Ethicann Pharmaceuticals starting cGMP Manufacturing Scale-Up, invited Presenter at Angel Capital Ass'n ACA-2022 Event

BETHESDA, MARYLAND, UNITED STATES, May 11, 2022 /EINPresswire.com/ -- Ethicann Pharmaceuticals Inc. today announced that following a successful animal pharmacokinetic (PK) study, it is to commence full CGMP manufacturing scale-up of its proprietary EPI-002 (THC 2.7 mg : CBD 2.5mg) Zydis® sublingual orally disintegrating tablet (ODT) to treat multiple sclerosis (MS) spasticity. EPI-002 uses Zydis ODT delivery technology reformulated from an ethanol-based oral spray cannabinoid drug (THC 2.7 mg : CBD 2.5 mg) that is approved in over 30 countries to treat MS spasticity. The oral spray contains 50% ethanol by volume per dose, and which some patients have reported to not taste good. MS spasticity patients need safer drugs, since three other MS spasticity drugs have FDA Black Box Safety Warnings.

Catalent's proprietary Zydis drug delivery technology is used in over 20 drugs approved in 60 countries and is protected by a strong international patent portfolio. The Zydis EPI-002 ODT dissolves in ~3 seconds without the need for water, and is rapidly absorbed through the sublingual mucosa into the blood, providing therapeutic advantage by bypassing the liver, which typically removes 30%-45% of cannabinoids absorbed through the stomach. Liver absorption of cannabinoid drugs swallowed and absorbed through the stomach can cause heightened liver toxicity. Ethicann intends to use the Zydis ODT sublingual technology for its entire pipeline of cannabinoid-based drugs, to treat chronic pain, post-traumatic stress disorder (PTSD), chemotherapy-induced nausea and vomiting (CINV), opioid dependency, and epilepsy.

Ethicann will use the CGMP EPI-002 tablets to perform a human bioequivalence study in 2023, required for its approval in Canada (2024-25), then use Canadian data in the United Kingdom, Germany and the rest of Europe (2025-28), before rolling out EPI-002 into global markets, where the noted alcohol-containing oral spray to treat MS spasticity is approved. In the US, Ethicann will pursue a 505(b)(2) New Drug Application (NDA) approval pathway. Ethicann is now outreaching to pharmaceutical companies seeking partnerships, who will gain regulatory approval for EPI-002 and do distribution, marketing and selling. This rapid-to-market reformulation strategy avoids the traditional 7 to 12 years of drug development, and need for $200 million investment.

Keiretsu Forum nominated Ethicann to present to the Angel Capital Association 2022 Summit event in Atlantic City, NJ., May 17th-19th, 2022. Keiretsu Forum is the world's largest and most successful accredited investor, venture capital and private equity community with 52 global

chapters. The ACA-2020 Summit is the annual flagship networking event of 31 national angel groups, involving invited entrepreneurs and companies to this investing community. In nominating Ethicann, Keiretsu just completed a positive deep dive due diligence into all aspects of the Ethicann drug reformulation business opportunity, analyzing the strengths of its business strategy, including its rapid-to-market global regulatory strategy and growth opportunities in the MS spasticity disease markets.

Business Summary: Ethicann (Canada/US) has positioned itself as a cost efficient pharmaceutical development company, using established multinational partners to source ultra-purified APIs and the proprietary sublingual Zydis orally disintegrating tablet (ODT) technology. Ethicann is leveraging these partnerships to formulate and further develop cannabinoid-based pharmaceutical drug products and avoid deploying capital in building and fully staffing its own facilities. This business reformulation strategy coupled with the use of abbreviated regulatory approval pathways in various countries will also be used for rapid development of its Zydis-based pipeline drugs to treat other clinical indications.

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