Update on the Status of Phase III GENERATION HD1

Posted on June 24, 2019 by MSabado

The purpose of the Phase III study is to evaluate the efficacy and safety of RG6042 treatment for manifest Huntington's disease. In March we announced our plan to amend the dosing frequency and study design in a way that makes study participation less demanding for patients, their families and HD centers. Since then, our team has been working to implement study changes and obtain approvals from clinical trial review boards and authorities around the world.

Today I am pleased to share that we have re-opened the study for recruitment of new patients. Initial clinical trial authorizations to start the amended GENERATION HD1 study have been received, and we expect to receive the remaining approvals soon. Recruitment timing will be different at each participating HD clinic/centre, because the protocol amendment must be fully approved and in place at each study site before local recruitment may open. Our team is working to rapidly activate the updated study protocol at each site.

Participant eligibility and enrollment are determined by the study investigator at each site. Some sites may enroll patients with an established history with their centre, before recruiting new patients. Anyone interested in participating in clinical research should first discuss with his/her HD specialist about what may be best for his/her situation.

The GENERATION HD1 study will run at more than 90 sites around the world. Below I have listed the 18 countries in which these clinical trial sites are located. In the next days, individual site information will be updated on ClinicalTrials.gov and our global ForPatients.Roche.com website.

The HD community has had a keen interest in our research efforts. We are extremely grateful for the ongoing support, and we are committed to completing the study as quickly as possible to provide data to health authorities.

I look forward to providing you further updates on our research progress.

Kind regards,

J.P., on behalf of our HD research team

The Roche Medical/Clinical Trial Information teams can be contacted for more information about the study/sites via Medinfo.Roche.com. Additionally, country-specific contact information is below.

Asia-Pacific

Australia (australia.medinfo@roche.com, +61 1800 233 950)

Japan (study is run under Chugai Pharmaceutical, a member of the Roche group, who can be directly contacted using this link)

New Zealand (auckland.medinfonz@roche.com, +64 0800 276 243)

Europe

Austria (austria.medical-information@roche.com)

Denmark (denmark.medinfo@roche.com, +45 3639 9999)

France (paris.imp@roche.com)

Germany (grenzach.miatlas@roche.com, +49 07624-14-2015)

Italy (milano.romis@roche.com)

The Netherlands (woerden.medinfo@roche.com)

Poland (warsaw.informacja-medyczna@roche.com)

Russia (moscow.medinfo@roche.com)

Spain (spain.medinfo@roche.com)

Switzerland (swiss.medinfo@roche.com)

United Kingdom (medinfo.uk@roche.com, +44 0800 3281629)

North America

Canada (mississauga.canada_medinfo@roche.com, +1-888-762-4388)

USA (study is run under Genentech, a member of the Roche group, who can be contacted via +1-888-662-6728)

South America

Argentina (argentina.informacion_medica@roche.com)

Chile (chile.informacionmedica@roche.com)

About the Phase III GENERATION HD1 study design

The GENERATION HD1 study will evaluate the efficacy and safety of RG6042 treatment given once every two months (every eight weeks) or every four months (every 16 weeks) over a period of 25 months. This amended global study will enroll up to 660 patients with manifest HD at more than 90 sites around the world.

GENERATION HD1 is designed to determine the efficacy and safety of RG6042, and therefore includes a comparison to placebo. Participants will be randomized to one of three study arms: 120mg RG6042 every eight weeks, 120mg RG6042 every 16 weeks or placebo every eight weeks. This means for every two participants randomized to RG6042 treatment, one will receive only placebo. The study is "double-blinded," meaning neither the participant nor his/her investigator or site staff will know which study arm the participant is assigned.

For all patients who complete the GENERATION HD1 study, the option of participation in an open-label extension study (GEN-EXTEND) evaluating RG6042 (no placebo control) is planned, pending eligibility, approval by local Authorities and Ethics Committees/Institutional Review Boards and if data support the continued development of RG6042.

Herwig Walter Lange • a day ago • edited

Are potential participants informed before the study that
1. RG6042 did not reduce mHtt in all patients (in 2 out of 34 patients mHtt did not go down),
2. RG6042 NFL is not reduced (did go up first, then returned to pretrial level),
3. RG6042 leads to an expansion of the brain ventricles not observed in the placebo-group
and what these unexpected findings mean?

HELP 4 HD INTERNATIONAL

Help4HD's mission is to educate the world about Huntington's disease (HD) and Juvenile Huntington's disease (JHD) through its multimedia communications platform.

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THE HUNTINGTON'S POST

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