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Title: “Phase 1b MAD Study of a Novel Drug (MW189) Targeting Neuroinflammation”

A Novel Therapy for Treating Traumatic Brain Injury May Lead to Answers for Alzheimer’s

Many studies show that a prior traumatic brain injury (TBI) increases the risk of developing dementias such as Alzheimer’s disease (AD). One mechanism by which this happens appears to be because head injuries cause an abnormally over-activation of brain cells called glia that can produce too much inflammation in the brain. While transient activation of these specialized brain cells can be beneficial, high levels of chronically activated glia cells result in overproduction of a number of detrimental molecules, such as “proinflammatory cytokines.” The release of these molecules can lead to nerve cell dysfunction and cell loss. Dr. Van Eldik’s team has developed a novel small molecule drug candidate called “MW189” that selectively suppresses these injurious proinflammatory cytokines.

The long-term goal is to develop MW189 as a potential disease-modifying therapy for AD. However, clinical trials for new potential drugs for AD are very expensive and extremely lengthy. Therefore, our current focus will be with TBI patients because we know they develop brain inflammation and we know when it is initiated. TBI will allow the rapid testing of the merit of this novel drug, which would further de-risk the drug and attract potential commercial, philanthropic, or government partners to pursue the much longer and more expensive trials required to develop MW189 as a therapy for AD.

Importantly, MW189 has successfully been administered to normal human volunteers in two phase 1a clinical trials with no safety issues. Based on this strong data, Dr. Van Eldik was awarded a Part the Cloud grant to do the next required step in the FDA approval process: a phase 1b clinical trial in healthy human volunteers, where individuals receive multiple doses that increase in concentration to assess its safety (i.e. multiple ascending dose trial). These types of studies are required before putting the drug into compromised individuals with a disease or injury. The safety and tolerability of the drug, as well as how much of the drug is present in the blood at different times after dosing are being evaluated.

Current progress is that two out of the three doses have been tested in humans with no safety problems reported. The 3rd dosing is planned to begin this month. If the remainder of the study proceeds as anticipated, the phase 1b trial could be completed by end of 2017, ahead of schedule! “The Part the Cloud funding has been a huge catalyst to accelerate our research because it is allowing us to take the first necessary step of making sure this novel drug is safe in healthy human volunteers,” said Dr. Van Eldik.

At AAIC17, Dr. Van Eldik presented a poster on the development of two additional classes of compounds that both selectively suppress neuroinflammation, but work through different molecular mechanisms than MW189. The AAIC poster summarized the drug discovery platform by which these two different compound classes were developed.