Alessa Therapeutics Announces IND Clearance for a Study in Collaboration with the National Cancer Institute

First patient enrollment anticipated in Q3 2021 for Phase 1 clinical study of Biolen in conjunction with radiation therapy in localized prostate cancer

SAN CARLOS, CALIFORNIA, UNITED STATES, June 7, 2021 /EINPresswire.com/ -- Alessa Therapeutics, Inc., a clinical-stage drug development company developing an innovative and proprietary localized drug delivery technology for the treatment of prostate disease, announced that the U.S. Food and Drug Administration (FDA) has accepted the Investigational New Drug application (IND) for Biolen®. Alessa, in collaboration with the Radiation Oncology Branch of the National Cancer Institute (NCI), will initiate a Phase 1 clinical study of Biolen in conjunction with radiation therapy.

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> *Dr. Pamela Munster, founder of Alessa Therapeutics*

The Biolen system consists of multiple implants containing a hormonal therapy agent. Clinicians insert the implants into the prostate through a minimally invasive approach similar to prostate biopsy. The Phase 1 study will evaluate the feasibility of replacing systemic androgen deprivation therapy (ADT) with targeted local delivery of an anti-androgen agent in patients indicated for ADT in conjunction with radiation therapy to treat localized prostate cancer. The first patient enrollment is anticipated in the third quarter of 2021.

Dr. Pamela Munster, a medical oncologist at the University of California San Francisco (UCSF) and

the company founder, commented, “The FDA’s acceptance of our IND is an important milestone and a validation of our clinical development plan. We are excited to be embarking on this upcoming study with the NCI. This study will allow us to evaluate the feasibility for Biolen to safely provide the therapeutic benefits of ADT without the systemic side effects.”

Dr. Deborah Citrin, Senior Investigator at the Radiation Oncology Branch, NCI, commented, “ADT delivered in combination with radiation has been proven to improve oncological outcomes in men with locally advanced prostate cancer. Unfortunately, the side effects of ADT negatively impact the quality of life for many of our patients. We at NCI are looking forward to conducting this study to explore the potential of this novel approach to improve quality of life for men receiving ADT and radiation therapy for treatment of prostate cancer.”

Prostate cancer is the second most prevalent cancer among men in the United States. According to the American Cancer Society, over 192,000 men in the U.S. are newly diagnosed each year, and three million men live with prostate cancer. For men with higher risk disease, anti-androgen and testosterone-lowering drugs are administered to sensitize tumor cells to radiation therapy. While ADT or chemical castration has demonstrated improved clinical outcomes, systemic ADT is associated with significant side effects, including muscle mass loss, cognitive issues, sexual dysfunction, and cardiovascular events. Alessa’s Biolen implant is designed for sustained release of an anti-androgen drug directly to the target tissue in the prostate, potentially eliminating significant side effects and improving the quality of life for men undergoing radiation therapy.

About Alessa Therapeutics
Founded in 2018 and based on technology developed at the UCSF, Alessa Therapeutics is a privately held company focusing on developing selective and sustained localized drug delivery for early interception of cancer. Alessa is financed by Mission Bay Capital and BioInnovation Capital (now Mission Biocapital: https://www.missionbiocapital.com/). For more information on Alessa Therapeutics, visit www.alessatherapeutics.com or email alessa@alessatherapeutics.com.

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