# Pivot Pharma To File Investigational New Drug (IND) Application With U.S. FDA For PVT-005

# Cannabinoid Topical Cream For Treatment Of Female Hypoactive Sexual Desire Disorder

VANCOUVER, BC - (June 27, 2018) – <u>Pivot Pharmaceuticals Inc.</u> (CSE: <u>PVOT</u> / OTCQB: <u>PVOTF</u> / FRA: <u>NPAT</u>) ("Pivot" or the "Company") is pleased to announce that it will file an Investigational New Drug (IND) application with the U.S. Food and Drug Administration (FDA) and Clinical Trial Application (CTA) with Health Canada to begin human clinical trials of PVT-005, the Company's pharmaceutical drug candidate for the treatment of Female Hypoactive Sexual Desire Disorder (HSDD).

HSDD, the most common type of female sexual dysfunction ("FSD"), affects approximately 12 million women in the U.S. alone. The condition is characterized by low sexual desire and marked distress which are not attributable to existing medical, pharmacologic, psychiatric, or relationship issues. Approximately 6 million premenopausal women meet the diagnosis for acquired, generalized HSDD.

Using Pivot's drug formulation and delivery platform technologies, the Company will develop and aim to commercialize a topical cream containing cannabinoids ("PVT-N005") for perimenopausal, menopausal and post-menopausal women who have noticed a decline in sexual desire and response. While erectile dysfunction in men has been extensively researched, very little has been completed on female sexual dysfunction which can involve reduced sex drive, difficulty becoming aroused, vaginal dryness, lack of orgasm and decreased sexual satisfaction.

"In vitro results from our contract research laboratory indicated that PVT-005 (1% CBD - formulated) was highly bioavailable. Additional studies showed that the product did not cause any local irritation in an in-vivo model. We have also successfully conducted degradation and stability studies with the product candidate. As a result, we have selected a drug candidate for HSDD which we will move to IND and CTA filings with health authorities to conduct clinical trials in women. Our cGMP manufacturing partner, BioV Pharma Inc., will produce the clinical trial made using our formulation technology," said Dr. Joseph Borovsky, Pivot's Executive Vice President, Product Development.

Pivot's Chief Medical Officer, Dr. Wolfgang Renz stated "Given that our topical delivery system has previously shown to be safe and well tolerated when administered intravaginally in a clinical trial setting, we believe that we can deliver cannibinoids to target female sexual dysfunction, a large unmet medical need with a multi-billion dollar market. The use of a highly bioavailable and safe topical cannabinoid is a great option for treating this indication, avoiding the known side effects of existing therapeutics."

While men have had Viagra, Cialis, and Levitra to address their sexual dysfunction issues, finding a solution for FSD has been more complicated. The market for female sexual dysfunction drugs is believed to be larger than the market for male sexual dysfunction treatments since the percentage of women with FSD between the ages 18 and 59 is higher than that for men. The FSD market in the U.S. is estimated to exceed \$4 billion with over 50 million potential sufferers.<sup>1</sup>

# About Pivot Pharmaceuticals Inc.

Pivot Pharmaceuticals Inc. is a biopharmaceutical company engaged in the development and commercialization of therapeutic pharmaceuticals and nutraceuticals using innovative drug delivery platform technologies. Pivot's wholly-owned medical cannabis products division, Pivot Green Stream Health Solutions Inc. ("PGS" or "Pivot Green Stream"), conducts research, development and commercialization of cannabinoid-based nutraceuticals and

<sup>&</sup>lt;sup>1</sup> https://www.researchgate.net/publication/7977139 Female sexual dysfunction

pharmaceuticals. Pivot's wholly-owned U.S. subsidiary, Pivot Naturals, LLC, based in Costa Mesa, California, will manufacture and supply finished powderized cannabis products such as food additives, capsules, bulk powder and stick packs to the California market. PGS has acquired worldwide rights to "RTIC" Ready-To-Infuse Cannabis oil-to-powder technology, BiPhasix<sup>TM</sup> Dermal Drug Delivery platform technology (topical), Solmic Solubilisation technology (oral) and Thrudermic Transdermal Nanotechnology (transdermal) for the delivery and commercialization of cannabinoid, cannabidiol (CBD), and tetrahydrocannabinol (THC)-based products. For more information please visit www.PivotPharma.com

#### **Cautionary Statement**

Except for historical information contained herein, the matters set forth above may be forward-looking statements that involve certain risks and uncertainties that could cause actual results to differ from those in the forward-looking statements. Words such as anticipate, believe, estimate, expect, intend, and similar expressions, as they relate to Pivot Pharmaceuticals Inc., Pivot Green Stream Health Solutions Inc., Pivot Naturals, LLC, or its management, identify forward-looking statements. Such forward-looking statements are based on the current beliefs of management, as well as assumptions made by and information currently available to management. Actual results could differ materially from those contemplated by the forward-looking statements as a result of certain factors, such as the failure to meet the conditions imposed by the CSE or other securities regulators, the level of business and consumer spending, the amount of sales of Pivot's products, statements with respect to internal expectations, the competitive environment within the industry, the ability of Pivot to continue to expand its operations, the level of costs incurred in connection with Pivot's expansion efforts, economic conditions in the industry, and the financial strength of Pivot's customers and suppliers. Pivot does not undertake any obligation to update such forward-looking statements. Investors are also directed to consider all other risks and uncertainties.

#### **Contact:**

Pivot Pharmaceuticals Inc. Patrick Frankham, PhD, MBA Chief Executive Officer

Email: Info@PivotPharma.com

Virtus Advisory Group Investor Relations

Email: Pivot@virtusadvisor.com

Phone: 416-644-5081