

****Published July 2013****

MarketVIEW: Cocaine dependence vaccines (CAT: VAMV048)

Product Name	:	MarketVIEW: Cocaine dependence vaccines
Description	:	Global vaccine commercial opportunity assessment
Contents	:	Executive presentation + 1 forecast model
Therapeutic Area	:	Novel vaccines
Publication date	:	July 2013
Catalogue No	:	VAMV048

Background

Cocaine is a highly addictive natural alkaloid where users experience a short-term feeling of energy and euphoria. The United Nations Office on Drugs and Crime (UNODC) estimates 0.3–0.5% of the world population aged 15–64 years used cocaine in 2009, corresponding to 14.3–20.5 million people. Potential adverse effects associated with cocaine use are cardiovascular disturbances, neurological effects, gastrointestinal complications and sudden death due to cardiac arrest/seizures. It is estimated that cocaine was involved in about 5100 deaths in the US in 2008.

There are currently no FDA-approved medications to treat cocaine addiction, although behavioural treatments have been proven to be effective in some cases. Some investigators are investigating a cocaine vaccine which would stimulate anti-cocaine antibody production, sequester the drug in the blood circulation and reduce the associated euphoric effects.

This **MarketVIEW** product is a comprehensive commercial opportunity assessment detailing the potential market for a cocaine dependence vaccine with a patient based value/volume forecast for the major seven markets to 2030. Two target product profiles (TPP) are forecasted with differing efficacy levels/administration profiles. The analysis also gives an up-to-date review of worldwide epidemiology/guidelines/classifications and an overview of current research and development in the field.

Methodology

VacZine Analytics has closely monitored all significant source material pertaining to cocaine dependence. Example, secondary source materials used are literature articles, government websites/databases, medical bodies and associations, conference proceedings and previously analyses (where publically available). Previously published research by **VacZine Analytics** in field of novel vaccines has also been utilised. *****See Bibliography for exact sources.**

PRODUCT CONTENTS:

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****This product is composed of a model and summary presentation

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Continued.....

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Bibliography
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About **VacZine Analytics**

PAGES: 88 MS PowerPoint slides, fully referenced/sourced. Available in .pdf form



Contents – Vaccine demand model(s) (MS Excel-based) – 1 model

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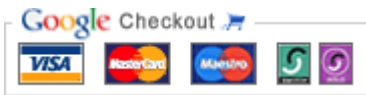
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BIBLIOGRAPHY:

