



HCP Training Deck

Associated Risk of Central Serous Retinopathy (CSR) for Erdafitinib-Treated Patients

Welcome to this training deck!



This slide deck is designed to support healthcare professionals in the screening, diagnosis, evaluation, and management of patients who experience **central serous retinopathy (CSR)** while receiving **erdafitinib**.



This training deck will:

- Outline that erdafitinib can cause ocular toxicities.
- Recommend a baseline ophthalmologist visit takes place.
- Confirm that patient training on the Amsler grid test should be provided.
- Recommend that follow-up visits should take place to monitor visual changes.
- Outline the management of CSR-related ocular toxicities.

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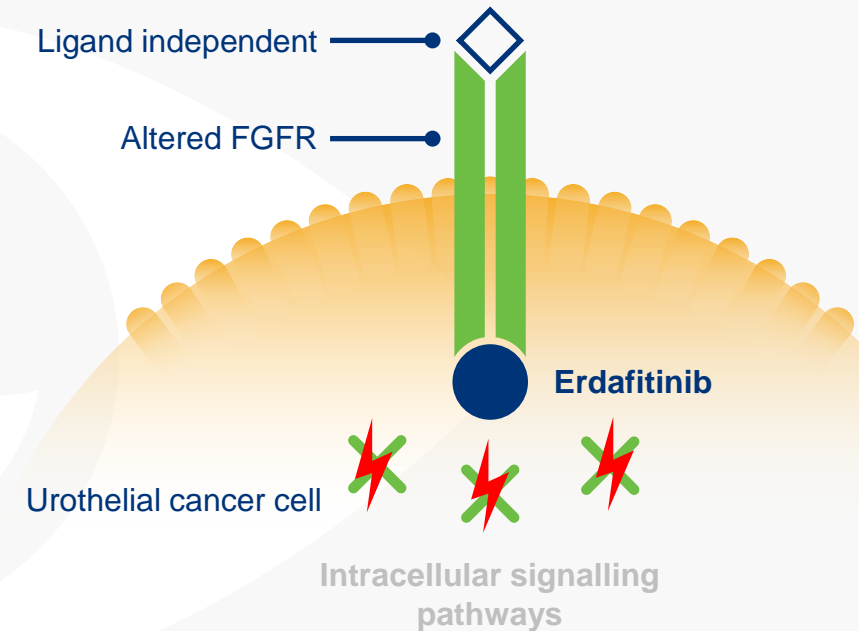
References



Introducing erdafitinib¹



- Erdafitinib is a tyrosine kinase inhibitor that binds to and inhibits enzymatic activity of **FGFR1, FGFR2, FGFR3 and FGFR4**.¹
- It is used to treat adults with **locally advanced metastatic urothelial carcinoma**.
 - With susceptible **FGFR2 or FGFR3 genetic alterations**.
 - And who have progressed during or following at least one line of prior platinum-containing chemotherapy, including within 12 months of neoadjuvant or adjuvant platinum-containing chemotherapy.



FGFR, fibroblast growth factor receptors

Erdafitinib: safety information¹



Since **erdafitinib** targets the **FGFR protein** and may affect other cells with this protein, it may cause side effects including:



Eye problems are common with erdafitinib and include:

- dry or inflamed eyes
- inflamed cornea
- and disorders of the retina (i.e. CSR) that could cause visual field defect

Overview of central serous retinopathy (CSR)²



- In patients with **central serous retinopathy (CSR)**, fluid accumulates under the retina causing a serous (fluid-like) detachment of the retinal epithelium and vision loss.
- This condition most often occurs in young and middle-aged adults, and in men more commonly than women.
- **Symptoms include:** blurry central vision, which often occurs in one eye
 - However, these patients may display no symptoms, especially if the affected areas fall outside the macula.
- CSR may be detected and quantified with optical coherence tomography (OCT)
- Treatment is often not necessary since **most cases of CSR resolve without treatment** after several weeks or months
 - If retinal swelling persists for more than three or four months, or if an examination reveals early retinal degeneration, laser surgery or photodynamic therapy may be helpful.



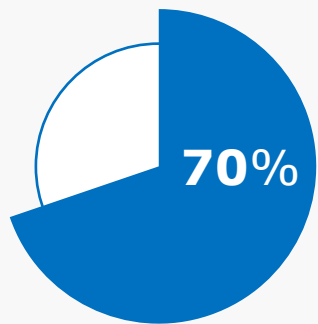
Mechanism of action

FGFR signalling is thought to be involved in the maintenance, protection, and repair of the retinal pigment epithelium for which inhibition could lead to **CSR**.

