# NARCAN<sup>®</sup> (Naloxone Hydrochloride) NASAL SPRAY Now Available in the United States for Emergency Treatment of Known or Suspected Opioid Overdose

### First and Only FDA-Approved Nasal Spray Form of Naloxone

Dublin, Ireland – February 25, 2016 – Adapt Pharma, Limited (www.adaptpharma.com) today announced the United States (U.S.) commercial availability of opioid antagonist NARCAN<sup>®</sup> (naloxone hydrochloride) Nasal Spray, for the emergency treatment of known or suspected opioid overdose, as manifested by respiratory and/or central nervous system (CNS) depression.

NARCAN<sup>®</sup> Nasal Spray is the first and only FDA-approved naloxone nasal spray. It is now available as a ready-to-use, needle-free, 4 mg concentrated dose of naloxone in a single spray. As the first of its kind, NARCAN<sup>®</sup> Nasal Spray provides an effective alternative to currently available opioid overdose emergency treatments. NARCAN<sup>®</sup> Nasal Spray is not a substitute for emergency medical care. See indications and important safety information below.

On January 25, 2016, Adapt Pharma announced a partnership with the **Clinton Health Matters Initiative**, an initiative of the Clinton Foundation, as part of its work to scale naloxone access efforts nationally. Through this partnership and in close collaboration with state departments of education, Adapt Pharma will offer a free carton of NARCAN<sup>®</sup> Nasal Spray to all high schools in the United States.

NARCAN<sup>®</sup> Nasal Spray is available for public interest pricing through U.S. Communities Cooperative Purchasing Program, an organization providing products at a discounted price to local and state government agencies, school districts (K-12), higher education institutions, and nonprofits. Through this cooperative, NARCAN<sup>®</sup> Nasal Spray is available at \$75 per dual-pack (\$37.50 per dose).<sup>1</sup>

NARCAN<sup>®</sup> Nasal Spray is also available through AmerisourceBergen Corporation (ABC), Cardinal Health, Inc., HD Smith and McKesson Corporation, as well as online directly through NARCANNasalSpray.com. NARCAN<sup>®</sup> Nasal Spray is also available from select specialty distributors.

"The U.S. is facing an unprecedented opioid overdose epidemic, and we are grateful for the opportunity to officially provide the communities on the frontline of this battle a ready-to-use, needle-free, effective emergency treatment," said **Seamus Mulligan, Chairman and CEO of Adapt Pharma**. "Opioid overdoses can occur anywhere and at any time. By making NARCAN® Nasal Spray available, we hope to increase everyone's access to emergency treatments across the U.S., when every second matters."

Adapt Pharma is responsible for all U.S. commercial activities for NARCAN<sup>®</sup> Nasal Spray including promotion and distribution. It is available in a carton containing two blister packages, each with a single NARCAN<sup>®</sup> Nasal Spray containing a single 4 mg dose of naloxone hydrochloride intranasal spray.

For questions regarding NARCAN<sup>®</sup> distribution, please call 1-844-4NARCAN<sup>®</sup> (462-7226).

#### ABOUT NARCAN® NASAL SPRAY

NARCAN<sup>®</sup> Nasal Spray is indicated for the emergency treatment of known or suspected opioid overdose, as manifested by respiratory and/or central nervous system depression.

NARCAN<sup>®</sup> Nasal Spray is intended for immediate administration as emergency therapy in settings where opioids may be present.

NARCAN<sup>®</sup> Nasal Spray is not a substitute for emergency medical care. Always seek emergency medical assistance in the event of a suspected, potentially life-threatening opioid emergency after administration of the first dose of NARCAN<sup>®</sup> nasal spray.

If the desired response is not obtained after 2 or 3 minutes, administer an additional dose of NARCAN<sup>®</sup> Nasal Spray using a new NARCAN<sup>®</sup> Nasal Spray. If the patient responds to NARCAN<sup>®</sup> Nasal Spray and relapses back into respiratory depression before emergency assistance arrives, administer an additional dose and continue surveillance of the patient. If there is still no response and additional doses are available, administer additional doses of NARCAN<sup>®</sup> Nasal Spray every 2 to 3 minutes using a new NARCAN<sup>®</sup> Nasal Spray with each dose until emergency medical assistance arrives. Additional supportive and/or resuscitative measures may be helpful while awaiting emergency medical assistance.