1. Degenhardt L et al. Toward a global view of alcohol, tobacco, cannabis, and cocaine use: findings from the WHO World Mental Health Surveys. *PLoS. Med.* 2008, 5(7): e141
2. Degenhardt L et al. What data are available on the extent of illicit drug use and dependence globally? Results of four systematic reviews. *Drug. Alcohol. Depend.* 2011, 117: 85
3. Anthony JC et al. Comparative epidemiology of dependence on tobacco, alcohol, controlled substances, and inhalants: basic findings from the National Comorbidity Study. *Exp. Clin. Psychopharmacol.* 1994, 2(3): 244
4. Lopez-Quintero C et al. Probability and predictors of transition from first use to dependence on nicotine, alcohol, cannabis, and cocaine: Results of the National Epidemiologic Survey on Alcohol and Related Conditions (NESARC). *Drug. Alcohol. Depend.* 2011, 115(1-2): 120
5. Moore T. Working estimates of the social costs per gram and per user for cannabis, cocaine, opiates and amphetals. 2007. Available at [http://www.dpmp.unsw.edu.au/DPMPWeb.nsf/resources/DPMP+Monographs3/\\$file/DPMP+MONO+14.pdf](http://www.dpmp.unsw.edu.au/DPMPWeb.nsf/resources/DPMP+Monographs3/$file/DPMP+MONO+14.pdf) Accessed: June 2013
6. Data360.org. US death rates by age group. 2004. Available at http://www.data360.org/dsg.aspx?Data_Set_Group_Id=587 Accessed: July 2013
7. Degenhardt L, Hall W. Extent of illicit drug use and dependence, and their contribution to the global burden of disease. *Lancet.* 2012, 379: 55
8. Degenhardt L et al. Mortality among cocaine users: a systematic review of cohort studies. *Drug. Alcohol. Depend.* 2011, 113: 88
9. DrugScope. How many people are addicted? 2004. Available at <http://www.drugscope.org.uk/resources/faqs/faqpages/how-many-people-are-addicted> Accessed: July 2013
10. SAMHSA. The NSDUH Report. Need for and receipt of substance use treatment among blacks. 2013. Available at <http://www.samhsa.gov/data/2k13/NSDUH124/sr124-african-american-treatment.htm> Accessed: July 2013
11. Martell BA et al. Cocaine vaccine for the treatment of cocaine dependence in methadone maintained patients: a randomized double-blind placebo-controlled efficacy trial. *Arch. Gen. Psychiatry.* 2009, 66(10): 1116
12. Everly JJ et al. Employment-based reinforcement of adherence to depot naltrexone in unemployed opioid-dependent adults: a randomized controlled trial. *Addiction.* 2011, 106(7): 1309
13. United Nations Office on Drugs and Crime. World Drug Report. 2011. Available at <http://www.unodc.org/unodc/en/data-and-analysis/WDR-2011.html> Accessed: June 2013
14. Dinis-Oliviera RJ et al. Clinical and forensic signs related to cocaine abuse. *Curr. Drug. Abuse. Rev.* 2012, 5: 64
15. National Institute on Drug Abuse. Research report series. Cocaine: abuse and addiction. 2010. Available at <http://www.drugabuse.gov/publications/research-reports/cocaine-abuse-addiction> Accessed: June 2013
16. Farrenkopf C. Cocaine and the Brain: the neurobiology of addiction. 2008. <http://serendip.brynmawr.edu/exchange/node/1704> Accessed: June 2013
17. Nutt D et al. Development of a rational scale to assess the harm of drugs of potential misuse. *Lancet.* 2007, 369(9566): 1047
18. Akkina SK et al. Illicit drug use, hypertension, and chronic kidney disease in the US adult population. *Transl. Res.* 2012, 160(6): 391
19. Arias F et al. Abuso o dependencia a la cocaína y otros trastornos psiquiátricos. Estudio Madrid sobre la prevalencia de la patología dual. *Rev. Psiquiatr. Salud. Ment. (Barc.).* 2012
20. Han B et al. Associations between duration of illicit drug use and health conditions: results from the 2005-2007 national surveys on drug use and health. *Ann. Epidemiol.* 2010, 20(4): 289
21. Lev-Ran S et al. Self-reported psychotic disorders among Individuals with substance use disorders: findings from the National Epidemiologic Survey on Alcohol and Related Conditions. *Am. J. Addict.* 2012, 21(6): 531
22. Tortajada S et al. Psychiatric morbidity among cocaine and heroin users in the community. *Addiciones.* 2012, 24(3): 201
23. Smith PH et al. Intimate partner violence and specific substance use disorders: findings from the National Epidemiologic Survey on Alcohol and Related Conditions. *Psychol. Addict. Behav.* 2012, 26(2): 236
24. Warner M et al. Drug poisoning deaths in the United States, 1980-2008. *NCHS Data Brief.* 2011, 81
25. Office for National Statistics. Figure 4. Age-standardised mortality rates for selected substances, males, England and Wales 2007-2011. 2012. Available at <http://www.ons.gov.uk/ons/rel/subnational-health3/deaths-related-to-drug-poisoning/2011/chd-drugs-figure-4.xls> Accessed: June 2013
26. National Institutes of Health. Uncovering the mechanism of cocaine addiction. 2010. Available at <http://www.nih.gov/researchmatters/january2010/01112010cocaine.htm> Accessed: June 2013
27. Maze I et al. Essential role of histone methyltransferase G9a in cocaine-induced plasticity. *Science.* 2010, 327(5962): 213
28. Cotto JH et al. Gender effects on drug use, abuse, and dependence: a special analysis of results from the National Survey on Drug Use and Health. *Gen. Med.* 2010, 7(5): 402

