



**FOR IMMEDIATE RELEASE**

**PANOQUELL®- CA1, becomes the first and only drug approved by the FDA for acute canine pancreatitis in the U.S.**

(November 22, 2022- Osaka, JP.) The first and only drug for the management of clinical signs associated with acute onset of pancreatitis in dogs. Panoquell-CA1 (fuzapladib sodium for injection) is now conditionally-approved in the U.S.

Developed by Ishihara Sangyo Kaisha, Ltd (ISK), Panoquell-CA1 will be marketed and distributed in the U.S. by Ceva Animal Health, LLC. Panoquell-CA1 addresses a major unmet need in veterinary medicine, Acute Canine Pancreatitis (ACP).

ACP is a potentially life-threatening disease often seen in general veterinary practice and veterinary emergency hospitals. Panoquell-CA1 inhibits activation of the leukocyte-function associated antigen-1 (LFA-1) which prevents inflammatory cells from infiltrating pancreatic tissue. This mode of action is different from that of conventional anti-inflammatory drugs including steroids and non-steroidal anti-inflammatory drugs (NSAIDs). Dosage administration is by intravenous injection 0.4 mg/kg 1x daily for 3 days. Panoquell-CA1 may be given in conjunction with current supportive care protocols.

Fuzapladib sodium, the active ingredient in Panoquell-CA1, has been approved since 2018 in Japan. Ceva plans to begin U.S. distribution of Panoquell-CA1 in the late first quarter or early second quarter of next year.

“We first launched fuzapladib in Japan and it has proven to be a valuable medicine in treating pancreatitis. We are excited to partner with Ceva to launch Panoquell-CA1 in the U.S. market. We believe the product is an important new tool to help veterinarians provide the highest standard of care possible,” said Hiroyuki Watanabe, Managing Executive Officer of ISK’s Healthcare Business Group and Chairman ISK Animal Health, LLC.

To learn more, consult the FDA News Release at <https://www.fda.gov/news-events/press-announcements/fda-conditionally-approves-first-drug-manage-acute-onset-pancreatitis-dogs>

**IMPORTANT SAFETY INFORMATION:** Panoquell-CA1 is conditionally approved by FDA pending a full demonstration of effectiveness under NADA 141-567 for the management of clinical signs associated with acute onset of pancreatitis in dogs. Do not use in dogs less than 6 months of age, or dogs with a known hypersensitivity to fuzapladib sodium. Use with caution with other medications that are highly protein bound, as concomitant use with these types of drugs have not been studied in dogs. During the pilot effectiveness field study, the concurrent medications used included, but were not limited to, pain medications (excluding NSAIDs), anti-emetics, parasiticides, vaccinations, and medications used to treat well-controlled pre-existing conditions. The safe use of Panoquell-CA1 has not been evaluated in dogs with cardiac disease, hepatic failure, renal impairment, or dogs that are pregnant, lactating, or intended for breeding. The most common side effects in the pilot field study were anorexia, digestive tract

disorders, and respiratory tract disorders. The most common side effects in foreign markets were facial and tongue swelling, collapse, and seizure. Panoquell-CA1 is not for use in humans. Anyone with known hypersensitivity to the active ingredient, any excipients, or who is pregnant, breast feeding, or planning to become pregnant should avoid contact with Panoquell-CA1. In case of accidental self-injection, skin contact, eye exposure, or ingestion, please follow label instructions and seek medical advice immediately and show the package insert or label to the physician. It is a violation of Federal Law to use this product other than as directed in the labeling. For additional information on the use of Panoquell-CA1, please refer to the package insert.

**About Ishihara Sangyo Kaisha, Ltd**

Ishihara Sangyo Kaisha, LTD. (ISK) is a chemical innovation company based in Japan and listed on Tokyo stock exchange market that develops a wide range of products in the areas of Agrochemical, Environmental Products, Functional Materials, Health Care Products and Titanium Dioxide Products. For more information on ISK visit <https://www.iskweb.co.jp/eng/>.

**About Ceva Animal Health, LLC**

Ceva offers a growing line of products for companion animals. The company's North American headquarters is in Lenexa, Kansas. Visit <https://www.ceva.us>

PANOQUELL is a registered trademark of Ishihara Sangyo Kaisha, Ltd.