



## **Reckitt Benckiser Pharmaceuticals Inc. Enters Into Agreement to Develop and Market First Naloxone Nasal Treatment for Opioid Overdose**

**RICHMOND, Va. (May 19, 2014)** – Reckitt Benckiser Pharmaceuticals Inc. (RBP) announced today that it has entered into a definitive agreement with AntiOp, Inc. to co-develop a naloxone nasal spray to aid in the reversal of opioid overdose with the option to acquire all rights to the product upon receipt of regulatory and marketing approval. The product has the potential to be the first of its kind to treat overdose from opioid prescription painkillers and heroin – a growing epidemic in the United States.<sup>1,2</sup>

Currently, the standard medical protocol for treating opioid overdose is to administer an injectable form of naloxone.<sup>3,4,5</sup> It must be administered intravenously or as a shot into muscle or under the skin.<sup>4,5</sup> There is a lack of familiarity or comfort with injectable medication administration among non-medical personnel and emergency first responders. This product aims to fulfill an unmet need by providing family members and caregivers – who are often on the frontlines at the time of overdose – with a nasal alternative utilizing the novel medication delivery expertise of AntiOp.

“This strategic agreement partners the innovative science of AntiOp, led by Dr. Daniel Wermeling, renowned for his work in the nasal delivery of medication, with the pioneering leadership of Reckitt Benckiser Pharmaceuticals as an innovator in opioid dependence treatment for more than a decade,” said Shaun Thaxter, CEO, Reckitt Benckiser Pharmaceuticals Inc. “Together, we are uniquely suited to bring this product to market and are excited about the potential to help the many patients each year who succumb to opioid overdose.<sup>6</sup> Naloxone nasal spray is a strong, strategic fit to our portfolio further strengthening our capabilities to provide much needed treatment services for the chronic relapsing conditions of addiction.”

Drug overdose deaths, driven largely by opioid prescription medication overdose deaths, are now the leading cause of injury death in the United States – surpassing motor vehicle crashes.<sup>6,7</sup> Use of opioids has been steadily increasing over the past decade,<sup>8,9</sup> while opioid-related drug overdose deaths have more than tripled in the past 12 years driven primarily by the abuse of opioid prescription painkillers.<sup>9</sup> The U.S. Centers for Disease Control and Prevention reports that more than 45 people died each day on average from opioid prescription painkiller overdoses, claiming more than 16,651 lives in 2010 alone.<sup>6</sup>

AntiOp’s nasal formulation is a pre-filled, unit-dose, disposable delivery system designed for insertion into the nose of an overdose victim to administer naloxone across the nasal mucosal membrane for absorption.<sup>10</sup> The needle-free device was selected to facilitate broader access to this treatment.

### **About Reckitt Benckiser Pharmaceuticals Inc.**

Reckitt Benckiser Pharmaceuticals Inc. is a specialty pharmaceutical company with a decade of heritage in serving the opioid dependence treatment community. Committed to expanding education and access to medical therapies, the company innovates, manufactures and markets



medications that, in conjunction with counseling and psychosocial support, treat opioid dependence. Reckitt Benckiser Pharmaceuticals Inc. continues to invest resources in raising awareness of opioid dependence within the community, while also sponsoring training programs for physicians to become certified to treat opioid addicted patients. The company aims to help patients by enabling opioid dependence to be managed within mainstream medical practice through medication-assisted treatment. Reckitt Benckiser Pharmaceuticals Inc. is a wholly owned subsidiary of Reckitt Benckiser Group plc, a global company publicly traded on the UK stock exchange.

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### References

<sup>1</sup> Substance Abuse and Mental Health Services Administration. (September 2010). Treatment Episode Data Set: Characteristics of Substance Abuse Treatment Admissions Reporting Primary Abuse of Prescription Pain Relievers: 1998 and 2008. Accessed May 6, 2014. Available at <http://www.oas.samhsa.gov/2k10/230b/230bPainRelvr2k10Web.pdf>.

<sup>2</sup> Centers for Disease Control and Prevention (CDC). Vital Signs: Overdoses of Prescription Opioid Pain Relievers—United States, 1999-2008. MMWR, 2011; 60: 1-6. Accessed May 6, 2014. Available at: [http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6043a4.htm?s\\_cid=mm6043a4\\_w](http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6043a4.htm?s_cid=mm6043a4_w).

<sup>3</sup> FDA News Release. FDA approves new hand-held auto-injector to reverse opioid overdose. April 3, 2014. Accessed May 6, 2014. Available at: <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm391465.htm>.

<sup>4</sup> Kaleo, Inc. Evzio Prescribing Information. April 2014. Accessed May 6, 2014. Available at: <http://www.evzio.com/pdfs/Evzio%20PI.PDF>.

<sup>5</sup> Hospira, Inc. Naloxone Hydrochloride Injection, USP Product Insert. Accessed April 24, 2014. Available at [http://www.hospira.com/Images/EN-1367\\_32-5515\\_1.pdf](http://www.hospira.com/Images/EN-1367_32-5515_1.pdf)

<sup>6</sup> Jones CM, Mack KA, Paulozzi LJ. Pharmaceutical overdose deaths, United States, 2010. *JAMA* 2013;309:657-659. Accessed May 6, 2014. Available at: <http://jama.jamanetwork.com/article.aspx?articleid=1653518>

<sup>7</sup> Centers for Disease Control and Prevention. Wide-ranging OnLine Data for Epidemiologic Research (WONDER) [online]. (2012) Available from URL: <http://wonder.cdc.gov/mortsql.html>.

<sup>8</sup> Substance Abuse and Mental Health Services Administration. (2011). Results from the 2010 National Survey on Drug Use and Health: Summary of National Findings, NSDUH Series H-41, HHS Publication No. (SMA) 11-4658. Accessed May 6, 2014. Available at <http://www.samhsa.gov/data/NSDUH/2k10ResultsRev/NSDUHresultsRev2010.htm>.

<sup>9</sup> Centers for Disease Control and Prevention (CDC). Policy Impact: Prescription Painkiller Overdoses. Accessed May 6, 2014. Available at: <http://www.cdc.gov/HomeandRecreationalSafety/pdf/PolicyImpact-PrescriptionPainkillerOD.pdf>.

<sup>10</sup> AntiOp, Inc. Press Release. Naloxone Nasal Spray on Development Fast Track as Emergency Treatment for Opioid Overdose. September 20, 2013. Accessed May 6, 2014. Available at: <http://www.businesswire.com/news/home/20130920005500/en/Naloxone-Nasal-Spray-Development-Fast-Track-Emergency>.