
27 October 2022

Update on IMPACT-FXS

Dear Fragile X Community,

We would like to begin by thanking you all for your support and collaboration. As our valued partners, we would like to directly share an update with you about our fragile X drug development program. Following extensive discussions, we have taken the difficult decision to stop recruiting for IMPACT-FXS. Instead, we are working on our plans for a different study, to be started next year.

Our approach in using artificial intelligence (AI) to find entirely new disease indications for investigational or approved compounds identified several promising candidates for fragile X syndrome. We initiated our IMPACT-FXS study earlier this year to explore the safety and efficacy of two of these investigational medications (HLX-0201 and HLX-0206), with plans to explore additional drug candidates in follow-on trials.

Despite extensive efforts and support from investigators, patient group partners and our bespoke patient engagement agency, the progress in the activation of IMPACT-FXS has been slow. This has had an adverse impact on the recruitment timeline, which is delaying the progress and jeopardising the timely completion of other projects in our fragile X programme, including the next study with our follow-on drug candidate (HLX-0205).

HLX-0205 has some very strong preclinical data both as a monotherapy and, as found in some recent new data, in combination with HLX-0206. Fragile X mice dosed with HLX-0205 were able to restore cognitive functions in a range of cognitive assays to the same level as wildtype mice and when combined with HLX-0206, restore behaviours in several domains including cognition, anxiety and hyperactivity.

Therefore, we have taken the tough decision to close IMPACT-FXS for recruitment, before anyone is enrolled, and to focus our efforts on the next study in the programme. We recognise the significant unmet need in fragile X and want to again assure you that we are fully committed to pursuing an effective therapy for this syndrome, and that we are continuing this work with a sense of urgency and purpose.

We look forward to continued collaboration with the fragile X community and commit to providing you with updates as we have more information available to share.

Sincerely,



Dr Anthony Hall
Chief Medical Officer

on behalf of the Healx Fragile X Therapy Development Team.