FDA Approves Sofpironium, First Treatment for Primary axillary Hyperhidrosis

Hyperhidrosis affects an estimated 10 million individuals in the US and is characterized by abnormally increased sweating, beyond what is necessary to regulate body temperature.

The FDA has approved sofpironium topical gel, 12.45% (Sofdra; Botanix) for the treatment of primary axillary hyperhidrosis in adults and children 9 years of age and older.[1]

Hyperhidrosis affects an estimated 10 million individuals in the US and is characterized by abnormally increased sweating, beyond what is necessary to regulate body temperature. According to a news release, the disproportionate sweat production has profound impacts on quality of life, including work productivity, daily activities, emotional well-being, and personal relationships. It is the third largest dermatology condition after acne and atopic dermatitis.[1]

“We are very excited to provide a new option for the 10 million patients with primary axillary hyperhidrosis in the United States,” said Vince Ippolito, Executive Chairman of Botanix, in a news release. “As the first and only new chemical entity, Sofdra represents a new therapeutic approach for dermatologists to treat patients with this disabling medical condition.”[1]

The approval was based on results from the 2 pivotal phase 3 CARDIGAN trials evaluating the safety and efficacy of sopironium versus vehicle. The CARDIGAN I study enrolled 350 participants who were randomly assigned to either sofpironium bromide 15% gel once daily or vehicle gel once daily. The primary outcome measures were number of participants with and without and observed ≥2-point improvement in Hyperhidrosis Disease Severity Measure-Axillary (HDSM-Ax) 7 Item total score from baseline to end of treatment, as well as observed change in participant ranked gravimetric sweat production (GSP) from baseline. Participants had to be 9 years of age or older with a diagnosis of primary axillary hyperhidrosis that had symptoms for at least 6 months’ duration, HDSM-Ax score of 3 or 4, and a minimum GSP of 50 mg in each axilla with a combined total of at least 150 mg.[2]

In total, the CARDIGAN I and II studies enrolled 701 patients. In both trials, treatment with sopironium met all primary and secondary end points with clinically and statistically meaningful changes from baseline in both HDSM-Ax 7 and GSP scores.[1]

Botanix plans to launch a patient experience program in the third quarter of fiscal year 2024 so that qualified patients can gain early access to the treatment. These patients will be guided through the telemedicine and payer reimbursement process to become the first commercial users of sopironium, and broader launch is expected in early quarter 4.[1]

“The approval of Sofdra is terrific news for the hyperhidrosis community, which has been frustrated by the lack of effective and convenient treatment options,” said David Pariser, MD, founding board member of the International Hyperhidrosis Society and past President of the American Academy of Dermatology, in the news release. “The availability of a new treatment alternative that is topical, well-tolerated, effective, and easy to use is truly exciting and would be welcomed amongst patients and physicians.”[1]

Primary hyperhidrosis is caused by faulty nerve signals triggering eccrine sweat glands to become overactive, and usually affects the palms, soles, underarms, and sometimes the face. It has no medical cause and can run in families. Secondary hyperhidrosis is caused by an underlying medical condition

or certain medications and can cause sweating all over the body. According to Mayo Clinic, it can be caused by diabetes, menopause, thyroid conditions, some forms of cancer, nervous system disorders, and infections.[3]

References

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About the Trials

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