Medical Xpress

Chorea reduced by deutetrabenazine in study

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People with Huntington disease (HD) experienced improvements in chorea while taking deutetrabenazine (SD-809) compared to placebo, according to a paper published today in the *Journal of the American Medical Association* (*JAMA*). Although the topline results of the trial have been released previously, the complete peer-reviewed publication about the First-HD clinical trial is now published in a premier medical journal.

Deutetrabenazine was investigated in the First-HD study, a Phase 3 clinical trial which was led by the Huntington Study Group (HSG) on behalf of Teva Pharmaceuticals. In the double-blind, placebo-controlled trial, deutetrabenazine significantly decreased chorea, the involuntary movements that many individuals with HD experience.

"Patients' chorea and motor scores improved compared to placebo over the course of 12 weeks," said Samuel Frank, MD, HSG's principal investigator of First-HD and director of the Huntington Disease Society of America Center of Excellence at Beth Israel Deaconess Medical Center in Boston. "In addition, both the participants and their study physicians reported overall improvement."

First-HD enrolled 90 patients at 34 HSG research sites between August 2013 and August 2014. The trial followed patients for 12 weeks on the medication and measured their chorea, as well as patients' and clinicians' impression of improvement.

"As a physician who cares for people with HD, it's gratifying to see

positive results from a well-designed, fully enrolled trial. Until we find a cure, we aim to bring our patients more treatment options to relieve symptoms," Frank said. "We are grateful to the people who participated in this trial and their families and support systems that made their participation possible. Research in the HD community depends on volunteers enrolling in trials."

At the end of May, Teva Pharmaceuticals announced that the U.S. Food and Drug Administration (FDA) asked for more data on deutetrabenazine, which had been under review to treat chorea associated with HD. The request for more data is common when the FDA is asked to approve new medications, and this is the first deuterated compound to be reviewed by the FDA. Michael Hayden, M.D., Ph.D., Teva's president of Global R&D and chief scientific officer said Teva plans to respond to the request in the third quarter of 2016.

There is only one drug currently approved to treat chorea associated with Huntington disease: tetrabenazine. Deutetrabenazine is structurally related to tetrabenazine with deuterium atoms placed at key positions in the molecule, prolonging plasma half-life and reducing metabolic variability, without changing target pharmacology. This can translate into effective symptom control with fewer medication doses a day, lower total daily doses, and improved tolerance. In First-HD, both patient and clinician overall assessments were significantly better in the deutetrabenazine treated group compared to placebo after 3 months. The deutetrabenazine group improved in a quality of life measure while the placebo group worsened.

"Overall status and quality of life measures are especially relevant in chorea, where no single number captures what is clinically meaningful to patients themselves," said Claudia Testa, MD, PhD, HSG's co-principal investigator for First-HD and director of the HDSA Center of

Excellence at Virginia Commonwealth University. "It's exciting to see how treating an HD symptom can make a real-life positive impact."

More information: *JAMA*, jama.jamanetwork.com/article.a … .1001/jama.2016.8655

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