



Emergent BioSolutions Receives NIH Research Grant to Further Develop AP007, Its Development Stage Sustained-Release Nalmefene Treatment for Opioid Use Disorder

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GAITHERSBURG, Md., Sept. 27, 2019 (GLOBE NEWSWIRE) -- Emergent BioSolutions Inc. (NYSE: EBS) today announced a research grant awarded by the National Institute on Drug Abuse (NIDA), a component of the National Institutes of Health (NIH), U.S. Department of Health and Human Services, valued at approximately \$6.3 million over two years, for the continued development of AP007, the company's sustained-release nalmefene formulation for the treatment of addiction in opioid use disorder (OUD). AP007 is an extended-release formulation of nalmefene, an opioid receptor antagonist, intended to continually release an effective dose of nalmefene for up to three months and to be administered through intramuscular injection. The award is being made under the Helping to End Addiction Long-term Initiative, or the NIH HEAL Initiative, which was launched to improve prevention and treatment strategies for opioid misuse and addiction and enhance pain management.

Doug White, SVP and devices business unit head at Emergent BioSolutions, said, "OUD is a complex public health epidemic that is estimated to impact more than two million people in the U.S. today.¹ Through this research grant, Emergent has the opportunity to advance the development of AP007, an extended-release formulation of nalmefene, intended to help improve OUD treatment outcomes, including adherence to medication and reduction in relapse. We are pleased to partner with NIDA and are committed to working with federal, state and community organizations to help address this public health crisis."

"It's clear that a multi-pronged scientific approach is needed to reduce the risks of opioids, accelerate development of effective non-opioid therapies for pain and provide more flexible and effective options for treating addiction to opioids," said NIH Director Francis S. Collins, M.D., Ph.D., who launched the initiative in early 2018. "This unprecedented investment in the NIH HEAL Initiative demonstrates the commitment to reversing this devastating crisis."

The two-year grant award will enable the company to conduct necessary non-clinical studies and activities leading up to submission of an Investigational New Drug application to the U.S. Food and Drug Administration. Upon completion of milestones from the awarded period, the project may transition to a second project phase that would provide three years of additional funding for further clinical safety and efficacy testing. Emergent's award is one of 375 grant awards across 41 states made by the NIH in fiscal year 2019 to apply scientific solutions to reverse the national opioid crisis.

This grant award is supported by the National Institute on Drug Abuse of the National Institutes of Health under Award Number UG3DA048745. The content of this press release is solely the responsibility of the company and does not necessarily represent the official views of the National Institutes of Health.

About the NIH HEAL Initiative

The National Institutes of Health launched the Helping to End Addiction Long-term Initiative, or NIH HEAL Initiative, in April 2018 to improve prevention and treatment strategies for opioid misuse and addiction and enhance pain management. The NIH HEAL Initiative aims to improve treatments for chronic pain, curb the rates of opioid use disorder and overdose and achieve long-term recovery from opioid addiction.

About Opioid Use Disorder (OUD)

Opioids produce high levels of positive reinforcement, increasing the odds that people will continue using them despite negative resulting consequences. Opioid use disorder is a chronic lifelong disorder with serious potential consequences, including disability, relapses, and death. The Diagnostic and Statistical Manual of Mental Disorders, 5th Edition describes opioid use disorder as a problematic pattern of opioid use leading to problems or distress, with at least two of the following occurring within a 12-month period:

1. Taking larger amounts or taking drugs over a longer period than intended.
2. Persistent desire or unsuccessful efforts to cut down or control opioid use.
3. Spending a great deal of time obtaining or using the opioid or recovering from its effects.
4. Craving, or a strong desire or urge to use opioids.
5. Problems fulfilling obligations at work, school or home.
6. Continued opioid use despite having recurring social or interpersonal problems.

7. Giving up or reducing activities because of opioid use.
8. Using opioids in physically hazardous situations.
9. Continued opioid use despite an ongoing physical or psychological problem likely to have been caused or worsened by opioids.
10. Tolerance (*i.e.*, need for increased amounts or diminished effect with continued use of the same amount).
11. Experiencing withdrawal (opioid withdrawal syndrome) or taking opioids (or a closely related substance) to relieve or avoid withdrawal symptoms.

While opioid use disorder is similar to other substance use disorders in many respects, it has several unique features. Opioids can lead to physical dependence within a short time, as little as 4-8 weeks. In chronic users, the abruptly stopping use of opioids leads to severe symptoms, including generalized pain, chills, cramps, diarrhea, dilated pupils, restlessness, anxiety, nausea, vomiting, insomnia, and very intense cravings. Because these symptoms are severe, it creates significant motivation to continue using opioids to prevent withdrawal.

About Emergent BioSolutions

Emergent BioSolutions Inc. is a global life sciences company seeking to protect and enhance life by focusing on providing specialty products for civilian and military populations that address accidental, deliberate, and naturally occurring public health threats. We aspire to be a Fortune 500 company recognized for protecting and enhancing life, driving innovation, and living our values. Additional information about the company may be found at www.emergentbiosolutions.com. Find us on LinkedIn and follow us on Twitter@emergentbiosolu and Instagram @life_at_emergent.

Safe Harbor Statement

This press release includes forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Any statements, other than statements of historical fact, including statements regarding the ability of the AP007 candidate to improve OUD treatment outcomes and the submission of an Investigational New Drug application to the FDA and any other statements containing the words "believes," "expects," "anticipates," "intends," "plans," "seeks," "estimates" and similar expressions, are forward-looking statements. These forward-looking statements are based on our current intentions, beliefs and expectations regarding future events. We cannot guarantee that any forward-looking statement will be accurate. Investors should realize that if underlying assumptions prove inaccurate or unknown risks or uncertainties materialize, actual results could differ materially from our expectations. Investors are, therefore, cautioned not to place undue reliance on any forward-looking statement. Any forward-looking statement speaks only as of the date of this press release, and, except as required by law, we do not undertake to update any forward-looking statement to reflect new information, events or circumstances.

There are a number of important factors that could cause the company's actual results to differ materially from those indicated by such forward-looking statements, including the results of non-clinical studies and our ability to reach milestones that may trigger additional funding from the U.S. government for further development of the AP007 candidate. The foregoing sets forth many, but not all, of the factors that could cause actual results to differ from our expectations in any forward-looking statement. Investors should consider this cautionary statement, as well as the risk factors identified in our periodic reports filed with the SEC, when evaluating our forward-looking statements.

¹ Results from the 2016 National Survey on Drug Use and Health conducted by Substance Abuse and Mental Health Services Administration (SAMHSA) can be found here: <https://www.samhsa.gov/data/sites/default/files/NSDUH-DeTubs-2016/NSDUH-DeTubs-2016.pdf>.

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