The double-blind study met its primary outcome measure of angiomyolipoma response rate.*

The most common adverse reaction reported for Votubia (incidence ≥3%) was stomatitis [see below for important safety information].

How Does Votubia Work?

Votubia works by inhibiting mTOR, a protein that is overactive in those with TSC with mTORC1 or mTORC2 contributors to tumour growth and metastasis.

About Novartis

Novartis is committed to supporting individuals affected by TSC through therapeutic innovation, patient assistance and support of advocacy organizations. Building on the Phase III EXIST clinical trial program, examining everolimus in manifestations of TSC, Novartis is currently conducting additional research for everolimus in TSC including its potential neurocognitive benefits and impact on autism associated with TSC.

About Votubia® (everolimus)

Votubia® (everolimus) tablets are approved in the EU for the treatment of adult patients with renal angiomyolipoma associated with TSC who are at risk of complications (based on factors such as tumor size or presence of aneurysm, or presence of multiple or bilateral tumors) but who do not require immediate surgery. The evidence is based on analysis of change in SEGA volume. Further clinical development of Votubia will be guided by ongoing Phase III trials; EVEROL trial, examining everolimus in adult patients with refractory SEGA and renal angiomyolipoma associated with TSC; EXIST-3 trial, examining the effect of everolimus in adult patients with TSC who are at risk of complications (based on factors such as tumor size or presence of aneurysm, or presence of multiple or bilateral tumors) but who do not require immediate surgery; and the EXIST-2 trial examining the effect of everolimus in adult patients with renal angiomyolipomas associated with TSC who are not at risk of complications (based on factors such as tumor size or presence of aneurysm, or presence of multiple or bilateral tumors) but who do not require immediate surgery.

Important Safety Information

Votubia®/Afinitor® can cause serious side effects including lung or breathing problems, infections (including sepsis), and kidney failure, which can lead to death. Patients taking concurrent angiotensin-converting enzyme (ACE) inhibitors may be at an increased risk for angioedema. Other serious reactions can include changes in blood chemistry laboratory tests. Additionally, Votubia may cause fetal harm in pregnant women. Highly effective contraception is recommended for women of child-bearing potential while receiving Votubia/Votubia-approved contraception and use of barrier contraceptive and spermicides is recommended in men receiving Votubia. A medication guide should be distributed with each prescription of Votubia.

Non-Functional TSC Complex

P13K Reduced Cell Proliferation Reduced Angiogenesis Reduced Cell Death

About Votubia® (everolimus)

Votubia tablets and dispersible tablets are also approved in the EU for the treatment of patients with SEGA associated with TSC who require therapeutic intervention but are not amenable to surgery. The evidence is based on analysis of change in sum of angiomyolipoma volume. Further clinical development of Votubia will be guided by ongoing Phase III trials; EVEROL trial, examining everolimus in adult patients with refractory SEGA and renal angiomyolipomas associated with TSC; EXIST-3 trial, examining the effect of everolimus in adult patients with TSC who are at risk of complications (based on factors such as tumor size or presence of aneurysm, or presence of multiple or bilateral tumors) but who do not require immediate surgery; and the EXIST-2 trial examining the effect of everolimus in adult patients with renal angiomyolipomas associated with TSC who are not at risk of complications (based on factors such as tumor size or presence of aneurysm, or presence of multiple or bilateral tumors) but who do not require immediate surgery.

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