
Dr Sarah Wollaston
Chair, Health and Social Care Committee
House of Commons
London
SW1A 0AA

23 May 2019

Dear Dr Wollaston,

As requested, we are writing to update you on progress with our discussions with NHS England and NICE regarding access to our CF medicines. We remain highly committed to these negotiations and to bringing our potentially life-changing, precision medicines to patients as soon as possible.

In the spirit of this commitment, we have met with NHS England five times since the Health Select Committee hearing. In these meetings, we have brought numerous, different offers and solutions to the table, providing various flexible proposals for how we might solve the shared challenge that we have of securing access to CFTR modulators for English patients while meeting the expressed needs of NHS England.

These include:

- A commitment to provide additional, significant discounts on both Orkambi and Symkevi and significant concessions on the already agreed upon pricing of Kalydeco reflecting the Health Select Committee's recommendations and subsequent discussions between the Secretary of State for Health and Dr Leiden - to relieve NHSE of a substantial part of the budget needed to fund Orkambi
- These additional discounts would significantly improve on our 2018 offer, which was already the best offer ever proposed to any Government reflecting England's unique situation as the country with the second highest number of CF patients in the world. This unique situation is also a unique opportunity for large numbers of patients to benefit from the medicines today and from the R&D investment we continue to make to discover and develop the medicines of tomorrow
- These proposals offer significant discounts of tens of thousands of pounds below the regularly quoted cost per patient, list price of £104,000/year for Orkambi
- An interim access deal to provide immediate access to eligible patients to Orkambi, the only medicine that NICE has reviewed to date, on terms similar to those accepted in Scotland where many patients are already benefitting from our CFTR modulators now through the PACS-2 scheme
- A commitment to submit Symkevi for NICE appraisal
- The continuation of our compassionate use programme, which supports the sickest CF patients with free medicines, for an agreed period following an agreement. Since its inception, this programme has supported over 800 patients in England

In addition to these different solutions, we also provided NICE with substantial new evidence on Kalydeco, Orkambi and Symkevi, reflecting the most recent clinical studies on our medicines since our initial submission on Orkambi. This was done in response to comments made at the HSC Inquiry hearing to ensure that NHS England and NICE had the latest evidence on our medicines. For example, Kalydeco has already demonstrated substantial impact on mortality and reduced lung transplants in the UK

We are disappointed with NHSE's characterisation of our participation in the negotiations in their response to you. As NHS England knows, we are working hard to be flexible and collaborative in our approaches and are expecting to further discuss these various solutions with them at a planned call with them on Friday and in person at a meeting next week

Further, we want to correct the characterisation that our triple therapy was 'taken off the table' by Dr Leiden. We would of course consider the triple therapy as part of any agreement should we be able to do so in a way that meets NHSE's budget requirements and reflects the true value of this medicine. Exclusion of the triple as part of these current discussions was agreed by NHSE and Vertex due to the current budget constraints and the focus on access to our currently available medicines

NHSE has recently submitted to us a revised proposal, which we agreed with them would be reviewed at our meeting next week. We note however that their offer reflects the same annual spend on our CF medicines as their July 2018 offer

We look forward to the planned continuation of our discussions and remain committed to finding solutions to secure reimbursement for our CF medicines. As we have said previously, any agreement must recognise the significant value of these medicines and the substantial investment made in developing them, and it cannot jeopardise Vertex's ability to deliver on its mission of developing future innovations for the treatment of CF and other rare diseases.

In the interim, we want to reassure the CF community that Vertex will continue to provide free medicines to patients who are the most seriously ill, based on agreed clinical criteria, through our compassionate use programme

Thank you for your continued interest in this matter and your shared commitment to helping us reach a solution

Yours sincerely,

A handwritten signature in black ink, appearing to read 'Simon Lem', with a long horizontal stroke extending to the right.

Simon Lem
Vice President & General Manager
Northern Europe Region