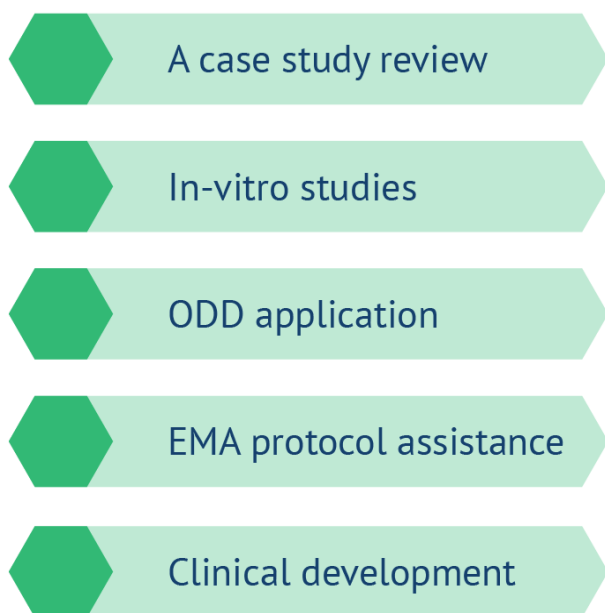


Our journey in Cystic fibrosis



Tamoxifen citrate for the treatment of Cistic Fibrosis



— The beginning

Our journey begins from a **case study** medical review, where it was mentioned the potential benefits of Tamoxifen (TMX) in the treatment of women affected by cystic fibrosis.

“an anti-estrogen effects”





— In-vitro studies

We have subsequently sponsored in-vitro studies to better investigate the potential effects of TMX in patients affected by Cistic Fibrosis. What we found was an additional and direct mechanism of TMX on CaCCs leading to TMF to potentially have beneficial effects to both women and men.

“a direct mechanism on calcium-chloride channels (CaCCs)”



— CYSTIC FIBROSIS

-  Genetic Rare Disease
-  CFTR gene mutation
-  More than 70.000,00 patients affected
-  1.000 new cases of CF are diagnosed each year

Our journey in Cystic fibrosis



— ODD Application

The in-vitro studies results lead us to assume that the Treatment with TMX might be complementary to and synergistic with other new therapeutic agents such as those acting on the CFTR defect and trafficking, and/or those inhibiting epithelial sodium channel activity. The convergent therapeutic effects of such agents could be highly beneficial for CF patients.

Supporting the thesis above on 2017 GB Pharma applied for on ODD to EMA

“We have been granting a Positive Opinion for an ODD”

— EMA Protocol Assistance

- Need of expert opinions
- Generate robust evidences
- Perform appropriate studies

Three main reason that lead us to seek for scientific advice. Working also with **European Network of Cistic Fibrosis** we agreed a protocol for an international Phase II Study.

— The OTTAWA Study

We start working on Phase II program and we have complete the feasibility process

- Study Phase : Phase II, dose finding
- Patients Target : 148
- Countries: ES, DE, IE, IT , UK
- Sites: 25

“The OTTAWA Study is endorsed by the European Network of Cistic Fibrosis”

— Current status

The OTTAWA study requires a significant economic efforts. In the meantime we are conducting a pivotal Phase II study.

“We are looking for Company interested in co-development partnership”

— Contacts



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