For Immediate Release

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Fidelis Pharmaceuticals Launches New Ethiqa XR™
Long-Lasting Control of Post-Procedural Pain Relief for Laboratory Rats and Mice

The only FDA-indexed, pharmaceutical grade, extended-release buprenorphine available

NORTH BRUNSWICK, N.J., August 18, 2020 – Fidelis Pharmaceuticals today announced the availability of new Ethiqa XR (buprenorphine extended-release injectable suspension) 1.3 mg/mL. Ethiqa XR is the only pharmaceutical grade extended-release buprenorphine specifically developed for the control of post-procedural pain in mice and rats. Ethiqa XR provides up to 72 hours of pain relief with just one injection.

"This breakthrough innovation meets the essential need for effective, long-acting pain management in mice and rats. Leading laboratory associations, including the American College of Laboratory Animal Medicine (ACLAM), increasingly recognize the ethical and scientific importance of protecting the welfare of research animals through routine use of the highest quality analgesics," says Michael Wells, Chairman and CEO of Fidelis Pharmaceuticals. In fact, the American Association of Laboratory Animal Science (AALAS) is supporting the 2020 Global Year for the Prevention of Pain initiative from the International Association for the Study of Pain (IASP), further emphasizing this important professional responsibility. Fidelis Pharmaceuticals is a proud member of AALAS focused on supporting the laboratory animal profession.

"We in the profession believe it's our moral and ethical obligation to do all we can to provide, when necessary, therapeutic interventions that help ensure both high-quality research and humane animal care and use. Pain management is an important element of that care, and we are excited about the opportunity to further elevate and refine our approach with new options such as Ethiqa XR," says James G. Fox, DVM, MS, DACLAM, Director, Division of Comparative Medicine, Professor, Department of Biological Engineering, Massachusetts Institute of Technology.

Safety and effectiveness studies of Ethiqa XR were conducted to validate performance, reviewed by an expert panel, and then submitted to the FDA's Office of Minor Use/Minor Species division (OMUMS). Ethiqa XR is the only pharmaceutical grade FDA-indexed extended-release buprenorphine available for the control of post-procedural pain in mice and rats. It is manufactured in Harleysville, Pa., in accordance with current Good

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Manufacturing Practices (cGMPs). These facilities are regulated and inspected by the FDA, and product components are free of endotoxins to meet pharmaceutical grade standards.

Laboratory veterinarians and researchers can order Ethiqa XR on a research DEA license (and any applicable state license or registration) directly from distributors, including MWI Animal Health (a subsidiary of AmerisourceBergen). Ethiqa XR's formulation provides a favorable viscosity profile for ease of administration and less waste. It is packaged in 3-mL multi-dose vials that do not require refrigeration.

To learn more, visit ethiqaxr.com, email info@fidelisrx.com, or call toll-free 833-ETHIQAXR (833-384-4729). Fidelis is offering free 20-minute webinars about Ethiqa XR throughout 2020. Research and veterinary professionals may register for these educational webinars, receive updates, and access the latest distributor information by visiting ethiqaxr.com. Click here for full Ethiqa XR Prescribing Information.

Important Safety Information

For Rats and Mice:

Only administer Ethiqa XR™ by subcutaneous injection. Ethiqa XR is not intended for intravenous, intra-arterial, intrathecal, intramuscular, or intra-peritoneal injection. Do not use on mice or rats with pre-existing respiratory deficiencies. Do not keep rats on wood chip-type bedding after administration of Ethiqa XR. Use caution with concomitant administration of Ethiqa XR with drugs that cause respiratory depression.

For Humans:

Ethiqa XR should only be administered by a veterinarian or laboratory staff trained in the handling of potent opioids. Protective clothing is recommended to avoid direct contact with human skin or mucus membranes which could result in absorption of buprenorphine and adverse reactions. Ethiqa XR should be handled appropriately to minimize the risk of misuse, abuse, addiction, and criminal diversion, including restriction of access, the use of accounting procedures, and proper disposal methods as appropriate to the laboratory setting and as required by law. *Not for use in humans. Keep out of reach of children.*
For more information, consult the Prescribing Information, including the Boxed Warning.

BOXED WARNING
WARNING: ABUSE POTENTIAL, LIFE-THREATENING RESPIRATORY DEPRESSION, and ACCIDENTAL EXPOSURE

Abuse Potential

This formulation contains buprenorphine, a high-concentration (1.3 mg/mL) opioid agonist and Schedule III controlled substance with an abuse potential similar to other Schedule III opioids. The high concentration may be a particular target for human abuse. Buprenorphine has opioid properties that in humans may lead to dependence of the morphine type. Abuse of buprenorphine may lead to low or moderate physical dependence or high psychological dependence. The risk of abuse by humans should be considered when storing, administering, and disposing. Persons at increased risk for opioid abuse include those with a personal or family history of substance abuse (including drug or alcohol abuse or addiction) or mental illness (suicidal depression). Because of human safety risks, this drug should be used only with veterinary supervision.

Do not dispense Ethiqa XR.

Life-Threatening Respiratory Depression

The concentration of buprenorphine in Ethiqa XR is 1.3 mg/mL. Respiratory depression, including fatal cases, may occur with abuse of Ethiqa XR by humans. There are additive CNS depressant effects when used with alcohol, other opioids, or illicit drugs that cause central nervous system depression. Because of the potential for adverse reactions associated with accidental injection, Ethiqa XR should only be administered by a veterinarian or trained laboratory staff.

Please see full Ethiqa XR™ Prescribing Information **for additional Important Safety Information.**

About Fidelis Pharmaceuticals, LLC

Fidelis Pharmaceuticals, the U.S.-based manufacturer of Ethiqa XR, is deeply committed to developing unique veterinary pharmaceuticals specifically designed to enhance and protect animal health and welfare. The company's newest innovation, Ethiqa XR, safely and effectively manages post-procedural pain in laboratory animals. Fidelis is actively building a pipeline of high-quality veterinary medical and humane care solutions to serve the animal health community. The Fidelis leadership team supports the foremost veterinary and laboratory research and humane healthcare industry associations and initiatives, including the American Association for Laboratory Animal Science (AALAS) and the American Veterinary Medical Association (AVMA). Visit ethiqaxr.com to learn more.

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