25 February 2016
EMA/CHMP/130102/2016
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Lonsurf

trifluridine / tipiracil

On 25 February 2016, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Lonsurf, intended for the treatment of adult patients with metastatic colorectal cancer. The applicant for this medicinal product is Les Laboratoires Servier.

Lonsurf will be available as film-coated tablets (15 mg / 6.14 mg and 20 mg / 8.19 mg). It is an antineoplastic agent combined with a thymidine phosphorylase inhibitor (ATC code: L01BC59). The active substances are trifluridine and tipiracil.

Trifluridine is phosphorylated by thymidine kinase, further metabolised in cells to a deoxyribonucleic acid (DNA) substrate, and incorporated directly into DNA, thereby interfering with DNA function and preventing cell proliferation. The role of tipiracil is to inhibit the degradation of trifluridine by thymidine phosphorylase.

When added to best supportive care (BSC) Lonsurf improved survival compared to BSC alone. The most common side effects are neutropenia, nausea, fatigue, anaemia and leucopenia.

The full indication is:

"Lonsurf is indicated for the treatment of adult patients with metastatic colorectal cancer (CRC) who have been previously treated with, or are not considered candidates for, available therapies including fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapies, anti-VEGF agents, and anti-EGFR agents". It is proposed that Lonsurf be prescribed by physicians experienced in the administration of anticancer therapy.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5520
Send a question via our website www.ema.europa.eu/contact