Changes to Product Information as approved by the CHMP on 23 June 2016, pending endorsement by the European Commission

Annex III
Amendments to relevant sections of the product information

Summary of Product Characteristics:

Section 4.3 – Contraindications:

- Patients with pulmonary hypertension associated with idiopathic interstitial pneumonias (PH-IIP) (see Section 5.1)

Section 5.1 - Pharmacodynamic properties:

Clinical efficacy and safety:

Patients with pulmonary hypertension associated with idiopathic interstitial pneumonias (PH-IIP)

A randomised, double blind, placebo-controlled phase II study (RISE-IIP) to evaluate the efficacy and safety of riociguat in patients with symptomatic pulmonary hypertension associated with idiopathic interstitial pneumonias (PH-IIP) was terminated early. Interim results showed an increased risk of mortality and serious adverse events in subjects receiving riociguat compared to those receiving placebo. The available data do not indicate a clinically significant benefit from riociguat treatment in these patients.

Riociguat is therefore contraindicated in patients with pulmonary hypertension associated with idiopathic interstitial pneumonias (see section 4.3).

Patient Information Leaflet

Section 2 - What you need to know before you take Adempas
Do NOT take Adempas:

- If you have increased pressure in your pulmonary circulation associated with scarring of the lungs, of unknown cause (idiopathic pulmonary pneumonia).