Witty Health Inc. Announces Regulatory Submission of a Digital Oncology Product for Metastatic Breast Cancer

*Witty Health Inc., a technology company focused on technology enabled cancer drug development, today announced submission of pre-Request For Designation (RFD) documents for its software-enabled Fulvestrant product for treating certain types of breast cancer to the Office of Combination Products (OCP), Food And Drug Administration.*

Houston, TX (PRWEB) September 16, 2017 -- Witty Health Inc., a technology company focused on technology enabled cancer drug development, today announced submission of pre-Request For Designation (RFD) documents for its software-enabled Fulvestrant product for treating certain types of breast cancer to the Office of Combination Products (OCP), Food And Drug Administration. A Request For Designation (RFD) filing helps the OCP to identify and assign reviewing responsibility for the drug within the FDA.

“We are excited to achieve this milestone to determine a regulatory pathway for first of its kind digital pharmaceutical product- Fulvestrant Cancer Treatment Platform (FCTP™),” said Co-Founder Ram Sesha. “Witty Health’s Cancer Treatment Platform (CTP™) is designed to develop value-based cancer pharmaceutical products. We are applying software and machine learning tools to oncology products to improve cancer care. This will enable Witty Health to actively customize its Cancer Treatment Platform (CTP™) to other oncology drugs to improve cancer care. To seek a Fast Track designation, the development is in frequent collaboration with the Food and Drug Administration (FDA).”

“The current cancer treatment model does not monitor a patient’s condition between office visits and it is not working. Fulvestrant Cancer Treatment Platform (FCTP™) is designed to improve outcomes associated with Fulvestrant. This is more so when Fulvestrant is used in combination with CDK 4/6 inhibitors Ibrance®, Abemaciclib, and Kisqali®. Further, we believe our product can significantly reduce preventable health care costs by reducing ER visits and hospitalizations due to symptom exacerbations as well,” said Dr. Karthik Koduru, the Chief Oncologist of Witty Health.

Fulvestrant
Fulvestrant (marketed under brand name Faslodex® by AstraZeneca) is an Estrogen Receptor Modulator. Fulvestrant is approved for the treatment of metastatic breast cancer intolerant to anti-estrogen therapy and in combination with Pfizer’s palbociclib (Ibrance) for the advanced breast cancer intolerant to endocrine therapy. Fulvestrant, which is likely to lose patent protect protection in January 2021, generated over $ 700 million in revenue during 2016 with an annual estimated growth of around 17%. It is additionally evaluated as combination therapy with Lilly’s Abemaciclib (Lilly), Roche’s Taselisib and three Novartis’s approved drugs; Ribociclib (Kisqali), Lapatinib (Tykerb) and experimental drug; Alpelisib.

Cancer Treatment Platform
Witty Health’s Cancer Treatment Platform (CTP™) is a digital platform with a suite of tools that help improve cancer care. It can be connected with up to eight devices: a wireless weighing scale, blood pressure cuff, pulse oximeter, stethoscope, thermometer, multi-scope camera, Electrocardiogram (ECG) and blood glucose monitor. These tools create data which can be remotely uploaded while the patient is video conferencing with the physician - in real-time or offline, from home or office. Cancer Treatment Platform (CTP™) includes drug specific toxicity management pathways to help oncologists address toxicity effectively and promptly to improve Quality of Life (QoL) and potentially improve outcomes of the treatment.
It is protected by a number of novel patent applications covering the treatment with Checkpoint, CDK 4/6, PARP, CR and Factor X inhibitors and pain management during cancer therapy. The Cancer Treatment Platform (CTP™) is customizable to a number of medications: five Checkpoint inhibitors; Opdivo™, Keytruda®, Imfinzi™, TecentriQ® and Bavencio™, three CDK 4/6 inhibitors: Ibrance®, Abemaciclib, and Kisqali®, PARP inhibitor; Lynparza™ and for any pain medication.

About Witty Health;
Witty Health, Inc. (www.wittyhealth.com) is a Houston, TX-based technology company focusing on developing intelligence-powered pharmaceutical products to improve cancer care. Witty Health, privately held by employees and outstanding physician/oncology leaders, is redefining the immunotherapy-based cancer treatments through the development and commercialization of its proprietary Cancer Treatment Platform (CTP™). The Company uses the InstaMD platform which includes: a telemedicine-based remote clinic, home health monitoring, patient diagnosis, and messaging application modules. Witty Health Inc. has assembled an experienced management team and invested by some outstanding physician/oncology leaders.

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