Endorsement and Support of Navega Pharmaceuticals
Grant Application No: TRAN-16022

I am PK Agarwal expressing wholehearted support of the Grant Application TRAN-16022 for Navega Therapeutics. I am a Dean at University of California, Santa Cruz and also a volunteer for The Erythromelalgia Association, on behalf of which I run a Zoom based support group for those afflicted by this terrible condition with no cure. Due to my own affliction with this debilitating disease, I am intimately familiar with the challenges faced by those suffering from Erythromelalgia or EM, often labeled as the "Man on Fire" syndrome. It should be more appropriately labeled as “Woman on Fire " since 79% of those afflicted by this disease are women. EM is characterized by episodes of burning pain, redness, and swelling, primarily affecting the extremities. The mean of various studies combined results in an EM estimation incidence of 4.7/100,000. EM is considered a rare disease and is listed in the database of the National Organization for Rare Disorders (NORD).

The journey of a patient with EM is fraught with challenges. Imagine living with unpredictable flare-ups of intense, burning pain triggered by mild warmth or even moderate exercise. For many, even a warm shower can provoke a painful episode. These symptoms not only cause physical discomfort but also emotional and psychological distress. Patients often must alter their lifestyles drastically, avoiding activities that most of us take for granted, like walking on a sunny day. Those with EM live with severe, burning episodes that drastically hinder their quality of life, forcing them into the shadows, away from normalcy and light.

Current treatment paradigms are grossly insufficient. The medications available primarily focus on symptom management rather than addressing the underlying mechanisms of the disease. Patients are often prescribed a regimen of pain relievers, from anticonvulsants to opioids, which carry side effects and offer little more than temporary relief. This gap in effective treatment highlights a significant unmet need—a need for innovative, targeted, and transformative approaches.

This is where Navega Therapeutics and its groundbreaking research on the epigenetic downregulation of Nav1.7 come into play. Nav1.7 is a critical sodium channel involved in pain signaling in humans. Research has demonstrated that individuals who naturally lack functioning Nav1.7 due to genetic mutations experience no pain. By harnessing this insight, Navegatx aims to develop therapies that can modulate the expression of Nav1.7, offering not just relief but a potential cure to those plagued by the incessant pain.

Navega’s approach for treatment of primary erythromelalgia utilizes the precision of its AI-enabled zinc-finger epigenome regulation platform. Navega’s epigenetic therapy addresses a gain-of-function mutation in the Nav 1.7 gene, linked to inherited erythromelalgia, small fiber neuropathy and other chronic, debilitating pain disorders. With over 17 million Americans living with high-impact chronic pain, Navega’s non-opioid gene therapy for chronic pain may also be used in other intractable pain indications, including neuropathic and inflammatory pain.

I wholeheartedly support Navega Therapeutics and their application for Grant Application TRAN-16022, hopeful for their continued advancements in treating EM.