Idebenone also resulted in a 37% reduction in loss of FVC as a percentage of predicted normal, although not significantly (–5.67 vs –8.95; $P = .08$), and a 78% reduction in loss of FEV_1 as a percentage of predicted normal (–2.40 vs –10.68; $P = .03$) in the ITT population.

This study represents the first successful phase 3 trial in DMD, and it demonstrates significant benefit of idebenone treatment in patients with this disease. Treatment with idebenone was also safe and well tolerated, concluded Prof Buyse.

TARGET: Nasal Delivery of Sumatriptan Powder Improves Functioning in Patients With Migraine

Written by Maria Vinall

Data presented by Peter J. McAllister, MD, New England Institute for Neurology and Headache, Stamford, Connecticut, USA, indicate that, in addition to providing migraine relief, breath-powered nasal delivery of low-dose sumatriptan powder (AVP-825) is associated with significantly improved functioning and a reduction in disability.

AVP-825 is an investigational drug-device combination product containing sumatriptan powder (22 mg) delivered intranasally via breath-powered technology. Clinical trials of AVP-825 in the acute treatment of migraine have shown headache relief at levels comparable with the most effective triptans [Cady RK et al. *Headache.* 2015; Djupesland PG et al. *Cephalalgia.* 2010]. Dr McAllister presented secondary outcomes from a recent phase 3 study [Cady RK et al. *Headache.* 2015] showing that AVP-825 shortens the time to meaningful relief and lowers clinical disability scores compared with placebo.

TARGET [NCT01462812] was a phase 3, multicenter, parallel-group trial composed of men and women diagnosed with episodic migraine ≥1 year prior to screening who reported 1 to 8 migraines per month during the 12 months prior to prescreening, had verified airflow through both nostrils, had the ability to close the soft palate, and demonstrated ability to use the breath-powered device. Participants were randomized to AVP-825 (n = 108) or a placebo (n = 104). Migraine symptoms were recorded predose and at 10, 15, 30, 45, 60, 90, and 120 minutes postdose. The Headache Impact Test (HIT-6) and clinical disability scale scores were used to measure headache-associated burden and disability at baseline.

Participants (mean age 42 years; 83.5% women; 85.8% white) reported a mean of 4.5 headaches per month; most (83%) associated with moderate pain and without aura (81.1%). HIT-6 results showed substantial headache burden and associated disability, ie, approximately 39% of patients routinely experience impairment with work and 34% with daily activities; 50% always or very often experience severe pain; and 80% always or very often wish they could lie down. At baseline, 57% of patients randomized to AVP-825 and 55% of placebo patients had clinical disability scale scores indicating moderate or severe disability.

The median time to meaningful headache relief with AVP-825 was 47.5 minutes. Compared with the placebo group, significantly more patients using AVP-825 reported experiencing meaningful relief by 120 minutes ($P = .0004$). Clinical disability scale scores improved over time; by 45 minutes postdose, these scores were significantly reduced in the AVP-825 group ($P = .0343$).

Disability was significantly reduced at 120 minutes postdose in the AVP-825 group compared with the placebo group ($P = .0430$). Specifically, by the 120-minute end point, 19% of patients treated with AVP-825 and 35% of placebo-treated patients reported moderate or severe disability compared with 57% and 55%, respectively, at baseline ($P < .05$).

MR CLEAN: Endovascular Therapy Improves Outcomes in Acute Ischemic Stroke

Written by Nicola Parry

Diederik Dippel, MD, PhD, Erasmus University Medical Center, Rotterdam, the Netherlands, presented updated data from MR CLEAN, a multicenter randomized clinical trial of endovascular treatment for acute ischemic stroke (AIS) in the Netherlands [ISRCTN10888758]. The results demonstrated improved functional outcomes in patients who received endovascular therapy up to 6 hours after stroke onset in the proximal anterior circulation, in addition to best medical care [Berkhemer OA et al. *N Engl J Med.* 2015].

According to Prof Dippel, more than one-third of patients with AIS have a proximal intracranial arterial occlusion. Intravenous (IV) administration of tissue plasminogen activator (tPA) within 4.5 hours of stroke onset clears the blockage in only about one-third of these and leads to recovery in only 10%.

Although previous trials showed no effect of intra-arterial treatment on functional outcomes in AIS, a new study was needed, he stressed, owing to improved patient selection from widespread use of computed tomography, rapid access to treatment in the Netherlands, and new endovascular treatment modalities. Prof Dippel and colleagues therefore conducted MR CLEAN to evaluate the