

**STRICTLY EMBARGOED UNTIL 14:01 ON Monday 12 April, 2021**

**FORXIGA (DAPAGLIFLOZIN) ACCEPTED FOR USE WITHIN NHS SCOTLAND FOR THE TREATMENT OF SYMPTOMATIC CHRONIC HEART FAILURE WITH REDUCED EJECTION FRACTION IN ADULTS<sup>1</sup>**

- *Dapagliflozin has been accepted for use within NHS Scotland for the treatment of adult patients with symptomatic chronic heart failure with reduced ejection fraction (HFrEF), as an add-on to already optimised standard care.<sup>1</sup>*
- *AstraZeneca estimates the number of patients eligible for treatment could be up to 24,701.<sup>2</sup>*

**Luton, UK, Monday 12 April** – AstraZeneca today announced that Forxiga (dapagliflozin) has been accepted for use within NHS Scotland by the Scottish Medicines Consortium (SMC) as an additional option for the treatment of symptomatic chronic heart failure (HF) with reduced ejection fraction (rEF) in adults, as an add-on to already optimised standard care.<sup>1</sup>

**John McMurray, MD, Cardiovascular Research Centre, Institute of Cardiovascular and Medical Sciences, University of Glasgow, UK, said:** “Today’s announcement is great news for people in Scotland living with [chronic] heart failure and a reduced ejection fraction. This decision means there will be a novel treatment option available that can make a difference to their lives, by improving symptoms, reducing their risk for hospitalisation for heart failure and cardiovascular death in this life-restricting and life-threatening condition.”

HF is a life-threatening, complex, chronic condition where a person’s heart is unable pump enough blood around their body.<sup>3</sup> An estimated 46,000 people are living with HF in Scotland and the risk of death over five years associated with HF is worse than some of the most common cancers, such as prostate, bladder, colorectal, and breast cancer.<sup>4,5,6</sup> HF is also the cause of over 17,000 hospital admissions per year in Scotland.<sup>7</sup> With COVID-19 placing such a large burden on the health system,<sup>8</sup> it is critical that people living with heart failure have access to care options that can help reduce the risk of their symptoms worsening and need for admission to hospital.<sup>9</sup>

Dapagliflozin is in a class of medicines called SGLT2-inhibitors and is the first medicine of this kind to be recommended for use in adults with symptomatic chronic HFrEF in Scotland. The acceptance by the SMC was based on the positive results from the DAPA-HF Phase III clinical trial, which showed dapagliflozin reduced the risk of cardiovascular (CV) death, unplanned hospitalisation or an urgent visit to hospital requiring IV therapy for HF, when compared to placebo on top of standard care.<sup>10</sup> The overall safety profile of dapagliflozin in patients with HF was consistent with the known safety profile of the medicine.<sup>10,11</sup>

**Tom Keith-Roach, President, AstraZeneca UK, said:** “We are thrilled with the SMC’s decision, which provides access to an additional treatment [option] for people living with [symptomatic chronic] heart failure [with reduced ejection fraction]. Now more than ever, it is vital that we find ways to reduce the strain on our health services. We are committed to collaborating with our NHS partners to eradicate unplanned admissions for heart failure in the UK and implement innovative approaches that help people live a better quality of life and stay out of hospital.”

– ENDS –

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## Notes to editors

### About Heart Failure

Heart Failure (HF) is a life-threatening disease in which the heart cannot pump enough blood around the body.<sup>3</sup> It affects approximately 64 million people worldwide (at least half of which have a reduced ejection fraction), including almost one million in the UK.<sup>12,13,14</sup> It is a chronic disease where around half of patients will die within five years of diagnosis.<sup>15</sup>

HF mortality risk is worse than some of the most common cancers (prostate, breast, and bladder cancer).<sup>6</sup> The rate of hospitalisation for HF is growing three times as quickly as all other hospital admissions and represents a significant clinical and economic burden.<sup>16,17,18</sup>

There are two main categories of HF related to ejection fraction (EF), a measurement of the percentage of blood leaving the heart each time it contracts: HFrEF and HFpEF. HFrEF occurs when the left ventricle (LV) muscle is not able to contract adequately and therefore, expels less oxygen-rich blood into the body.<sup>19,20</sup>

### About dapagliflozin

Dapagliflozin is an oral, once-daily selective inhibitor of human sodium-glucose co-transporter 2 (SGLT2).<sup>21</sup> Dapagliflozin is indicated in adults for the treatment of symptomatic chronic heart failure with reduced ejection fraction.<sup>21</sup> In addition to this, dapagliflozin is also indicated in adults for the treatment of insufficiently controlled type 2 diabetes mellitus as an adjunct to diet and exercise, as monotherapy when metformin is considered inappropriate due to intolerance, and in addition to other medicinal products for the treatment of type 2 diabetes.<sup>21</sup>

Common (frequency,  $\geq 1/100$  to  $< 1/10$ ) adverse events associated with dapagliflozin in placebo-controlled clinical studies and post-marketing experience include: genital infections; genital fungal infections; urinary tract infection; dizziness; rash; back pain; dysuria; polyuria; haematocrit increased, and creatinine renal clearance decreased during initial treatment; and dyslipidaemia.<sup>21</sup>

*For complete information on dapagliflozin the summary of product characteristics, including a full list of side effects and adverse reactions is available here:*

<https://www.medicines.org.uk/emc/product/7607/smpc#gref>; For Northern Ireland please visit: <https://www.medicines.org.uk/emc/product/12071/smpc>.

### About AstraZeneca

AstraZeneca is a global, science-led biopharmaceutical company that focuses on the discovery, development and commercialisation of prescription medicines, primarily for the treatment of diseases in three therapy areas - Oncology, Cardiovascular, Renal & Metabolism and Respiratory & Immunology. AstraZeneca operates in over 100 countries and its innovative medicines are used by millions of patients worldwide.

With its global headquarters in Cambridge, AstraZeneca operates in five different locations in the UK, where around 8,300 employees work in research and development, manufacturing, supply, sales and marketing. We supply 40 different medicines to the NHS. The UK is also an important location for AstraZeneca's clinical trials; in 2018, we undertook 201 trials in the UK, involving 376 centres and over 7,000 patients.

For more information, please visit [www.astrazeneca.co.uk](http://www.astrazeneca.co.uk) and follow us on Twitter [@AstraZenecaUK](https://twitter.com/AstraZenecaUK).

## References

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