

Project Title: BTK Inhibitor Subcutaneous Implant for the Prevention of Anaphylaxis

Five percent of the US population –that is, 16 million people– experience anaphylaxis per year. Anaphylaxis is a life-threatening allergic reaction that is characterized by swelling of the face, skin rashes, nausea, and difficulty breathing. The most common treatment is injection of epinephrine (Epipen®) once a person is experiencing anaphylaxis. This epinephrine shot is administered into the thigh of a person who is experiencing anaphylaxis to slow or block allergic response progression. However, these injections are both expensive and inefficient. The injector needs to be replaced every 12-18 months, which means that patients who practice food and allergen safety often discard them prior to use. The devices are also non-reusable, and a person who is at risk for anaphylaxis must always carry one to prevent a reaction that might become life-threatening. Our group proposes a solution that prevents anaphylaxis from happening at all: a refillable Bruton's Tyrosine Kinase (BTK) inhibitor implant. BTK inhibitors are drugs that bind to the BTK enzyme in the bloodstream. This enzyme plays a role in the allergic response system, and by inhibiting this enzyme with our drug, studies suggest that it could prevent severe allergic reactions all together. BTK inhibitors are already FDA approved to treat lymphoma and leukemia, which makes the transition to an anaphylaxis-preventing product easier. Inspired by contraceptive implants, our proposed design consists of a 5 cm long, 1 cm wide cylinder rod made out of a flexible plastic attached to a 2 cm long refill reservoir with a refill port. We developed computer models with to determine the diffusive parameters and implant wall thickness, as well as models to test the strength and flexibility of our implant. The center is hollow and connected to the refill reservoir, which will allow for regular refills. From our computer models, we found that the implant would release an average of 25 mg per day, and a refill would be necessary every 35 days. Though the implant is larger than contraceptive implants on the market due to the required daily dose necessary to prevent anaphylaxis, our implant leverages the benefits of preventing a life-threatening anaphylactic shock against the inconvenience of its size. Our goal is to prevent anaphylaxis from occurring and eliminate the need for an emergency injection of epinephrine.