Tracleer® (bosentan) – New formulation approval

- On September 6, 2017, Actelion announced the FDA approval of Tracleer (bosentan) tablet for oral suspension, to support a new indication for the treatment of pulmonary arterial hypertension (PAH) [WHO Group I] in pediatric patients ≥ 3 years old with idiopathic or congenital PAH to improve pulmonary vascular resistance, which is expected to result in an improvement in exercise ability.
    - Tracleer is also available as 62.5 mg and 125 mg film-coated oral tablets.
- Tracleer is also indicated for the treatment of PAH in adults to improve exercise ability and to decrease clinical worsening.
    - Studies establishing effectiveness included predominantly patients with WHO Functional Class II – IV symptoms and etiologies of idiopathic or heritable PAH (60%), PAH associated with connective tissue diseases (21%), and PAH associated with congenital heart disease with left-to-right shunts (18%).
- The new indication for Tracleer was approved based on an open-label, uncontrolled study in 19 pediatric patients (3 – 15 years old) with PAH.
    - In this study, cardiopulmonary hemodynamic improvements were similar to those seen in adults treated with Tracleer.
    - In addition, the safety of Tracleer in pediatric patients is supported by data from 100 pediatric patients treated with Tracleer for a median of 17 months.
- Tracleer carries a boxed warning regarding the risk of hepatotoxicity and embryo-fetal toxicity.
- The recommended dosage of Tracleer is as follows:

Population	Initial 4 weeks	Maintenance (after 4 weeks)
Patients > 12 years old and > 40 kg	62.5 mg orally twice daily	125 mg orally twice daily
Patients > 12 years old and < 40 kg	62.5 mg orally twice daily	62.5 mg orally twice daily
Patients ≤ 12 years old and ≥ 4 – 8 kg	16 mg orally twice daily	16 mg orally twice daily
Patients ≤ 12 years old and > 8 – 16 kg	32 mg orally twice daily	32 mg orally twice daily
Patients ≤ 12 years old and > 16 – 24 kg	48 mg orally twice daily	48 mg orally twice daily
Patients ≤ 12 years old and > 24 – 40 kg	64 mg orally twice daily	64 mg orally twice daily

    - Tracleer tablets for oral suspension should be dispersed in a minimal amount of water immediately before administration.
- Actelion plans to launch the new formulation of Tracleer in the 4th quarter of 2017. The new formulation will be available as a 32 mg tablet for oral suspension.