29. American Psychiatric Association. Highlights of changes from DSM-IV-TR to DSM-5. 2013. Available at <http://www.psychiatry.org/File%20Library/Practice/DSM/DSM-5/Changes-from-DSM-IV-TR--to-DSM-5.pdf>. Accessed: June 2013
30. Blazer DG, Wu LT. The epidemiology of substance use and disorders among middle aged and elderly community adults: National Survey on Drug Use and Health (NSDUH). *Am. J. Geriatr. Psychiatry.* 2009, 17(3): 237
31. Fiedler KK et al. Cocaine use in the past year is associated with altitude of residence. *J. Addict. Med.* 2012, 6(2): 166
32. Hedden SL et al. Differences between adult non-drug users versus alcohol, cocaine and concurrent alcohol and cocaine problem users. *Addict. Behav.* 2009, 34(3): 323
33. Haasen C et al. Cocaine use in Europe - a multi-centre study. Methodology and prevalence estimates. *Eur. Addict. Res.* 2004, 10(4): 139
34. Prinzleve M et al. Cocaine use in Europe - a multi-centre study: patterns of use in different groups. *Eur. Addict. Res.* 2004, 10(4):147
35. White JW et al. Intelligence quotient in childhood and the risk of illegal drug use in middle-age: the 1958 National Child Development Survey. *Ann. Epidemiol.* 2012, 22(9):654
36. Wagner FA, Anthony JC. Male-female differences in the risk of progression from first use to dependence upon cannabis, cocaine, and alcohol. *Drug. Alcohol. Depend.* 2007, 86: 191
37. O'Brien MS, Anthony JC. Risk of becoming cocaine dependent: epidemiological estimates for the United States, 2000-2001. *Neuropsychopharmacology.* 2005, 30: 1006
38. Wu LT et al. Using a latent variable approach to inform gender and racial/ethnic differences in cocaine dependence: A National Drug Abuse Treatment Clinical Trials Network study. *J. Subst. Abuse. Treat.* 2010, 38S1: S70
39. Lev-Ran S et al. Gender differences in prevalence of substance use disorders among individuals with lifetime exposure to substances: results from a large representative sample. *Am. J. Addict.* 2013, 22(1): 7
40. Lopez-Quintero C et al. Probability and predictors of remission from lifetime nicotine, alcohol, cannabis, or cocaine dependence: Results from the National Epidemiologic Survey on Alcohol and Related Conditions. *Addiction.* 2011, 106(3): 657
41. Kleber HD et al. Practice Guideline for the Treatment of Patients With Substance Use Disorders, Second Edition. 2006. Available at <http://psychiatryonline.org/content.aspx?bookid=28§ionid=1675010> Accessed: June 2013
42. National Institute on Drug Abuse. Principles of drug addiction treatment: a research-based guide. 2012. Available at <http://www.drugabuse.gov/publications/principles-drug-addiction-treatment> Accessed: June 2013
43. Lingford-Hughes AR et al. BAP updated guidelines: evidence-based guidelines for the pharmacological management of substance abuse, harmful use, addiction and comorbidity: recommendations from BAP. *J. Psychopharmacology.* 2012, 26(7): 899
44. National Institute for Health and Care Excellence. Drug misuse: psychosocial interventions. Clinical guidelines CG51. 2007. Available at <http://www.nice.org.uk/CG51> Accessed: June 2013
45. Davies L et al. The Drug Treatment Outcomes Research study (DTORS): Cost-effectiveness analysis. Research Report 25. 2009.
46. Shen X, Kosten TR. Immunotherapy for drug abuse. *CNS. Neurol. Disord. Drug. Targets.* 2011, 10(8): 876
47. Shen X, et al. Vaccines for drug abuse. *Clin. Pharmacol. Ther.* 2012, 91(1): 60
48. Montoya ID. Advances in the development of biologics to treat drug addictions and overdose. *Addictions.* 2012, 24(2): 95
49. Narasimhan D. Bacterial cocaine esterase: a protein-based therapy for cocaine overdose and addiction. *Future. Med. Chem.* 2012, 4(2): 137
50. Shorter D, Kosten TR. Novel pharmacotherapeutic treatments for cocaine addiction. *BMC. Med.* 2011, 9: 119
51. Koob G et al. Anti-cocaine vaccine based on coupling a cocaine analog to a disrupted adenovirus. *CNS. Neurol. Disord. Drug. Targets.* 2011, 10(8): 899
52. Wee S et al. Novel cocaine vaccine linked to a disrupted adenovirus gene transfer vector blocks cocaine psychostimulant and reinforcing effects. *Neuropsychopharmacology.* 2012, 37: 1083
53. Maoz A et al. Adenovirus capsid-based anti-cocaine vaccine prevents cocaine from binding to the nonhuman primate CNS dopamine transporter. *Neuropsychopharmacology.* 2013, doi: 10.1038/npp.2013.114. [Epub ahead of print]
54. Carrera MR et al. Evaluation of the anticocaine monoclonal antibody GNC92H2 as an immunotherapy for cocaine overdose. *Pharmacol. Biochem. Behav.* 2005, 81(40): 709
55. Treweek JB et al. Immunopharmacotherapeutic manifolds and modulation of cocaine overdose. *Pharmacol. Biochem. Behav.* 2011, 98(3): 474
56. Rosenberg JB et al. AAVrh.10-mediated expression of an anti-cocaine antibody mediates persistent passive immunization that suppresses cocaine-induced behavior. *Hum. Gene. Ther.* 2012, 23: 451
57. Heading CE. TA-CD. *Xenova. IDrugs.* 2002, 5(11): 1070

