Ivatori V, Gobburu J, Gopalakrishnan M, Zhang W, Jones JP III, Yongzhen L, Twumasi-Ankrah P, Heidbreder C, Laffont C (2017) Exposure Response Analysis for a New Once a Month Long Acting Risperidone. *Br. J. Clin. Pharmacol.*, 83(7):1476-1498. http://dx.doi.org/10.1111/bcp.13246

Treatment of Substance Use Disorder

15. Bani M, Andorn A, Heidbreder C (2014) Pharmacologically, are smokers the same as non-smokers? *Curr. Opin. Pharmacol.*, 14:42-49. http://dx.doi.org/10.1016/j.coph.2013.11.003

Rescue Medications

16. Liu Y, Zheng B, Strafford S, Orugunty R, Sullivan M, Gus J, Heidbreder C, Fudala PJ, Nasser A (2014) Liquid chromatography/tandem mass spectrometry method for simultaneous determination of cocaine and its metabolite (−)ecgonine methyl ester in human acidified stabilized plasma samples. *J. Chromatogr. B.*, 961:77-85. http://dx.doi.org/10.1016/j.jchromb.2014.04.052
17. Nasser A, Fudala PJ, Zheng B, Liu Y, Chen Y, Heidbreder C (2014) A randomized, double-blind, placebo-controlled trial of RBP-8000 in cocaine abusers: Pharmacokinetic profile of RBP-8000 and cocaine and effects of RBP-8000 on cocaine-induced Physiological effects. *J Addict Dis.*, 33(4):289-302. http://dx.doi.org/10.1080/10550887.2014.969603

18. Nasser AF, Heidbreder C, Gomeni R, Fudala PJ, Zheng B, Greenwald MK (2014) A population pharmacokinetic and pharmacodynamic modelling approach to support the clinical development of RBP-6000, a new, subcutaneously injectable, long-acting, sustained-release formulation of buprenorphine, for the treatment of opioid dependence. *Clin. Pharmacokinetics*, 53(9):813-824. http://dx.doi.org/10.1007/s40262-014-0155-0

19. Nasser A, Heidbreder C, Liu Y, Fudala PJ (2015) Pharmacokinetics of Sublingual Buprenorphine and Naloxone in Subjects with Mild to Severe Hepatic Impairment (Child-Pugh Classes A, B, and C), in Hepatitis C Virus-Seropositive Subjects, and in Healthy Volunteers. *Clin. Pharmacokinetics*, 54(8): 837-849. http://dx.doi.org/10.1007/s40262-015-0238-6

20. Liu Y, Li X, Xu A, Heidbreder C, Nasser AF (2016) Simultaneous determination of buprenorphine, norbuprenorphine and naloxone in human plasma by liquid chromatography/tandem mass spectrometry. *J. Pharm. Biomed. Analysis*, 120:142-152. http://dx.doi.org/10.1016/j.jpba.2015.12.008

21. Nasser AF, Greenwald MK, Vince B, Fudala PJ, Twumasi-Ankrah P, Liu Y, Jones JP III, Heidbreder C (2016) Sustained-Release Buprenorphine (RBP-6000) Blocks the Effects of Opioid Challenge with Hydromorphone in Subjects with Opioid Use Disorder. *J Clin Psychopharmacol.,* 36(1):18-26. http://dx.doi.org/10.1097/JCP.0000000000000434

22. Laffont CM, Gomeni R, Heidbreder C, Jones JP 3rd, Nasser AF (2016) Population Pharmacokinetic Modeling After Repeated Administrations of RBP-6000, a New, Subcutaneously Injectable, Long-Acting, Sustained-Release Formulation of Buprenorphine, for the Treatment of Opioid Use Disorder. *J Clin Pharmacol*., 56(7):806-815. http://dx.doi.org/10.1002/jcph.665

23. Boscarino JA, Kirchner HL, Pitcavage JM, Nadipelli VR, Ronquest NA, Fitzpatrick MH, Han JJ (2016) Factors associated with opioid overdose: a 10-year retrospective study of patients in a large integrated health care system. Subst Abuse Rehabil. 7:131-141. http://dx.doi.org/10.2147/SAR.S108302

24. Joshi A, Parris B, Liu Y, Heidbreder C, Gerk P, Halquist M (2017) Quantitative determination of buprenorphine, naloxone and their metabolites in rat plasma using hydrophilic interaction liquid chromatography coupled with tandem mass spectrometry. *Biomed Chromatogr*., 31(2). http://dx.doi.org/10.1002/bmc.3785

25. Joshi A, Halquist M, Konsoula Z, Liu Y, Jones JP 3rd, Heidbreder C, Gerk PM (2017) Improving the oral bioavailability of buprenorphine: an in-vivo proof of concept. *J. Pharm. Pharmacol.*, 69(1):23-31. http://dx.doi.org/10.1111/jphp.12652

26. Ruetsch C, Tkacz J, Nadipelli, VR, Brady BL, Ronquest N, Un H, Volpicelli J (2017) Heterogeneity of Nonadherent Buprenorphine Patients: Subgroup Characteristics and Outcomes. *Am J Manag Care*. 23(6):e172-e179. https://www.ncbi.nlm.nih.gov/pubmed/28817294

27. Wollschlaeger BA, Willson TM, Montejano LB, Ronquest NA, Nadipelli, VR (2017) Characteristics and treatment patterns of US commercially insured and Medicaid patients with opioid dependence or abuse. *J Opioid Manag.* 13(4), 207-220. http://dx.doi.org/10.5055/jom.2017.0389