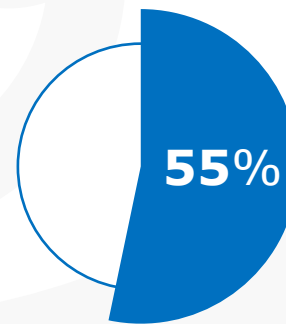
CSR has been reported in erdafitinib clinical studies³,



- Ocular disorders, including **CSR**/retinal pigment epithelial detachment (RPED) resulting in visual field defect, have been reported in patients receiving **erdafitinib** in clinical studies.
- In the Phase II BLC2001 study of patients with **locally advanced and unresectable or metastatic urothelial carcinoma and** prespecified **FGFR alterations**, **CSR** was observed in 23% of **erdafitinib**-treated patients
 - Median time to first onset was 53 days.



An abnormal Amsler grid test result was identified in **70%** of patients who developed CSR.

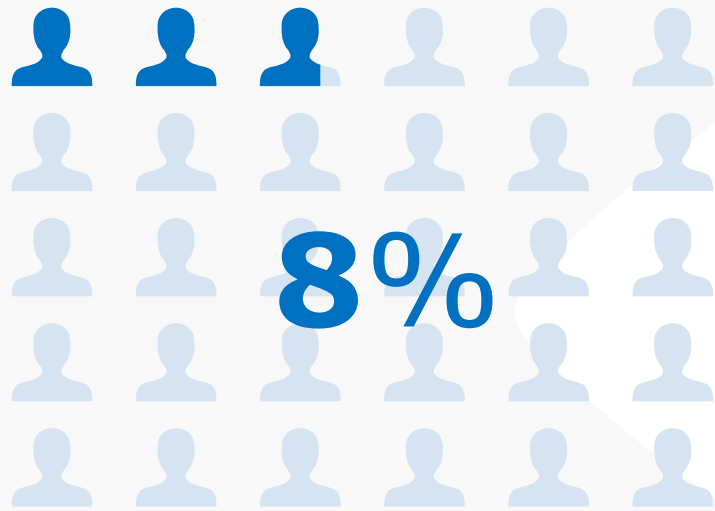


Ocular disorders other than **CSR** occurred in **55%** of patients, including **dry eye (19%)** and **blurred vision (17%)**.

Management of CSR in erdafitinib clinical studies³



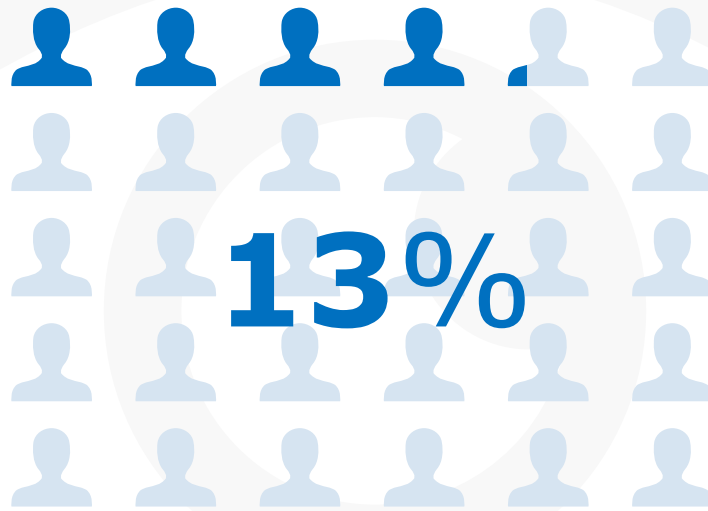
In clinical studies, **CSR** was primarily managed by dose modification. From the total patient population in the study:



8%



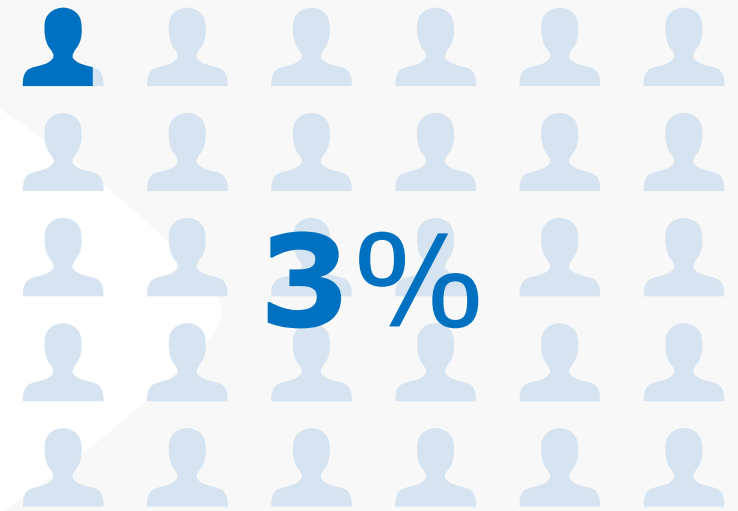
Dose interruptions due to CSR



13%



Dose reduction due to CSR



3%



Permanent discontinuation of erdafitinib due to CSR

Screening recommendations for CSR prior to and during erdafitinib¹



Prior to initiating erdafitinib, a baseline ophthalmological exam is recommended and should include an Amsler grid test, fundoscopy, visual acuity, and an optical coherence tomography (OCT) if available.



