

Erdosteine gets Orphan Drug designation by FDA for the treatment of bronchiectasis

A significant recognition to the value of the Italian pharmacological research comes from the United States: the Food and Drug Administration (FDA) has granted the Orphan Drug Designation to Erdosteine, a molecule discovered and developed by the R&D division of the Italian company Edmond Pharma. The “designation” refers to the new indication for the treatment of bronchiectasis, a rare disease for which no drug therapies are available in U.S. nowadays.

Today Erdosteine is marketed in over 40 countries worldwide for the treatment of various respiratory diseases, more than 3.000 patients have been already treated in 60 clinical trials and additional studies, involving 600 patients in 10 European countries, are currently ongoing.

Erdosteine, the newest molecule in the class of mucoactive drugs, discovered and developed by Edmond Pharma’s research laboratories, has received the Orphan Drug Designation for the treatment of bronchiectasis by the FDA Office of Orphan Products Development (OOPD). This status is granted by the American regulatory Agency to drugs that can treat rare diseases affecting fewer than 200.000 patients in United States.

Already marketed in over 40 countries worldwide for the treatment of chronic bronchitis and COPD, Erdosteine has started its registration process in U.S. for bronchiectasis.

Considering the promising results for this new indication, Edmond Pharma is investing on further developments of the molecule.

“We are excited for the achievement of the orphan drug status for Erdosteine, thanks to the commitment of our U.S. partner Alitair Pharmaceuticals” says Roberto Teruzzi, CEO of Edmond Pharma and Corvette Group SpA (holding company of the group). “This result represents a very important achievement in the process of worldwide expansion of our group and I believe it is a source of pride for the pharmacological research made in Italy. The market potential of this new therapy in the United States is considerable and corresponds to a therapeutic unmet need. Indeed there are no other drugs approved by the FDA for the treatment of bronchiectasis, a condition which has a heavy impact on the quality of life of the people affected”.

Erdosteine will now be used in studies targeted on bronchiectasis, conducted in the United States as part of the clinical development plan aimed to obtain the final authorization of the product as orphan drug.