**Please see Indications and Important Safety Information below.** Full prescribing information for NARCAN<sup>®</sup> Nasal Spray, including important safety information, is also available at www.NARCAN<sup>®</sup>NasalSpray.com.

#### **AVAILABILITY OF NARCAN® NASAL SPRAY**

Once launched, in early 2016, we expect NARCAN<sup>®</sup> Nasal Spray will be available at retail pharmacies.

Qualifying group purchasers may source NARCAN<sup>®</sup> Nasal Spray directly from wholesalers and distributors. To place a pre-order immediately or for assistance in sourcing NARCAN<sup>®</sup> Nasal Spray please contact Adapt Pharma's dedicated Customer Service Team at 844-4-NARCAN<sup>®</sup> (844-462-7226) or email <u>customerservice@adaptpharma.com</u>

# NARCAN® NASAL SPRAY INDICATION AND IMPORTANT SAFETY INFORMATION

#### Indication

NARCAN<sup>®</sup> (naloxone hydrochloride) Nasal Spray is an opioid antagonist indicated for the emergency treatment of known or suspected opioid overdose, as manifested by respiratory and/or central nervous system depression. NARCAN<sup>®</sup> Nasal Spray is intended for immediate administration as emergency therapy in settings where opioids may be present. NARCAN<sup>®</sup> Nasal Spray is not a substitute for emergency medical care.

#### **Important Safety Information**

NARCAN<sup>®</sup> Nasal Spray is contraindicated in patients known to be hypersensitive to naloxone hydrochloride.

Seek emergency medical assistance immediately after initial use, keeping the patient under continued surveillance.

<u>Risk of Recurrent Respiratory and CNS Depression</u>: Due to the duration of action of naloxone relative to the opioid, keep the patient under continued surveillance and administer repeat doses of naloxone using a new nasal spray with each dose, as necessary, while awaiting emergency medical assistance.

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<u>Risk of Limited Efficacy with Partial Agonists or Mixed Agonists/Antagonists</u>: Reversal of respiratory depression caused by partial agonists or mixed agonists/antagonists, such as buprenorphine and pentazocine, may be incomplete. Larger or repeat doses may be required.

<u>Precipitation of Severe Opioid Withdrawal</u>: Use in patients who are opioid dependent may precipitate opioid withdrawal and acute withdrawal syndrome. In neonates, opioid withdrawal may be life-threatening if not recognized and properly treated. Monitor for the development of opioid withdrawal.

<u>Risk of Cardiovascular (CV) Effects</u>: Abrupt postoperative reversal of opioid depression may result in adverse CV effects. These events have primarily occurred in patients who had pre-existing CV disorders or received other drugs that may have similar adverse CV effects. Monitor these patients closely in an appropriate healthcare setting after use of naloxone hydrochloride.

The following adverse reactions were observed in a NARCAN<sup>®</sup> Nasal Spray clinical study: increased blood pressure, musculoskeletal pain, headache, nasal dryness, nasal edema, nasal congestion, and nasal inflammation.

See Instructions for Use and full prescribing information in the use of this product.

Full prescribing information for NARCAN<sup>®</sup> Nasal Spray, including important safety information, is also available at <u>www.NARCAN<sup>®</sup>NasalSpray.com</u>.

To report SUSPECTED ADVERSE REACTIONS, contact Adapt Pharma, Inc. at 1-844-4NARCAN<sup>®</sup> (1-844-462-7226) or FDA at 1-800-FDA-1088 or <u>www.fda.gov/medwatch</u>.

### ABOUT U.S. COMMUNITIES

U.S. Communities was founded in 1996 as a partnership between the Association of School Business Officials, the National Association of Counties, the National League of Cities and the United States Conference of Mayors. U.S. Communities is the leading national government purchasing cooperative, providing world class government procurement resources and solutions to local and state government agencies, school districts (K-12), higher education institutions, and non-profits looking for the best overall supplier government pricing.

## **ABOUT ADAPT PHARMA**

Adapt Pharma is a privately-held pharmaceutical company committed to positively impacting the lives of patients. Adapt Pharma's strategy is to identify, evaluate, selectively acquire and enhance the value of late stage development, and FDA approved, pharmaceutical products. Adapt Pharma's company headquarters is in Dublin, Ireland and its U.S. headquarters is in Radnor, Pennsylvania. For more information, please visit <u>www.adaptpharma.com</u>.

#### **For Media Inquiries**

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1. Access to Public Interest Price is restricted to qualifying entities and subject to terms and conditions.

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