58. Kosten TR et al. Human therapeutic cocaine vaccine: safety and immunogenicity. *Vaccine*. 2002, 20(7-8): 1196
59. Martell BA et al. Vaccine pharmacotherapy for the treatment of cocaine dependence. *Biol. Psychiatry*. 2005, 58(2): 158
60. Multisite Controlled Trial of Cocaine Vaccine (TA-CD). 2012. Available at <http://clinicaltrials.gov/ct2/show/NCT00969878>
Accessed: June 2013
61. Gruzca RA et al. Discrepancies in estimates of prevalence and correlates of substance use and disorders between two national surveys. *Addiction*. 2007, 102(4): 623
62. Kasperski SJ et al. College students' use of cocaine: Results from a longitudinal study. *Addict. Behav.* 2011, 36(4): 408
63. Havens JR et al. Nonmedical prescription drug use in a nationally representative sample of adolescents. *Arch. Pediatr. Adolesc. Med.* 2011, 165: 250
64. National Institute on Drug Abuse. Monitoring the Future Study: trends in prevalence of various drugs. 2012. Available at <http://www.drugabuse.gov/related-topics/trends-statistics/monitoring-future/trends-in-prevalence-various-drugs> Accessed: June 2013
65. Substance abuse and mental health services administration. 2010-2011 National Survey on Drug Use and Health National Maps of Prevalence Estimates, by State. 2011. Available at: <http://www.samhsa.gov/data/NSDUH/2k11State/NSDUHsaeMaps2011.htm> Accessed: June 2013
66. Kaye S et al. An evaluation of cocaine dependence among injecting and non-injecting cocaine users in Sydney. 2001. Available at <http://ndarc.med.unsw.edu.au/sites/default/files/ndarc/resources/TR.116.pdf> Accessed: July 2013
67. Kraus L et al. Drug use patterns and drug-related disorders of cocaine users in a sample of the general population in Germany. *Eur. Addict. Res.* 2007, 13(2): 116
68. Kracmarova L et al. Tobacco, alcohol and illegal substances: experiences and attitudes among Italian university students. *Rev. Assoc. Med. Bras.* 2011, 57(5): 523
69. Manzoli L et al. Different use/abuse patterns (overweight/obesity, alcohol, smoking, drugs, cannabis, opiates, cocaine) according to job category. Results of a survey on 4024 young workers from Abruzzo, Italy: the Valentino Study. *Ann. Ig.* 2009, 21(3): 211
70. Davoli M et al. Changing pattern of drug abuse among patients entering treatment in Lazio, Italy, between 1996 and 2003: transition from heroin to cocaine use. *Eur. Addict. Res.* 2007, 13(4): 185
71. Roncero C et al. Prevalence and risk factors of psychotic symptoms in cocaine-dependent patients. *Actas. Esp. Psiquiatr.* 2012, 40(4): 187
72. Saiz PA et al. Use of cocaine by secondary school students in northern Spain. *Eur. Addict. Res.* 2003, 9(3): 138
73. Brugal MT et al. Prevalence of problematic cocaine consumption in a city of southern Europe, using capture-recapture with a single list. *J. Urban. Health.* 2004, 81(3): 416
74. Hope VD et al. Capturing crack cocaine use: estimating the prevalence of crack cocaine use in London using capture-recapture with covariates. *Addiction*. 2005, 100(11): 1701
75. Vivancos R et al. Sexual behaviour, drugs and alcohol use of international students at a British university: a cross-sectional survey. *Int. J. STD. AIDS.* 2009, 20: 619
76. Public Health England. Drug treatment activity in England 2011-12. Tables. 2012. Available at <http://www.nta.nhs.uk/statistics.aspx> Accessed: June 2013
77. Public Health England. Substance misuse among young people: the data for 2011-12. Tables. 2012. Available at <http://www.nta.nhs.uk/statistics.aspx> Accessed: June 2013
78. Vivancos R et al. Crack/cocaine use in a rural county of England. *J. Public. Health.* 2006, 28(2): 96

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About VacZine Analytics:

VacZine Analytics is an established strategic research agency based in the United Kingdom. Its aim is to provide disease and commercial analysis for the vaccine industry and help build the case for developing new vaccines and biologics.

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