

# Acesion Pharma Receives Approval for Phase I Study in Atrial Fibrillation

### **Appoints Internationally Renowned Scientific Advisors**

**COPENHAGEN, Denmark— 8 February 2018:** Acesion Pharma ("Acesion" or the Company), a Danish biotech company developing novel treatments for atrial fibrillation (AF), the most common cardiac arrhythmia, announces today it has received approval to commence its first clinical study for its lead compound AP30663. The phase 1 study in healthy subjects will be conducted at the Centre for Human Drug Research (CHDR) in the Netherlands and is due to start in March 2018. Acesion also announces the appointment of internationally renowned AF experts as scientific advisors.

Atrial fibrillation is the most common cardiac arrhythmia, affecting at least 10 million people in the US and Europe and 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. It is a progressive disease that is associated with significant morbidity and a 5-fold increased risk of stroke. Existing drug therapies for AF, using other modes of action, have encountered major safety issues due to their effects on the ventricles, leading to life threatening pro-arrhythmia and/or depression of the myocardial function. In addition, their efficacy and/or tolerability has limited their use and there remains a significant need for developing better, safer and tolerable treatments.

Acesion is developing a portfolio of drugs addressing both acute and persistent AF. Acesion's novel approach is based on inhibition of SK channels - ion channels present in the atria that 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 safety and tolerability profile.

With the approval of the CTA, Acesion will start the Phase 1 study of AP30663 in March 2018 to determine the safety and tolerability profile of a single ascending dose in healthy subjects. AP30663 has successfully completed the preclinical development program demonstrating a good safety profile and efficacy in converting AF to a normal sinus rhythm.

Acesion has appointed a group of scientific advisors comprising world-renowned experts in atrial fibrillation, including:

- Prof John Camm, Professor of Clinical Cardiology at St George's Hospital Medical School, University
  of London and Professor of Cardiology at Imperial College London
- Dr Jeremy Ruskin, Professor of Medicine at Harvard Medical School and Founder and Director Emeritus of the Cardiac Arrhythmia Service at Massachusetts General Hospital
- Prof Dobromir Dobrev, Professor at the Institute of Pharmacology at the Universitätsklinikum Essen, Germany
- Bob Humphries, pharmacologist with 30+ years of pharma experience (Fisons, Astra and AstraZeneca) as scientific and cross-functional project team leader.

**Commenting on the news, Frans Wuite, CEO of Acesion Pharma said**: "Atrial fibrillation affects a large global population where current treatments have safety and efficacy limitations. We are very pleased to receive CTA approval for our first in-man study for our lead candidate. This is an important milestone for Acesion in our path towards developing first-in-class treatments that offer a unique efficacy and safety profile for AF patients.



"Our world leading scientific advisors are a validation of Acesion's approach and technology platform. Their knowledge and expertise will be invaluable as we progress our pipeline of promising new AF treatments through clinical development."

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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 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 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 addressing both acute and persistent AF.

Acesion Pharma has a highly 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. The Company received the EY Entrepreneur of the Year 2016 award in life sciences in Denmark. For more information, please visit <a href="http://www.acesionpharma.com/">http://www.acesionpharma.com/</a>

## **About Atrial fibrillation**

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. The increasing ageing population is one of the reasons for the expected increase in the prevalence of AF, which in the US has been projected to increase from 2.2 million patients in 2006 to 5.6 - 15.9 million in 2050. The lifetime risk for developing AF is 25% for individuals over 40 years of age.

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.