Patients should be examined every month thereafter; examinations should include performing an Amsler grid test.



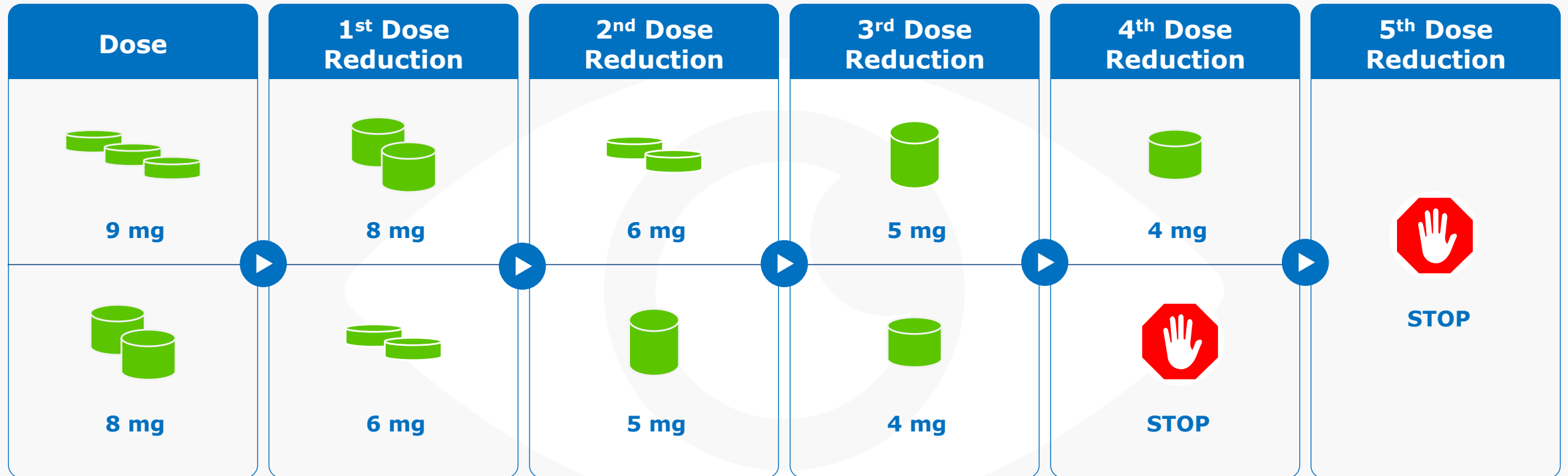
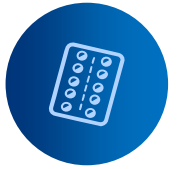
Guidance should also be provided for patients to self-administer the Amsler grid test to detect visual abnormalities between physician visits.




Management recommendations for CSR during erdafitinib¹



Severity Grading	Erdafitinib Drug Management
Grade 1: Asymptomatic; clinical or diagnostic observations only	<ul style="list-style-type: none">• Withhold until resolution• If resolves within 4 weeks, resume at the next lower dose level. Then, if no recurrence for a month, consider re-escalation• If stable for 2 consecutive eye exams but not resolved, resume at the next lower dose level
Grade 2: Visual acuity 20/40 or better or ≤ 3 lines of decreased vision from baseline	<ul style="list-style-type: none">• Withhold until resolution• If resolves within 4 weeks, may resume at the next lower dose level
Grade 3: Visual acuity worse than 20/40 or > 3 lines of decreased vision from baseline	<ul style="list-style-type: none">• Withhold until resolution• If resolves within 4 weeks, may resume two dose levels lower• If recurs, consider permanent discontinuation
Grade 4: Visual acuity 20/200 or worse in affected eye	<ul style="list-style-type: none">• Permanently discontinue

Erdafitinib dose reduction schedule¹



 3 mg tablet  4 mg tablet  5 mg tablet

References



1. Balversa™ Prescribing Information. April 2022.
2. Central Serous Chorioretinopathy. Retina Health Series. American Society of Retina Specialists. 2016.
3. Data on File. Erdafitinib. Clinical Study Report Protocol 42756493BLC2001. Janssen Research & Development, LLC. EDMS-ERI-150533049; 2018.



Guidance for Adverse events reporting

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