Acesion Pharma Announces Positive Results for Novel Drug

Targeting Atrial Fibrillation

Phase 1 data show favourable safety profile

Data support further development of AP30663 for cardioversion therapy

COPENHAGEN, Denmark — 5 November 2018: Acesion Pharma (“Acesion” or the Company), a Danish biotech company developing novel treatments for atrial fibrillation (AF), the most common cardiac arrhythmia, announces positive results from the Phase 1 clinical trial of its lead compound AP30663. The results of the study demonstrated that intravenous AP30663 was well tolerated with ascending doses, with no significant adverse events.

Atrial fibrillation (AF) is the most common cardiac arrhythmia, affecting an estimated 10 million people in the US and the EU (30 million people worldwide). The incidence of AF increases with age and it is estimated that 5-10% of the population above the age of 70 have AF.

Acesion’s novel approach is based on inhibition of SK channels - ion channels present in the atria where they play a role in regulating the cardiac rhythm. Blocking these ion channels with a functionally atrial selective drug helps avoid deleterious effects on the ventricles. Targeting the SK channels thereby constitutes a novel and promising approach for an effective treatment of AF with an expected higher cardiac safety profile.

Commenting on the news, Frans Wuite, CEO of Acesion Pharma said: “It is very exciting to see these promising Phase 1 results that indicate safety even at levels above expected therapeutic doses. This is an important milestone for AP30663 and validates the concept of SK-inhibition for atrial fibrillation and thereby the promise of Acesion’s portfolio. We will continue to progress the development of AP30663 for cardioversion therapy and are preparing to initiate a Phase 2 study in the second quarter of 2019.”

The Phase 1 study was a randomized, double-blind, placebo-controlled single ascending dose study to assess the safety and tolerability of AP30663 in 47 healthy subjects, conducted at the Centre for Human Drug Research (CHDR) in the Netherlands. The subjects were exposed to plasma concentrations within and above the predicted therapeutic range. Based on the encouraging data, Acesion aims to conduct a Phase 2 Proof-of-Concept study in AF-patients who suffer from atrial fibrillation that has lasted up to 7 days.

Prof John Camm, Scientific Advisor to Acesion Pharma and Professor of Clinical Cardiology at St George’s Hospital Medical School, London, added:

“Atrial fibrillation is increasingly common, and the medical community must make a special effort to find new and more successful therapies to treat this condition. When the rhythm disturbance begins it is often very symptomatic and distressing – it requires urgent and effective treatment - but to date available therapies are far from optimal. AP30663 has the potential to be the solution that we need. Prompt and effective treatment of this heart rhythm disturbance promises to significantly reduce the long-term consequences of the disease.”
Frans Wuite, CEO of Acesion Pharma and other Acesion team members will be attending Bio-Europe from November 5–7, 2018 at the Bella Center Copenhagen and hosting meetings.

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Notes to Editors

About Acesion Pharma
Acesion Pharma ApS is a privately held Danish biotech company developing novel treatments for atrial fibrillation (AF), the most common cardiac arrhythmia. Founded in 2011 and based in Copenhagen, Acesion’s compounds are based on a novel target giving a potentially unique efficacy and safety profile for the treatment of AF. Existing drug therapies generally have a limited effect or are associated with risk of serious cardiac adverse events, and there is therefore a considerable patient need for developing better and safer drugs. Acesion aims to develop first-in-class SK channel inhibitors as a more efficacious, safe and tolerable treatment of AF. Inhibition of SK channels with relevance for regulating the heart rhythm constitutes a new and promising approach for the treatment of AF. Acesion is developing a portfolio for both intervention and prevention of AF in hospitals and by patients themselves.

Acesion Pharma has an experienced Management Team and Board as well as world leading scientific advisors. It is backed by blue chip investors including Novo Holdings, Wellcome Trust and Broadview Ventures. For more information, please visit http://www.acesionpharma.com/

About Atrial fibrillation
Atrial fibrillation is the most common cardiac arrhythmia, affecting an estimated 10 million people in the US and the EU (30 million people worldwide). Estimates indicate that the number of AF patients in Europe will increase by 120,000–215,000 new cases per year. The incidence of AF increases with age and it is estimated that 5-10% of the population above the age of 70 have AF. The lifetime risk for developing AF is 25% for individuals over 40 years of age.

Awareness of AF is low, with patients often under-diagnosed and/or referred too late. AF is associated with a variety of symptoms that cause an impaired quality of life, increased rate of hospitalisation, and increased risk of stroke and death. AF-related strokes are estimated to account for up to 20% of all strokes, and the expected dramatic rise in the numbers of AF patients predict a major increase in the economic burden of AF. Patients with atrial fibrillation also face an increased risk of cognitive dysfunction and dementia. In a recent study, 41% patients with AF, but without a history of stroke, had at least one type of previously unknown brain damage as verified by magnetic resonance imaging.
To improve awareness and detection, the FDA has approved the Apple Watch Series 4 along with Apple apps to monitor for atrial fibrillation and record the data for a medical professional.

1 Prof John Camm is the Professor of Clinical Cardiology at St George's Hospital Medical School, University of London, UK, and Professor of Cardiology at Imperial College, London. Professor Camm is a Fellow of the Medical Academy of Science, the Royal College of Physicians, the American College of Cardiology, the American Heart Association, the Heart Rhythm Association, and the European Society of Cardiology (ESC). He is President of the Arrhythmia Alliance, Founder of the Atrial Fibrillation Association, Editor-in-Chief of Europace and Clinical Cardiology, Editor of European Heart Journal, and an editorial board member of a further 15 journals.