To Our Community:

As we are all faced with an unimaginable situation, we wanted to reach out and share information in response to questions we have been receiving about edasalonexent and COVID-19.

As always, we are closely monitoring the trial for the safety of participating boys. To date, we have not identified any safety concerns related to COVID-19. We encourage reviewing your local recommendations to reduce risk for boys and their families, and please consult your physician regarding specific medical advice.

For additional information and resources related to COVID-19 and Duchenne, check out these links that are being shared to our community by several advocacy organizations:

CureDuchenne: https://www.cureduchenne.org/coronavirus-health-update-guide/
Jett Foundation: https://www.jettfoundation.org/covid19

FREQUENTLY ASKED QUESTIONS

Q Does edasalonexent affect the immune system?

A Long-term toxicology studies with edasalonexent using higher doses than those in our clinical trials have found no evidence for immunosuppression using standard clinical and anatomic physiology methods. In clinical studies, now with over 100 patient-years of exposure to edasalonexent, we have found no evidence of immunosuppression or increased infections. In the Phase 3 PolarisDMD trial of edasalonexent, as well as the GalaxyDMD open-label trial, boys are not on steroids.

Q Should trial participants still go to the hospital for their assessments?

A We are fortunate that site visits are relatively infrequent during the Phase 3 PolarisDMD trial with assessments every 3 months. Currently, we are focused on ensuring that patients have uninterrupted drug supply as well as safety monitoring. We are working closely with our clinical trial sites with frequent communication.

Q Will the outcome of ongoing trials be endangered by not being able to carry them out as per protocol?

A We are actively monitoring the situation and have plans in place to address potential disruptions. Fortunately, we designed our clinical trial so that visits are relatively infrequent. We are working with sites to support drug supply, as well as safety and efficacy assessments.
Earlier this week, Dr. Erika Finanger spoke during the MDA Virtual Clinical Trials Session. If you missed our presentation about edasalonexent, you can view it on our website here.

ABOUT EDASALONEXENT

In Duchenne, the loss of dystrophin leads to chronic activation of NF-kB, which is a key driver of skeletal and cardiac muscle disease progression. By inhibiting NF-kB, edasalonexent has the potential to decrease inflammation and fibrosis, promote muscle regeneration, and slow disease progression. Edasalonexent is being developed as both a monotherapy and for use with other therapies, including exon-skipping therapies and other dystrophin-targeted therapies in development such as gene therapy.

The Phase 3 PolarisDMD trial and GalaxyDMD open-label extension study are both ongoing.

Top-line results for PolarisDMD are expected in the fourth quarter of 2020.

Stay in touch!

Join our mailing list: http://www.catabasis.com/patients-families/for-further-information.php
For trial-related questions: DMDtrials@catabasis.com
Follow us on social media: @CatabasisPharma.

The information provided here is for parents and caregivers of boys with Duchenne muscular dystrophy. Edasalonexent is an investigational drug that is not yet approved in any territory.