IMPORTANT SAFETY INFORMATION FOR TROGARZO

INDICATIONS AND USAGE

TROGARZO, in combination with other antiretroviral(s), is indicated for the treatment of HIV-1 infection in heavily treatment-experienced adults with multidrug resistant HIV-1 infection failing their current antiretroviral regimen.

WARNINGS AND PRECAUTIONS

Immune Reconstitution Inflammatory Syndrome

Immune reconstitution inflammatory syndrome has been reported in one patient treated with TROGARZO in combination with other antiretrovirals. During the initial phase of combination antiretroviral therapies, patients whose immune systems respond may develop an inflammatory response to indolent or residual opportunistic infections, which may necessitate further evaluation and treatment.

ADVERSE REACTIONS

The most common adverse reactions (all Grades) reported in at least 5% of subjects were diarrhea (8%), dizziness (8%), nausea (5%), and rash (5%).

Most (90%) of the adverse reactions reported were mild or moderate in severity. Two subjects experienced severe adverse reactions: one subject had a severe rash and one subject developed immune reconstitution inflammatory syndrome manifested as an exacerbation of progressive multifocal leukoencephalopathy.

Laboratory Abnormalities

Selected Laboratory Abnormalities (Grade 3 or 4) in Trial TMB-301

Laboratory Parameter	**% Subjects N=40**
Bilirubin (≥ 2.6 x ULN)	5%
Direct Bilirubin (> ULN)	3%
Creatinine (>1.8x ULN or 1.5x baseline)	10%
Blood Glucose (> 250 mg/dL)	3%
Lipase (>3.0 x ULN)	5%
Uric Acid (>12 mg/dL)	3%
Hemoglobin (< 8.5 g/dL)	3%
Platelets (< 50,000/mm^3)	3%

Leukocytes (< 1.5 10^9 cells/L)	5%
Neutrophils (<0.6 10^9 cells/L)	5%

Immunogenicity

As with all therapeutic proteins, there is potential for immunogenicity. The detection of antibody formation is highly dependent on the sensitivity and specificity of the assay. Additionally, the observed incidence of antibody (including neutralizing antibody) positivity in an assay may be influenced by several factors including assay methodology, sample handling, timing of sample collection, concomitant medications, and underlying disease. For these reasons, comparison of the incidence of antibodies to ibalizumab-uiyk in the studies described below with the incidence of antibodies in other studies or to other products may be misleading.

All subjects enrolled in clinical trial TMB-301 and trial TMB-202 (a Phase 2b clinical trial that studied TROGARZO administered intravenously as 2,000 mg every 4 weeks or 800 mg every 2 weeks; the safety and effectiveness of this dosing regimen has not been established), were tested for the presence of anti-TROGARZO IgG antibodies throughout their participation. One sample tested positive with low titer anti-ibalizumab antibodies. No adverse reaction or reduced efficacy was attributed to the positive sample reported in this subject.

Pregnancy

No adequate human data are available to establish whether or not TROGARZO poses a risk to pregnancy outcomes. Animal reproductive toxicology studies with ibalizumab-uiyk have not been conducted. Monoclonal antibodies, such as ibalizumab-uiyk, are transported across the placenta as pregnancy progresses; therefore, ibalizumab-uiyk has the potential to be transmitted from the mother to the developing fetus. The background risk of major birth defects and miscarriage for the indicated population is unknown. All pregnancies have a background risk of birth defect loss, or other adverse outcomes. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2-4% and 15-20%, respectively..

Lactation

The Centers for Disease Control and Prevention recommend that HIV-1-infected mothers in the United States not breastfeed their infants to avoid the risk of postnatal transmission of HIV-1 infection.

No data are available regarding the presence of TROGARZO in human milk, the effects on the breastfed child, or the effects on milk production. Human IgG is present in human milk, although published data indicate that antibodies in breast milk do not enter the neonatal or infant circulation system in substantial amounts. Because of the potential for HIV-1 transmission, instruct mothers not to breastfeed if they are receiving TROGARZO.

To report SUSPECTED ADVERSE REACTIONS, contact THERA patient support™ at 1-833-23THERA (1-833-238-4372) or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see the full Prescribing Information at TROGARZO.com.