Sofdra™ (sofpironium) – New drug approval

- On June 20, 2024, Botanix announced the FDA approval of Sofdra (sofpironium), treatment of primary axillary hyperhidrosis in adults and pediatric patients 9 years of age and older.

- Hyperhidrosis is a condition characterized by abnormally increased sweating, beyond that required to regulate body temperature.

- Sofdra is a competitive inhibitor of acetylcholine receptors that are located on certain peripheral tissues, including sweat glands. Sofdra indirectly reduces the rate of sweating by preventing the stimulation of these receptors.

- The efficacy of Sofdra was established in two randomized, vehicle-controlled studies (CARDIGAN 1 and CARDIGAN 2) in 701 patients 10 years of age or older with primary axillary hyperhidrosis. Patients were randomized to receive either Sofdra or vehicle applied once daily at bedtime to each axilla. The co-primary endpoints were the proportion of patients having at least a 2-point improvement in the Hyperhidrosis Disease Severity Measure-Axillary, 7-item (HDSM-Ax-7) scale score from baseline to day 43, and the change in gravimetric sweat production (GSP) from baseline to day 43.

	CARDIGAN 1		CARDIGAN 2	
	Sofdra	**Vehicle**	**Sofdra**	**Vehicle**
≥ 2-point improvement in HDSM-Ax-7 scale score	49%	29%	64%	48%
Treatment difference (95% CI)	18% (8, 29)		17% (6, 27)	
Baseline median GSP (mg/5 minutes)	214	229	208	231
Change from baseline to day 43 Median (mg/5 minutes) 25th percentile, 75th percentile	-128 -201, -52	-100 -228, -29	-143 -260, -75	-134 -230, -60

- Sofdra is contraindicated in patients with medical conditions that can be exacerbated by the anticholinergic effect of Sofdra (eg, glaucoma, paralytic ileus, unstable cardiovascular status in acute hemorrhage, severe ulcerative colitis, toxic megacolon complicating ulcerative colitis, myasthenia gravis, Sjögren's syndrome).

- Warnings and precautions for Sofdra include urinary retention, control of body temperature, and operating machinery or an automobile.

- The most common adverse reactions (≥ 2%) with Sofdra use were dry mouth, vision blurred, application site pain, application site erythema, mydriasis, application site dermatitis, application site pruritus, urinary retention, and application site irritation.

- Sofdra should be applied as a single pump actuation to each underarm, once daily at bedtime.

- Botanix plans to launch Sofdra in the third quarter 2024. Sofdra will be available as a 12.45% topical gel.