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Withdrawal of application for the marketing authorisation of Linhaliq (ciprofloxacin)

Aradigm Pharmaceuticals Limited withdrew its application for a marketing authorisation of Linhaliq for treating and preventing flare-ups of bronchiectasis in patients with long-term lung infection caused by *Pseudomonas aeruginosa* bacteria.

The company withdrew the application on 29 October 2019.

What is Linhaliq and what was it intended to be used for?

Linhaliq was developed as a medicine for preventing and reducing exacerbations (flare-ups) of bronchiectasis in adults who have long-term lung infection with *Pseudomonas aeruginosa* bacteria. Bronchiectasis is a long-term condition in which the airways have widened and become flabby and scarred, with a build-up of mucus.

Linhaliq was developed for patients with 'non-cystic fibrosis bronchiectasis', which means it was not intended for patients with bronchiectasis due to cystic fibrosis.

Linhaliq contains the active substance ciprofloxacin and was to be available for inhalation using an inhaler device.

How does Linhaliq work?

The active substance in Linhaliq, ciprofloxacin, is an antibiotic belonging to a group called fluoroquinolones. Fluoroquinolones work by preventing bacteria from making copies of their DNA (genetic material). As a result, bacteria cannot multiply and they die. In Linhaliq, some of the active substance is enclosed in tiny fat particles called liposomes. This was intended to slow down the medicine's release into the lungs, allowing it to act for longer.

What did the company present to support its application?

The company presented the results of two studies in a total of 582 patients with non-cystic fibrosis bronchiectasis. In each study Linhaliq was compared with placebo (a dummy treatment). The main measure of effectiveness was the time it took until patients had a flare-up of bronchiectasis.

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How far into the evaluation was the application when it was withdrawn?

The application was withdrawn after that the European Medicines Agency had evaluated the information from the company and prepared questions for the company. The company had responded to the last round of questions, and the Agency was completing its assessment of the responses at the time of the withdrawal.

What did the Agency recommend at that time?

Based on the review of the data, at the time of the withdrawal, the Agency had several concerns and its provisional opinion was that Linhaliq could not have been authorised for treating or preventing flare-ups in adults with non-cystic fibrosis bronchiectasis who have long-term lung infection with *Pseudomonas aeruginosa*. The Agency considered that the two studies presented did not show convincingly that the medicine was effective. In addition, more data were needed to show that the quality of the medicine is consistent.

Therefore, at the time of the withdrawal, the Agency's opinion was that the benefits of Linhaliq did not outweigh its risks.

What were the reasons given by the company for withdrawing the application?

In its letter notifying the Agency of the withdrawal of the application, the company stated that it decided to withdraw its application because the data provided do not allow EMA's committee for human medicines to conclude on a positive benefit-risk balance for the medicine.

Does this withdrawal affect patients in clinical trials or compassionate use programmes?

The company informed the Agency that there are no ongoing clinical trials or compassionate use programmes with Linhaliq.