Ethicann Pharma receives FDA Pre-IND Comments on Regulatory Pathways & Executes Agreement with Epilepsy Study Consortium

Ethicann receives FDA Pre-IND Comments confirming 505(b)(2) pathway / strategies
Ethicann executes Clinical Advisory agreement with Epilepsy Study Consortium

BETHESDA, MARYLAND, UNITED STATES, November 28, 2022 /EINPresswire.com/ -- Ethicann Pharmaceuticals Initiates Development of THC:CBD Drugs:

> These described activities are important developmental and implementation milestones that Ethicann Pharmaceuticals continues to achieve."
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> *Bruce F Mackler, Ph.D., J.D.*

 FDA Pre-IND Comments on EPI-002 MS Spasticity confirming 505(b)(2) NDA Pathway/Strategies
 Pipeline Products Formulated with Zydis Delivery Technology
 Execution of Agreement with Epilepsy Study Consortium and Formation of Advisory Consultant Group

thicann Pharmaceuticals Inc., a Canadian/US specialty pharmaceutical company, focused on the development of high-value cannabinoid drug therapies, announces the achievement of important milestones furthering development of its pipeline products. Each of Ethicann's pipeline products incorporate Catalent's Zydis® orally disintegrating tablet (ODT) technologies, a fast-dissolving oral dose tablet, which whose advantages include - administered without water, can improve product safety (avoids liver first pass effect), and may help improve patient experience and management.

Based on US Food & Drug Administration (FDA) Pre-IND meeting comments for EPI-002 for MS spasticity the company believes that the 505(b)(2) New Drug Application (NDA) approval process can be utilized for all Ethicann's pipeline drugs. Also, Ethicann has taken steps in initiating reformulation development of an approved epilepsy drug using the Zydis® delivery technology to improve safety. Furthermore, Ethicann has established a relationship with the Epilepsy Study Consortium, Inc., to form an Advisory Group to clinically guide the company in its epilepsy drug clinical development.

In Pre-IND comments to Ethicann , FDA confirmed that it has no specific concerns about the

incorporation of Zydis® oral disintegrating tablet (ODT) drug delivery technologies into the company's pipeline products. FDA also indicated that the 505(b)(2) NDA approval pathway is an acceptable approach for FDA approval of EPI-002 MS spasticity drug, as well as for its other pipeline THC:CBD drugs. Additionally, the agency provided constructive protocol design advice for Ethicann's draft Phase 2 dose-ranging studies, which will provide the basis for a subsequent pivotal Phase 3 study. This feedback provides a clear regulatory roadmap for the development of its MS spasticity drug, and Ethicann's other pipeline drugs in the US.

Concurrently, Ethicann is also developing EPI-002 in Canada using the abbreviated new drug approval process requiring only bioequivalence data, literature or clinical safety data and patient benefits. Ethicann has already met with Health Canada regarding EPI-002 (MS spasticity indication) in a pre-New Drug Submission (NDS) meeting Jan. 2020 and will do so again in early 2023 to review the limited human bioeqivalence study required for new drug approval and confirm again the prior Health Canada advice received on using the abbreviated new drug approval pathway and its' intent to seek a Canadian new drug approval in 2024-25. The Canadian data may be used to obtain rapid regulatory approvals in UK, German, and other EU countries (2026-2028+).

Ethicann has initiated development of other pipeline drug therapies intended to treat pediatric and/or adult epilepsy, and on the recommendation of the Epilepsy Foundation, the company has executed a clinical consulting agreement with the Epilepsy Study Consortium, Inc. (TESC). TESC is a group of academic based scientific investigators, who are dedicated to accelerating the development of new epilepsy therapies to improve patient care. Ethicann intends to begin consulting with the Consortium's designated Advisory Consultant Group regarding the clinical development of its CBD products to treat pediatric orphan epilepsy diseases and focal epilepsy in adult patient populations.

Forward-looking statements:
Information in this news release that is not current or historical factual information may constitute forward-looking information within the meaning of securities laws. Implicit in this information, particularly in respect of the outlook of Ethicann Pharmaceuticals, Inc. (Ethicann) and anticipated events or results, are assumptions based on beliefs of Ethicann's senior management as well as information currently available to it. While these assumptions were considered reasonable by Ethicann at the time of preparation, they may prove to be incorrect. Readers are cautioned that actual results are subject to several risks and uncertainties, including the availability of funds and resources to pursue R&D projects, the successful and timely completion of clinical studies, the ability of Ethicann to take advantage of business opportunities in the biomedical industry, the granting of necessary approvals by regulatory authorities, general economic, market and business conditions, as well as other risks and uncertainties. Ethicann does not undertake any obligation to update forward-looking statements should these assumptions change. Nothing in this document should be construed as either an offer to sell or

a solicitation to buy or sell Ethicann securities.

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