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Biogen and Alcyone Therapeutics Announce License and Collaboration Agreement to Evaluate a Novel Device to Improve Patient Experience and Access to Neurological ASO Therapies

Alcyone's ThecaFlex DRx™ System is an implantable medical device in development for intrathecal drug delivery

Biogen and Alcyone Therapeutics have entered into a license and collaboration agreement to develop Alcyone's ThecaFlex DRx™ System, an implantable medical device intended for subcutaneous delivery of antisense oligonucleotide (ASO) therapies into the intrathecal space. Through this agreement, Biogen aims to leverage the ThecaFlex DRx™ System with a goal of improving the patient treatment experience and accessibility for a broader population of people suffering from neurological disorders, such as spinal muscular atrophy (SMA) and amyotrophic lateral sclerosis (ALS).

The ThecaFlex DRx™ System has the potential to be the first implantable device designed to enable routine subcutaneous administration of ASO therapies to the cerebrospinal fluid. The ThecaFlex DRx™ System has received a CE Mark in Europe. In addition, it has also received Breakthrough Device Designation from the U.S. Food and Drug Administration (FDA) and will require further clinical studies before it can be submitted to the FDA for review.

"We are continually listening to the neuromuscular disease community and whenever possible, adapting our work to meet their evolving needs for treatment and patient care," said Priya Singhal, Interim Head of R&D at Biogen. "Biogen looks forward to working with Alcyone to explore the potential of this device, which we believe will provide greater flexibility to people with spinal muscular atrophy and other neurological disorders as well as their doctors in making the right treatment decisions."

"Alcyone designed the ThecaFlex DRx™ System to be a therapeutic delivery alternative for patients with a chronic neurological condition whose current treatment requires repeat lumbar puncture," said PJ Anand, Chief Executive Officer of Alcyone. "This agreement underscores Alcyone's expertise in cerebrospinal fluid delivery technology which we believe will lead to an improved treatment experience for some people living with neurological conditions and their caregivers. We consider Biogen, a global leader, an ideal collaborator toward this mutual goal."

Under the terms of the agreement, Biogen will make an upfront payment of $10 million to Alcyone for an exclusive global license to the ThecaFlex DRx™ System in SMA and ALS as well as a co-exclusive global license in an unnamed indication. Should certain development and commercial milestones be achieved, Alcyone will be eligible to receive up to $41 million in potential milestone payments. The deal also provides flexibility to expand the collaboration as additional ASO therapies progress through Biogen's pipeline.

Biogen and Alcyone will jointly collaborate on clinical development of the ThecaFlex DRx™ System for ASO therapies, and Alcyone will be solely responsible for its manufacture and commercialization. The ThecaFlex DRx™ System will initially be evaluated with SPINRAZA® (nusinersen) in SMA, which will inform pathways for Biogen's broader portfolio of investigational ASO therapies.

About The ThecaFlex DRx™ System
The ThecaFlex DRx™ System (ThecaFlex), a technology within Alcyone's Falcon™ Delivery Platform, is an implantable intrathecal (IT) catheter, catheter fixation device, and subcutaneous port system designed to provide access to the cerebrospinal fluid (CSF) for the infusion of therapy by IT bolus administration. Lumbar puncture (LP), commonly known as a spinal tap, is the current standard of care approach to delivering therapeutics into the CSF. ThecaFlex is designed to be an alternative to LP, especially for people with challenging anatomy or for those who require multiple anesthesia and radiation exposures for repeat LPs.

The ThecaFlex DRx™ System has received CE Mark in Europe and Breakthrough Device Designation from the U.S. Food and Drug Administration (FDA). ThecaFlex is not approved by the FDA.

Source: **Biogen Press release**