

## Bellerophon Therapeutics Completes Enrollment in PRESERVATION I, a Trial of Bioabsorbable Cardiac Matrix (BCM) for the Prevention of Congestive Heart Failure After a Heart Attack

Hampton, NJ, January 14, 2015 – Bellerophon Therapeutics, LLC, a clinical stage biotherapeutics company, today announced that it has completed enrollment of its PRESERVATION I clinical trial of Bioabsorbable Cardiac Matrix (BCM), an investigational implantable medical device being studied for the prevention of congestive heart failure following an acute myocardial infarction (AMI), commonly known as a heart attack. The treatment procedure has been completed in 303 patients at almost 90 clinical sites in Australia, Europe, Israel and North America. The company expects to report top line results in mid-2015, following a six month follow up period for all patients.

Over 1.9 million patients suffer a heart attack in the United States and European Union each year of which approximately 35-40% develop congestive heart failure within five years of the event. BCM is intended to prevent congestive heart failure after a heart attack. The PRESERVATION I clinical trial is a CE Mark registration trial in the European Union. If the results of this trial are positive, the company expects it would form the basis for its CE marking application. In addition, the company would expect to conduct a second, larger clinical trial to support approval in the United States through the premarket approval (PMA) pathway.

This ongoing study is being conducted as a randomized, double-blind, placebocontrolled trial. The purpose of the study is to evaluate the safety and efficacy of BCM for the prevention of ventricular remodeling and congestive heart failure when administered to subjects who had successful percutaneous coronary intervention (PCI) with stent placement after ST-Elevation Myocardial Infarction (STEMI), a type of severe heart attack. The primary endpoint is a change in Left Ventricular End Diastolic Volume Index (LVEDVI) at six months compared to baseline. LVEDVI is an anatomic measurement of ventricular remodeling assessed echocardiogram. Secondary endpoints include patient-reported assessment of symptoms, function, and quality of life (Kansas City Cardiomyopathy Questionnaire), functional capacity (Six Minute Walk Test), physician-assessed function (New York Heart Association Functional Classification), and cardiovascular events (death, hospitalization, and time to hospitalization).

## About BCM

BCM is a liquid medical device that is administered through an injection in the coronary artery leading to the damaged area of the heart after an AMI. The injection is made by a minimally invasive procedure called percutaneous coronary intervention (PCI) commonly used when opening up cardiac blood vessels and



placing a stent. Once BCM is deployed, it flows into damaged heart muscle where it forms a gel which acts as a protective meshwork or scaffold within the wall of the heart's left ventricle. This flexible scaffold provides physical support to the heart wall and prevents further damage while the heart heals after the AMI. BCM is bioabsorbable and eliminated from the body after the heart heals. Bellerophon has an exclusive worldwide license to BCM from BioLineRx Ltd.

## **About Bellerophon**

Bellerophon Therapeutics LLC, is a privately-held, clinical-stage biotherapeutics company focused on developing innovative therapies at the intersection of drugs and devices that address significant unmet medical needs in the treatment of cardiopulmonary and cardiac diseases. The company's other product candidates are based on its proprietary pulsatile nitric oxide delivery device, INOpulse, and are in Phase 2 clinical trials – one for the treatment of Pulmonary Arterial Hypertension (PAH) and a second for the treatment of pulmonary hypertension associated with chronic obstructive pulmonary disease (PH-COPD). Bellerophon acquired exclusive worldwide rights to develop and commercialize the INOpulse programs in PAH, PH-COPD and pulmonary hypertension associated with idiopathic pulmonary fibrosis (PH-IPF) from Ikaria, Inc. in February 2014 as part of Ikaria's spin-out of certain of its research and development assets and subsidiaries.

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