Cipher Pharmaceuticals Receives Health Canada Approval For Trulance® (Plecanatide)

OAKVILLE, ON, Oct. 18, 2019 /CNW/ - Cipher Pharmaceuticals Inc. (TSX: CPH) ("Cipher" or "the Company") today announced it has received Health Canada approval, on October 10, 2019, for TRULANCE® (plecanatide), a Guanylate cyclase-C (GCC) agonist in the form of a once-daily tablet for the treatment of adults with irritable bowel syndrome with constipation ("IBS-C").

"We are pleased to announce TRULANCE® has achieved Health Canada approval and we are excited to be able to bring this new and effective treatment option to Canadians who suffer from this condition," said Craig Mull, Interim CEO of Cipher.

It is estimated that one in four Canadians has symptoms of constipation and an estimated 38% of Canadians report constipation within the previous 12 months[1]. According to IQVIA the total Canadian laxative and antispasmodic market (prescription and OTC) was valued at over CDN $200 million for the 12 months ending December 2018.

Consistent with its strategy to focus on partnering assets, Cipher is in the process of selecting a distribution partner for TRULANCE® that possesses the expertise and scale to successfully bring this novel product to market.

Cipher acquired the Canadian rights to develop, market, distribute and sell TRULANCE® from Bausch Health Companies Inc.

About Irritable Bowel Syndrome with Constipation (IBS-C)

Irritable bowel syndrome (IBS) is a chronic gastrointestinal disorder characterized by recurrent abdominal pain and associated with either a change in the frequency of stool, or a change in the form (appearance) of the stool. IBS can be subtyped by the predominant stool form: constipation (IBS-C), diarrhea (IBS-D) or mixed (IBS-M). Those within the IBS-C subtype experience hard or lumpy stools more than 25% of the time.

About TRULANCE®

TRULANCE® is a once-daily tablet approved by Health Canada for adults with IBS-C. With the exception of a single amino acid substitution for greater binding affinity, TRULANCE® is structurally identical to uroguanylin, a naturally occurring and endogenous human GI peptide. Uroguanylin activates GC-C receptors in a pH-sensitive manner primarily in the small intestine, stimulating fluid secretion and maintaining stool consistency necessary for regular bowel function.

About Cipher Pharmaceuticals Inc.

Cipher Pharmaceuticals (TSX: CPH) is a specialty pharmaceutical company with a robust and diversified portfolio of commercial and early to late-stage products. Cipher acquires products that fulfill unmet medical needs, manages the required clinical development and regulatory approval process, and markets those products either directly in Canada or indirectly through partners in Canada, the U.S., and South America. For more information, visit www.cipherpharma.com.

Forward-Looking Statements
This document includes forward-looking statements within the meaning of applicable securities laws. These forward-looking statements include, among others, statements with respect to our objectives, goals and strategies to achieve those objectives and goals, as well as statements with respect to our beliefs, plans, expectations, anticipations, estimates and intentions and statements

relating to Cipher's acquisition of Cardiome Pharma Corp. ("Cardiome") pursuant to which Cipher acquired the Canadian business portfolio of Cardiome, including statements in respect of the anticipated strategic and/or financial benefits of the arrangement, anticipated regulatory approvals of products and the timing thereof. The words "may", "will", "could", "should", "would", "suspect", "outlook", "believe", "plan", "anticipate", "estimate", "expect", "intend", "forecast", "objective", "hope" and "continue" (or the negative thereof), and words and expressions of similar import, are intended to identify forward-looking statements.

