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[redacted]

Dr. Tomas Salmonson
Chairman of CHMP
European Medicines Agency
Ontario Way
Canary Wharf
London E14 4HB
UK

Munich , 24th July 2014

Withdrawal of an initial Marketing Authorisation Application:
Procedure No. EMEA/H/C/002347
Project: Imagify, 232mg lyophilisate for suspension for injection
Applicant: Acusphere Ltd

Dear Dr. Salmonson, Chairman CHMP,

I would like to inform you that, at this point of time, Acusphere Ltd has taken the decision to withdraw the application for Marketing Authorisation of Imagify, 232mg lyophilisate for suspension for injection, which was intended to be used as an ultrasound imaging agent indicated for the detection of coronary artery disease (CAD) based on assessment of myocardial perfusion and wall motion in adults with stable chest pain and suspected inducible ischemia.

This withdrawal is based on the identification of major clinical trial design issues.

There are currently no on-going clinical trials or a compassionate programme for this product. Accordingly, there are no anticipated consequences of this withdrawal.

Acusphere reserves the right to make further submissions at a future date in this or other therapeutic indication(s).

I agree for this letter to be published on the EMEA website.

Yours sincerely,

[redacted]

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[redacted]

[redacted] I Senior Consultant
Granzer Regulatory Consulting and Services
Tel: [redacted]
Fax:
e-mail: [redacted]

Authorised Consultants to Acusphere Ltd

CC: Dr Patrick Salmon (Rapporteur), Dr Harald Enzmann (Co-Rapporteur), [redacted]

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