PFIZER EXECUTIVE SUMMARY

Pulmonary arterial hypertension (PAH) is a rare, progressive, and life-threatening disease. Treatment is focused upon improving survival and alleviating symptoms. Sildenafil citrate provides a new mode of action with regards to PAH therapy.

Sildenafil is an effective treatment for PAH; sildenafil increases exercise capacity and improves the haemodynamic profile in patients. Survival at 1 year in patients treated with sildenafil is 94%; in addition, sildenafil offers patients significant improvement in quality of life (QoL) as measured by the SF-36 and EQ-5D.

Sildenafil is well tolerated, with adverse events generally mild to moderate and transient. Sildenafil provides ease of use in patients with functional class III PAH (FCIII) without any serious administration related adverse events associated with epoprostenol.

Based on the evidence presented in a Cochrane review of bosentan (Liu 2004), it would appear that sildenafil and the other licensed therapies, including bosentan have comparable efficacy in terms of both the primary outcome of 6 minute walking distance (6MWD) and secondary outcomes.

With an incremental cost per QALY at one year of £15,252 sildenafil at its licensed dose, is the most cost-effective of the targeted therapies available in England and Wales. Over a lifetime the incremental cost-effectiveness ratio for sildenafil versus background therapy is £22,058.

Using a cost minimisation approach, at an average cost of £38,328 per QALY over a lifetime, sildenafil provides a highly cost-effective treatment option for PAH in England and Wales. This compares favourably to that of the other oral therapies, bosentan, which has an average cost of £58,264 per QALY, and sitaxentan with an average cost per QALY of £57,456.

Sildenafil is a treatment that augments the options available to physicians for treatment of this severe and life threatening illness as it provides an effective, low cost, well-tolerated, oral formulation that improves patient's Quality of Life and survival.