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EARLY TREATMENT OF VVA LEADS TO IMPROVED OUTCOME

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Vulvar and vaginal atrophy (VVA) of the menopause is caused by the reduction in circulating oestrogen in postmenopausal women. It causes symptoms in approx. 50% of postmenopausal women, most commonly vaginal dryness and dyspareunia, but also vulvar and vaginal irritation and itching, dysuria and post-coital bleeding. Unlike vasomotor symptoms, which are often self-limiting and reduce over time, postmenopausal VVA is a progressive disorder, which, if left untreated, generally worsens over time. Many women do not recognise it as being associated with the menopause and the condition often goes underreported. Healthcare professionals also underdiagnose and, as a result, undertreat the condition. This may lead to many women presenting at an advanced stage of disease with severe symptoms of VVA.

Senshio® (ospemifene), a Selective Estrogen Receptor Modulator (SERM), is a new oral treatment for moderate to severe symptomatic VVA in post-menopausal women who are not candidates for local vaginal oestrogen therapy. Since Senshio® has been proven to be effective in both severe and moderate VVA, we have analysed the clinical database from Senshio® to assess whether early treatment of VVA symptoms, when symptoms are still moderate rather than severe, leads to greater treatment benefit.

Two 12-week pivotal efficacy trials enrolled women with at least one moderate or severe symptom of vaginal dryness or dyspareunia. In addition, the effect on all VVA symptoms was recorded for all women. Symptom severity was reported by the patient as none, mild, moderate or severe. Improvement was defined as one or more steps in reduction of severity and relief was defined as mild or no symptoms after 12 weeks.

The co-primary endpoints in two pivotal efficacy trials of Senshio® included the effect on the Most Bothersome Symptom (MBS) of VVA (dryness or dyspareunia). In the placebo population, approximately 10% of women saw a worsening of their symptoms in only 12 weeks, confirming the progressive nature of the condition. Improvement in MBS was not substantially different in women with moderate or severe MBS at baseline (74.1% vs. 76.7% respectively). However, relief was substantially higher in the group with moderate MBS compared to those with severe MBS at baseline (74.1% vs. 55.0%).

Selecting one MBS per patient underestimates the impact of treatment, since 80% of the women in the studies had more than one moderate or severe symptom of VVA. Therefore we also considered the

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effect of early treatment based on all symptoms of VVA. There was only 4% difference in improvement of all moderate or severe symptoms of VVA (78.3% VS. 82.4%, respectively), confirming that Senshio® is equally effective in improving moderate as well as severe symptoms of VVA. But, like for the MBS only, there was nearly a 20% difference in the proportion of symptoms whose severity was none or mild at 12 weeks between those moderate or severe at baseline (76.2% vs. 56.8% respectively).
We conclude that the relief given to patients is greater when treatment of VVA with Senshio® is started early, when symptoms may still be moderate, rather than late.