By their very nature, forward-looking statements involve inherent risks and uncertainties, both general and specific, which give rise to the possibility that predictions, forecasts, projections and other forward-looking statements will not be achieved. Certain material factors or assumptions are applied in making forward-looking statements and actual results may differ materially from those expressed or implied in such statements. We caution readers not to place undue reliance on these statements as a number of important factors, many of which are beyond our control, could cause our actual results to differ materially from the beliefs, plans, objectives, expectations, anticipations, estimates and intentions expressed in such forward-looking statements. These factors include, but are not limited to, our ability to enter into in-licensing, development, manufacturing and marketing and distribution agreements with other pharmaceutical companies and keep such agreements in effect; our dependency on a limited number of products; our dependency on protection from patents that will expire; integration difficulties and other risks if we acquire or in-license technologies or product candidates; reliance on third parties for the marketing of certain products; the product approval process is highly unpredictable; the timing of completion of clinical trials, regulatory submissions and regulatory approvals; reliance on third parties to manufacture our products and events outside of our control that could adversely impact the ability of our manufacturing partners to supply products to meet our demands; we may be subject to future product liability claims; unexpected product safety or efficacy concerns may arise; we generate license revenue from a limited number of distribution and supply agreements; the pharmaceutical industry is highly competitive; requirements for additional capital to fund future operations; products in Canada may be subject to pricing regulation; dependence on key managerial personnel and external collaborators; no assurance that we will receive regulatory approvals in the U.S., Canada or any other jurisdictions and current uncertainty surrounding health care regulation in the U.S.; certain of our products are subject to regulation as controlled substances; limitations on reimbursement in the healthcare industry; limited reimbursement for products by government authorities and third-party payor policies; products may not be included on list of drugs approved for use in hospitals; hospital customers may make late payments or not make any payments; various laws pertaining to health care fraud and abuse; reliance on the success of strategic investments and partnerships; the publication of negative results of clinical trials; unpredictable development goals and projected time frames; rising insurance costs; ability to enforce covenants not to compete; risks associated with the industry in which it operates; we may be unsuccessful in evaluating material risks involved in completed and future acquisitions; we may be unable to identify, acquire or integrate acquisition targets successfully; legacy risks from operations conducted in the U.S.; inability to meet covenants under our long term debt arrangement; compliance with privacy and security regulation; our policies regarding returns, allowances and chargebacks may reduce revenues; certain current and future regulations could restrict our activities; additional regulatory burden and controls over financial reporting; reliance on third parties to perform certain services; general commercial litigation, class actions, other litigation claims and regulatory actions; the difficulty for shareholders to realize in the United States upon judgments of U.S. courts predicated upon civil liability of the Company and its directors and officers who are not residents of the United States; the potential violation of intellectual property rights of third parties; our efforts to obtain, protect or enforce our patents and other intellectual property rights related to our products; changes in U.S., Canadian or foreign patent laws; litigation in the pharmaceutical industry concerning the manufacture and supply of novel and generic

versions of existing drugs; inability to protect our trademarks from infringement; shareholders may be further diluted if we issue securities to raise capital; volatility of our share price; the actions of a significant shareholder; we do not currently intend to pay dividends; our operating results may fluctuate significantly; and our debt obligations will have priority over the common shares of the Company in the event of a liquidation, dissolution or winding up.

We caution that the foregoing list of important factors that may affect future results is not exhaustive. When reviewing our forward-looking statements, investors and others should carefully consider the foregoing factors and other uncertainties and potential events. Additional information about factors that may cause actual results to differ materially from expectations, and about material factors or assumptions applied in making forward-looking statements, may be found in the "Risk Factors" section of this MD&A and the Annual Information Form for the year ended December 31, 2018, and elsewhere in our filings with Canadian securities regulators. Except as required by Canadian securities law, we do not undertake to update any forward-looking statements, whether written or oral, that may be made from time to time by us or on our behalf; such statements speak only as of the date made. The forward-looking statements included herein are expressly qualified in their entirety by this cautionary language.

(1) "Understanding the Prevalence and Impact of Constipation in Canada*": A Special Report from the Canadian Digestive Health Foundation.*

SOURCE Cipher Pharmaceuticals Inc.

View original content: http://www.newswire.ca/en/releases/archive/October2019/18/c5969.html

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