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Ã¢â?¬Å?ATH434 has the potential to address the underlying pathology of Multiple System AtrophyÃ¢â?¬Â•

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Melbourne-based biotech company Alterity Therapeutics has just announced the opening of its Phase 2 clinical trial for lead candidate ATH434 for patients with Multiple System Atrophy (MSA)- a rare neurodegenerative disease, similar to Parkinson's, for which there are no known therapies that can slow disease progression and there is no cure.



In conversation with BioSpectrum Asia, Dr David Stamler, Chief Executive Officer, Alterity Therapeutics reveals more about the company's plans in this direction.

Edited excerpts-

What is the current scenario of neurodegenerative diseases in Australia & New Zealand?

Neurodegenerative diseases come in many forms with two of the most common being Parkinson's disease and Alzheimer's disease. While there are some treatments addressing the symptoms of these diseases, there are currently no cures.

What are the options available in terms of treatment, and what are the challenges being faced?

We are focusing first on a treatment for Multiple System Atrophy (MSA) which is rare neurodegenerative disease. While it is similar to Parkinson's disease, MSA progresses more rapidly and causes profound disability. In addition to the motor symptoms characteristic of Parkinson's disease, MSA manifests with more severe autonomic nervous system impairment resulting in bladder dysfunction and the inability to maintain normal blood pressure, as well as uncoordinated or clumsy movements that contribute to falling.

Currently available treatments only address certain symptoms of MSA. There are no therapies that slow disease progression and there is no cure. ATH434 is designed to reduce the toxic accumulation of ?-synuclein, a pathological hallmark of MSA, and preserve nerve cells by restoring normal iron balance in the brain. Therefore, ATH434 has the potential to address the underlying pathology of the disease and preserve function in individuals with MSA.

How is Alterity addressing the growing burden of neurodegenerative diseases in Australia & New Zealand? What are your expectations from the new government in this regard?

Alterity is focused on creating an alternate future for people living with neurodegenerative diseases. By this we mean that we are targeting the underlying pathology or cause of the disease versus just addressing the symptoms. If successful, we would be able to preserve the bodily functions for those living with the disease for a period of time so they can maintain their lives.

When do you plan to launch ATH434 in the market? Would it be a global launch or local?

We just announced the launch of our Phase 2 clinical trial with our first location in New Zealand, and over the course of this year, we will expand the trial into other regions globally. The results from the conclusion of the Phase 2 trial will then inform the trial design, patient numbers, and other specifics to run a global Phase 3 trial. We will need to complete the Phase 3 trial then file for regulatory approval if the trial achieves its endpoint. Therefore, we will determine at a future date whether we would commercialize the drug ourselves or partner the program with another company.

How much is being invested in the development and trials related to this molecule?

We don't disclose the specific expenses related to each clinical trial. Since I joined the company in 2017, we have raised approximately 70-75 million AUD most of which has been dedicated to advancing ATH434, supporting ongoing research and other administrative costs. While our first indication for ATH434 is for MSA, we plan to expand that to Parkinson's disease in the future if it proves successful.

Are you reaching out to Asian countries for the treatment of neurodegenerative diseases? Please share details.

Currently we are planning to expand our trial in Australia, Europe and the U.S. for the Phase 2 trial. We will consider expansion into Asia for our Phase 3 trial. With our trial now open for enrolment in New Zealand and regulatory authorizations in the UK and Italy, we are focused on opening study sites in these regions and expanding access to other countries throughout the year.

How many other candidates are there in the pipeline for the treatment of neurodegenerative diseases?

'Neurodegenerative diseases' is a very broad category so there are several other companies working in this area targeting diseases such as Parkinson's and Alzheimer's. For MSA in particular, there are only three other agents in either Phase 1 or Phase 2 development.

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