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Tetra Bio-Pharma Inc. (TBP-T) Announces Joint Venture with Thorne Research & Onegevity Health to Apply Expertise in Cannabinoid Therapies to Conditions Caused by Chronic Inflammation

On August 21, Tetra Bio-Pharma announced a new joint venture with Thorne Research Inc. and Onegevity Health LLC — CB2 Therapeutics. The new company will combine TBP's expertise in cannabinoid research, Thorne's robust distribution network and Onegevity's data-driven microbiome platform to target diseases caused by chronic inflammation. The joint venture is raising US\$10M and will be 50% owned by TBP with the remaining 50% split evenly between Thorne and Onegevity. This allows TBP to leverage the expertise and distribution network of key partners while accessing new therapeutic markets, conserving existing resources, and avoiding dilution of the company's shareholder value.

Summary

Commercialization of β -caryophyllene to support patients with interstitial cystitis: CB2 Therapeutics' initial product will be an orally administered form of β -caryophyllene marketed as a dietary supplement to support individuals who have a functional form of bladder inflammation called interstitial cystitis. The product will be supported by a structure/function claim under the U.S. Dietary Supplement Health and Education Act (DSHEA) and is being prepared for launch in 2020. β -caryophyllene is a terpene molecule found in the oil of cannabis plants as well as cloves, rosemary and hops that activates cannabinoid type 2 (CB2) receptors. According to the Interstitial Cystitis Association, a non-profit patient advocacy organization, interstitial cystitis results in bladder pain and frequent urination and impacts at least 3M women and 1M men across the U.S. Current treatments are not widely effective, and a 2017 Research and Markets report estimates the global market for interstitial cystitis treatment will grow to US\$427M by 2023. With Thorne's existing network of 35,000 physicians across the U.S. who are providing nutritional supplements to their patients, CB2 Therapeutics will be able to quickly reach and educate medical professionals about the benefits of this new treatment option for their patients.

Cannabinoid-based treatment of IBS and IBD: CB2 Therapeutics is also preparing to advance several endocannabinoid system-targeting therapies into the clinic with a Phase II trial evaluating each candidate in IBS and IBD patients. In addition to testing the safety and efficacy of the treatments, the trial will leverage Onegevity's data platform to identify differences in patient's gut microbiome. CB2 Therapeutics can then apply this unique dataset to identify the microbiome patterns that respond to the therapy, which can help identify candidates for future clinical trials and, ultimately, identify patients who will benefit from these new therapies.

With worldwide prevalence rates of 10–15%, IBS is the most common functional gastrointestinal disorder, according to the International Foundation for Gastrointestinal Disorders. Individuals with IBS may present with diarrhea (IBS-D), constipation (IBS-C) or a combination of diarrhea and constipation (IBS-M). A recent report from Acumen Research and Consulting estimated that the IBS market will grow at a CAGR of 9.8% to US\$3.4B by 2026. For IBD, the U.S. Centers for Disease Control (CDC) estimates that 3M Americans are currently diagnosed with either Crohn's or ulcerative colitis, the two diseases that compose IBD. A 2018 report from Transparency Market Research estimated the global IBD market at US\$10.5B in 2016 and growing at a CAGR of 2.6% to US\$14.8B by 2025.

Together, these disorders represent a significant market opportunity that are connected by chronic inflammation and alterations to the gut microbiome. This creates an opportunity to leverage the anti-inflammatory activity of TBP's cannabinoid molecules with Onegevity's microbiome data pipeline to create a unique platform to drive new treatments into the clinic.

Leveraging Partnerships to Bring Treatments to Patients: TBP is currently developing numerous consumer-focused, over-the-counter (OTC) and prescription products, including Hemp Energy Drink, hemorrhoid and cold core creams, eye drops and therapies for breakthrough cancer pain and chemotherapy-induced nausea and vomiting (CINV). By partnering with Thorne Research and Onegevity to form CB2 Therapeutics, the company can access indication-specific expertise as well as a dedicated commercial partner, thereby focusing the clinical development and commercialization of TBP's cannabinoid molecules toward the treatment of chronic inflammatory diseases.

Conclusion

Chronic inflammation is a challenge for numerous health conditions. CB2 Therapeutics will develop and commercialize a clinical pipeline of cannabinoid molecules against inflammatory disorders, including interstitial cystitis, IBD and IBS. We believe this joint venture yields a powerful platform for the development of novel therapies and a blueprint for future partnerships to efficiently access new therapeutic areas and markets.

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