Acesion Pharma Commences Phase 1 Study in Atrial Fibrillation

Developing potential first-in-class treatments with unique efficacy and safety profile

COPENHAGEN, Denmark—12 March 2018: Acesion Pharma (“Acesion” or the Company), a Danish biotech company developing novel treatments for atrial fibrillation (AF), the most common cardiac arrhythmia, announces it has commenced the clinical study for its lead compound AP30663. Acesion is developing a portfolio of drugs addressing both paroxysmal (acute) and persistent AF.

AP30663 has successfully completed the preclinical development program demonstrating a good safety profile and efficacy in converting AF to a normal sinus rhythm. The phase 1 study is a randomized, double-blind, placebo-controlled single ascending dose study to assess the safety and tolerability of AP30663 in 48 healthy subjects. The trial is expected to be completed in June 2018 with data expected by the end of August 2018. The trial is being conducted at the Centre for Human Drug Research (CHDR) in the Netherlands.

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 with incapacitating symptoms, which decrease the health-related quality of life and is associated with significant morbidity including a 5-fold increased risk of stroke and a two-fold increase in mortality. Existing drug therapies for AF, using other modes of action, have encountered major safety issues due to their effects on the ventricles, leading to potentially life threatening pro-arrhythmia and/or depression of the myocardial function. In addition, their low level of efficacy and/or tolerability has limited their use, hence there remains a significant need for improved pharmacological treatments.

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.

Commenting on the news, Frans Wuite, CEO of Acesion Pharma said: “I am delighted to announce the first in-man study for our lead candidate is progressing as planned. Acesion’s mission is to develop first-in-class treatments that offer unique efficacy and safety profile for atrial fibrillation patients. There is a large unmet medical need for these patients where current treatments have safety, tolerability and efficacy limitations.”

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For more information, please contact:

Acesion Pharma
Frans Wuite, CEO
Email: fgw@acesionpharma.com

Jakob Dynnes Hansen, CFO
Email: jdh@acesionpharma.com

Optimum Strategic Communications
Mary Clark, Supriya Mathur, Hollie Vile
Tel: +44 203 714 1787
Email: healthcare@optimumcomms.com
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. For more information, please visit http://www.acesionpharma.com/

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.